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WHEN: December 7, 1999 at 9:00 am.

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

FEDERAL RETIREMENT THRIFT INVESTMENT BOARD

5 CFR Part 1630

Privacy Act Regulations; Implementation

AGENCY: Federal Retirement Thrift Investment Board.

ACTION: Final rule.

SUMMARY: The Executive Director of the Federal Retirement Thrift Investment Board (Board) is adopting as final the Board’s proposed rule adding procedures to access records of spouses, former spouses, and beneficiaries of Thrift Savings Plan (TSP) participants. The change is necessary because the Board is updating its computerized data base for the TSP record keeping system. The Board maintains FRTIB–1, Thrift Savings Plan Records, which is a Governmentwide system of records. Under the new TSP record keeping system, in addition to records of participants, FRTIB–1 will include records of spouses, former spouses, and beneficiaries of participants. This change adds procedures for granting access to those records. The Board received no comments on the proposed rule; therefore, it is adopting the proposed rule without change.

Regulatory Flexibility Act

I certify that this amendment will not have a significant economic impact on a substantial number of small entities. It will affect only spouses, former spouses, and beneficiaries of TSP participants.

Paperwork Reduction Act

I certify that this amendment does not require additional reporting under the criteria of the Paperwork Reduction Act of 1980.

Unfunded Mandates Reform Act of 1995

Pursuant to the Unfunded Mandates Reform Act of 1995, section 201, Public Law 104–4, 109 Stat. 48, 64, the effect of this regulation on state, local, and tribal governments and on the private sector has been assessed. This regulation will not compel the expenditure in any one year of $100 million or more by any state, local, and tribal governments in the aggregate, or by the private sector. Therefore, a statement under section 202, 109 Stat. 48, 64–65, is not required.

Submission to Congress and the General Accounting Office

Under 5 U.S.C. 801(a)(1)(A), the Board submitted a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States before publishing this rule in today’s Federal Register. This is not a major rule as defined at 5 U.S.C. 804(2).

Catalog of Subjects in 5 CFR Part 1630

Privacy.

Roger W. Mehle, Executive Director, Federal Retirement Thrift Investment Board.

For the reasons set forth in the preamble, part 1630 of chapter VI of title 5 of the Code of Federal Regulations is amended as follows:

PART 1630—PRIVACY ACT REGULATIONS

1. The authority citation for part 1630 continues to read as follows:


2. Section 1630.2 is amended as follows:

(a) In paragraph (e) by adding the words “or the record keeper” after the word “Board”;

(b) By redesignating paragraphs (f), (h), (l), (m), and (n) as paragraphs (g), (h), (l), (m), and (n) as paragraphs (f), (h), (l), (m), and (n) as paragraphs (g), (h), (l), (m), and (n), respectively, and by adding paragraphs (f) and (m) to read as follows:

§ 1630.2 Definitions.

(f) Record keeper means the entity that is engaged by the Board to perform record keeping services for the TSP.

(m) TSP participant means any individual for whom a TSP account has been established. This includes former participants, i.e., participants whose accounts have been closed.

3. Section 1630.4 is amended by revising paragraph (a)(1) and the chart which follows that paragraph, by redesignating paragraphs (a)(2), (a)(3), and (a)(4) as paragraphs (a)(3), (a)(4), and (a)(5), and by adding a new paragraph (a)(2) to read as follows:

§ 1630.4 Request for notification and access.

(a) TSP records. (1) Records on TSP participants and the spouses, former spouses, and beneficiaries of TSP participants are maintained in the Governmentwide system of records, FRTIB–1, Thrift Savings Plan Records. A participant or a spouse, former spouse, or beneficiary of a participant must make his or her inquiry in accordance with the chart set forth in this paragraph. The mailing address of the Thrift Savings Plan Service Office is:
§1630.7 Identification requirements.

(a) * * * (1) Telephone identification procedures apply only to requests from participants and spouses, former spouses, or beneficiaries of participants for information in FRTIB–1, Thrift Savings Plan Records, which is retrieved by their respective Social Security numbers.

(b) By telephone. (1) Telephone identification procedures apply only to requests from participants and spouses, former spouses, or beneficiaries of participants for information in FRTIB–1, Thrift Savings Plan Records, which is retrieved by their respective Social Security numbers.

(c) By telephone. (1) Telephone identification procedures apply only to requests from participants and spouses, former spouses, or beneficiaries of participants for information in FRTIB–1, Thrift Savings Plan Records, which is retrieved by their respective Social Security numbers.

(2) A participant or a spouse, former spouse, or beneficiary of a participant must identify himself or herself by providing to the record keeper designee his or her Social Security number and PIN. Because a PIN is required to use these features, they are not available to former participants, whose PINs are canceled when their accounts are closed.

§1630.8 [Amended]

7. Section 1630.8 is amended as follows:

(1) In paragraph (a), by removing the second sentence;

(b) In paragraph (b)(1), by adding the words “or the record keeper” after the word “Board”; and

(c) In paragraph (b)(5), by adding the words “or the record keeper” after the word “Board” in the first sentence, and by adding the words “or record keeper designee” after the words “Privacy Act Officer” in the second sentence.

§1630.11 [Amended]

8. Section 1630.11 is amended as follows:

(1) In paragraph (a)(1), by adding the following sentence at the beginning of the paragraph:

(a) * * * (1) A spouse, former spouse or beneficiary of a participant who wants to correct or amend his or her record must write to the TSP record keeper. * * *

(b) In paragraph (a)(1) by revising the chart to read as follows:

<table>
<thead>
<tr>
<th>If you want:</th>
<th>If you are a participant who is a current Federal employee:</th>
<th>If you are a participant who has separated from Federal employment or a spouse, former spouse, or beneficiary:</th>
</tr>
</thead>
<tbody>
<tr>
<td>To make inquiry as to whether you are a subject of this system of records.</td>
<td>Call or write to your employing agency in accordance with agency procedures for personnel or payroll records.</td>
<td>Call or write to TSP record keeper.</td>
</tr>
<tr>
<td>To gain access to a record about you.</td>
<td>Call or write to your employing agency to request access to personnel and payroll records regarding the agency’s and the participant’s contributions, and adjustments to contributions. Call or write to the TSP record keeper to gain access to loan status and repayments, earnings, contributions allocation elections, interfund transfers, and withdrawal records.</td>
<td>Call or write to TSP record keeper.</td>
</tr>
<tr>
<td>To learn the history of disclosures of records about you to entities other than the participant’s employing agency or the Board or auditors see §1630.4 (a)(4).</td>
<td>Write to TSP record keeper.</td>
<td>Write to TSP record keeper.</td>
</tr>
</tbody>
</table>

§1630.9 [Amended]

5. Section 1630.9 is amended in paragraph (a) by removing at the end of the first sentence the phrase ‘by the Board’.

6. Section 1630.7 is amended as follows:

a. In paragraph (a), by adding the words “or record keeper designee,” after the words “Privacy Act Officer” in the third sentence; b. In paragraph (b), by adding the words “or record keeper designee,” after the words “Privacy Act Officer” in the second sentence; and c. By revising paragraph (c) to read as follows:

§1630.7 Identification requirements.

* * * * *

§1630.5 [Amended]

4. Section 1630.5 is amended in paragraphs (a) and (b) by adding the words “or the TSP record keeper” after the word “Board”.

§1630.6 [Amended]

5. Section 1630.6 is amended in paragraph (a) by removing at the end of the first sentence the phrase ‘by the Board’.

6. Section 1630.7 is amended as follows:

a. In paragraph (a), by adding the words “or record keeper designee,” after the words “Privacy Act Officer” in the third sentence; b. In paragraph (b), by adding the words “or record keeper designee,” after the words “Privacy Act Officer” in the second sentence; and c. By revising paragraph (c) to read as follows:

§1630.7 Identification requirements.

* * * * *

§1630.8 [Amended]

7. Section 1630.8 is amended as follows:

(1) In paragraph (a), by removing the second sentence;

(b) In paragraph (b)(1), by adding the words “or the record keeper” after the word “Board”; and

(c) In paragraph (b)(5), by adding the words “or the record keeper” after the word “Board” in the first sentence, and by adding the words “or record keeper designee” after the words “Privacy Act Officer” in the second sentence.

§1630.11 [Amended]

8. Section 1630.11 is amended as follows:

(a) * * * (1) A spouse, former spouse or beneficiary of a participant who wants to correct or amend his or her record must write to the TSP record keeper. * * *

(b) In paragraph (a)(1) by revising the chart to read as follows:

<table>
<thead>
<tr>
<th>If you want:</th>
<th>If you are a participant who is a current Federal employee:</th>
<th>If you are a participant who has separated from Federal employment or a spouse, former spouse, or beneficiary:</th>
</tr>
</thead>
<tbody>
<tr>
<td>To make inquiry as to whether you are a subject of this system of records.</td>
<td>Call or write to your employing agency in accordance with agency procedures for personnel or payroll records.</td>
<td>Call or write to TSP record keeper.</td>
</tr>
<tr>
<td>To gain access to a record about you.</td>
<td>Call or write to your employing agency to request access to personnel and payroll records regarding the agency’s and the participant’s contributions, and adjustments to contributions. Call or write to the TSP record keeper to gain access to loan status and repayments, earnings, contributions allocation elections, interfund transfers, and withdrawal records.</td>
<td>Call or write to TSP record keeper.</td>
</tr>
<tr>
<td>To learn the history of disclosures of records about you to entities other than the participant’s employing agency or the Board or auditors see §1630.4 (a)(4).</td>
<td>Write to TSP record keeper.</td>
<td>Write to TSP record keeper.</td>
</tr>
</tbody>
</table>

§1630.9 [Amended]

5. Section 1630.9 is amended in paragraph (a) by removing at the end of the first sentence the phrase ‘by the Board’.

6. Section 1630.7 is amended as follows:

a. In paragraph (a), by adding the words “or record keeper designee,” after the words “Privacy Act Officer” in the third sentence; b. In paragraph (b), by adding the words “or record keeper designee,” after the words “Privacy Act Officer” in the second sentence; and c. By revising paragraph (c) to read as follows:

§1630.7 Identification requirements.

* * * * *

§1630.8 [Amended]

7. Section 1630.8 is amended as follows:

(1) In paragraph (a), by removing the second sentence;

(b) In paragraph (b)(1), by adding the words “or the record keeper” after the word “Board”; and

(c) In paragraph (b)(5), by adding the words “or the record keeper” after the word “Board” in the first sentence, and by adding the words “or record keeper designee” after the words “Privacy Act Officer” in the second sentence.

§1630.11 [Amended]

8. Section 1630.11 is amended as follows:

(a) * * * (1) A spouse, former spouse or beneficiary of a participant who wants to correct or amend his or her record must write to the TSP record keeper. * * *

(b) In paragraph (a)(1) by revising the chart to read as follows:

<table>
<thead>
<tr>
<th>If you want:</th>
<th>If you are a participant who is a current Federal employee:</th>
<th>If you are a participant who has separated from Federal employment or a spouse, former spouse, or beneficiary:</th>
</tr>
</thead>
<tbody>
<tr>
<td>To make inquiry as to whether you are a subject of this system of records.</td>
<td>Call or write to your employing agency in accordance with agency procedures for personnel or payroll records.</td>
<td>Call or write to TSP record keeper.</td>
</tr>
<tr>
<td>To gain access to a record about you.</td>
<td>Call or write to your employing agency to request access to personnel and payroll records regarding the agency’s and the participant’s contributions, and adjustments to contributions. Call or write to the TSP record keeper to gain access to loan status and repayments, earnings, contributions allocation elections, interfund transfers, and withdrawal records.</td>
<td>Call or write to TSP record keeper.</td>
</tr>
<tr>
<td>To learn the history of disclosures of records about you to entities other than the participant’s employing agency or the Board or auditors see §1630.4 (a)(4).</td>
<td>Write to TSP record keeper.</td>
<td>Write to TSP record keeper.</td>
</tr>
</tbody>
</table>
To correct or amend a TSP record

If the type of record is:
Personnel or personal records (e.g., age, address, Social Security number, date of birth).
The agency’s and the participant’s contributions, and adjustments to contributions.
Earnings, investment allocation, interfund transfers, loans, loan repayments, and withdrawals.

If you are a participant who is a current Federal employee write to:
Write to your employing agency .............
Write to your former employing agency.
Write to TSP record keeper ........................

If you are a participant who has separated from Federal employment write to:
Write to TSP record keeper.

DEPARTMENT OF AGRICULTURE
Animal and Plant Health Inspection Service
9 CFR Part 78
[Docket No. 98–119–2]

Brucellosis in Cattle; State and Area Classifications; Kansas

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Affirmation of interim rule as final rule.

SUMMARY: We are adopting as a final rule, without change, an interim rule that amended the brucellosis regulations concerning the interstate movement of cattle by changing the classification of Kansas from Class A to Class Free. We have determined that Kansas meets the standards for Class Free status. The interim rule relieved certain restrictions on the interstate movement of cattle from Kansas.

DATES: The interim rule became effective on July 1, 1999.

FOR FURTHER INFORMATION CONTACT: Dr. Valerie Ragan, Senior Staff Veterinarian, National Animal Health Programs, VS, APHIS, 4700 River Road Unit 43, Riverdale, MD 20737–1231; (301) 734–7708.

SUPPLEMENTARY INFORMATION:

Background
In an interim rule effective July 1, 1999, and published in the Federal Register on July 8, 1999 (64 FR 36775–36777, Docket No. 99–051–1), we amended the brucellosis regulations in 9 CFR part 78 by removing Kansas from the list of Class A States or areas in §78.41(b) and adding it to the list of Class Free States or areas in §78.41(a). Comments on the interim rule were required to be received on or before September 7, 1999. We did not receive any comments. Therefore, for the reasons given in the interim rule, we are adopting the interim rule as a final rule. This action also affirms the information contained in the interim rule concerning Executive Order 12866 and the Regulatory Flexibility Act, Executive Orders 12372 and 12988, and the Paperwork Reduction Act.

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

List of Subjects in 9 CFR Part 78
Animal diseases, Bison, Cattle, Hogs, Quarantine, Reporting and recordkeeping requirements, Transportation.

PART 78—BRUCELLOSIS

Accordingly, we are adopting as a final rule, without change, the interim rule that amended 9 CFR part 78 and that was published at 64 FR 36775–36777 on July 8, 1999.

Authority: 21 U.S.C. 111–114a–1, 114g, 115, 117, 120, 121, 123–126, 134b, and 134f; 7 CFR 2.22, 2.80, and 371.2(d).

Done in Washington, DC, this 29th day of November 1999.
Bobby R. Acord,
Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 99–31372 Filed 12–2–99; 8:45 am]

BILLING CODE 3410–34–U

DEPARTMENT OF AGRICULTURE
Animal and Plant Health Inspection Service
9 CFR Part 94
[Docket No. 98–119–2]

Change in Disease Status of Liechtenstein Because of BSE

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Affirmation of interim rule as final rule.

SUMMARY: We are adopting as a final rule, without change, an interim rule that added Liechtenstein to the list of regions where bovine spongiform encephalopathy exists. We took this action because bovine spongiform
encephalopathy was detected in two bovine animals in Liechtenstein. The effect of the interim rule was to prohibit or restrict the importation of ruminants that have been in Liechtenstein and meat, meat products, and certain other products of ruminants that have been in Liechtenstein. The interim rule was necessary to reduce the risk that bovine spongiform encephalopathy could be introduced into the United States.

**EFFECIVE DATE:** The interim rule became effective on December 18, 1998.

**FOR FURTHER INFORMATION CONTACT:** Dr. Gary Colgrove, Chief Staff Veterinarian, National Center for Import and Export, VS, APHIS, 4700 River Road Unit 38, Riverdale, MD 20737–1231; (301) 734–8364.

**SUPPLEMENTARY INFORMATION:**

**Background**

In an interim rule effective December 18, 1998, and published in the *Federal Register* on December 24, 1998 (63 FR 71209–71210), Docket No. 98–119–1, we amended the regulations in 9 CFR part 94 by adding Liechtenstein to the list in § 94.18(a)(1) of regions where bovine spongiform encephalopathy (BSE) exists. We took this action because BSE was detected in two bovine animals born in Liechtenstein.

We solicited comments concerning the interim rule for 60 days ending February 22, 1999. We received one comment by that date. The comment was from an individual who did not oppose adding Liechtenstein to the list of regions where BSE exists but expressed the opinion that, at this time, animals and animal products derived from animals should be banned from importation into the United States until techniques are developed that will inactivate transmissible spongiform encephalopathy (TSE) agents, including BSE. The commenter also stated that the exporting country’s regulations should be equal to or stronger than ours, and the country’s animal population should be TSE-free. In addition, the commenter raised issues regarding human health and the labeling of certain animal products. These comments are outside the scope of this rulemaking.

We currently prohibit or restrict the importation of ruminants, ruminant meat and meat products, and certain other ruminant products from regions where BSE is known to exist and from regions where we believe BSE may exist. This rulemaking added Liechtenstein to the list of those regions. If we determine that other changes to our regulations are necessary to prevent the introduction of BSE into the United States, we will publish another document in the *Federal Register* for public comment.

Therefore, for the reasons given in the interim rule and in this document, we are adopting the interim rule as a final rule.

This action also affirms the information contained in the interim rule concerning Executive Orders 12866 and 12998 and the Paperwork Reduction Act.

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

**Regulatory Flexibility Act**

This rule affirms an interim rule that amended the regulations by adding Liechtenstein to the list of regions where BSE exists. We took this action because BSE was detected in two bovine animals in Liechtenstein. The effect of the interim rule was to prohibit or restrict the importation of ruminants that have been in Liechtenstein and meat, meat products, and certain other products of ruminants that have been in Liechtenstein. The interim rule was necessary to reduce the risk that BSE could be introduced into the United States.

The following analysis addresses the economic effect of this rule on small entities, as required by the Regulatory Flexibility Act.

BSE is a slowly progressing, fatal, degenerative disease that affects the central nervous system of cattle. The disease was first diagnosed in 1986 in Great Britain, where it is sometimes called “mad cow disease.” Infected animals may display changes in temperament, abnormal posture, incoordination and difficulty in rising, decreased milk production, and loss of body condition despite continued appetite. The causative agent of BSE is not completely charactORIZED, and there is no treatment for the disease. At this time, the disease is not known to exist in the United States. There is no vaccine to prevent BSE nor is there a test to detect the disease in live animals. Given these factors, the import restrictions imposed by the interim rule are the most effective means available for ensuring that BSE does not enter the United States from Liechtenstein.

Preventing the introduction of BSE into the United States is critical. BSE has the potential to cause severe economic hardship for the U.S. livestock industry. Great Britain’s experience with the disease provides an insight into how damaging BSE can be to livestock. Between November 1996 (when BSE was first diagnosed in Great Britain) and May 1996, an estimated 160,540 head of cattle in approximately 33,455 herds were diagnosed with BSE in Great Britain. The epidemic peaked there in January 1993, with almost 1,000 new cases per week. All of the animals in Great Britain showing signs of BSE, most of which were dairy cows between 3 and 5 years of age, were destroyed.

If BSE were introduced into the United States, livestock losses would likely be much greater than in Great Britain because the United States raises more cattle. However, assuming the same number of cattle losses in the United States as in Great Britain (160,540), the introduction of BSE into the United States would cost U.S. livestock producers $189 million, based on the October 1998 price of $1,180 per head for dairy cows. The $189 million figure does not include higher production costs that would likely be incurred by U.S. producers due to the presence of the disease.

U.S. export and consumer markets would also be affected. The United States currently restricts the importation of live ruminants and ruminant products from all regions where BSE is known to exist and from regions that present an undue risk of introducing BSE into the United States due to import requirements that are less restrictive than those that would be acceptable for import into the United States and/or because of inadequate surveillance. Presumably, if BSE were introduced into the United States, other regions would adopt similar restrictions on the exportation of live ruminants and ruminant products from the United States. Such restrictions by other regions would be devastating economically. In 1997, for example, the dollar value of U.S. exports of both ruminants (bovine, sheep, and goats) and ruminant products (bovine, sheep, lamb, and goat meat and bovine, sheep, and goat offal) was more than $3.1 billion. Those export sales could be lost in their entirety. Consumers could incur higher costs due to higher prices for ruminant products and increased prices for competitive products, such as poultry.

We expect that restricting the importation of live ruminants and ruminant products from Liechtenstein will have little or no effect on U.S. consumers. No ruminants, ruminant meat, or ruminant offal were imported into the United States from Liechtenstein in the last 5 years. Total imports into the United States of ruminant meat in 1997 had a value of more than $1.6 billion. Because Liechtenstein is a significant supply source of ruminants and ruminant products for the U.S. market,
restrictions on imports from Liechtenstein should not have a significant effect on consumer prices in the United States.

Placing Liechtenstein on the list of regions where BSE is known to exist also restricts the importation of bones, products made from bone meal, blood meal, meat meal, offal, fat, glands, and serum from ruminants from this region. Little economic effect should be associated with any of these restrictions. Further, the importation into the United States of any pet or animal feed from Liechtenstein that may contain ruminant products is restricted as a result of this action. The United States has imported dog and cat food from Liechtenstein since 1995. In 1997, total imports of dog and cat food into the United States had a value of more than $149 million; of this, only $52,191 worth was imported from Liechtenstein. Therefore, we expect that there will be very little or no effect on U.S. consumers as a result of this restriction.

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.

List of Subjects in 9 CFR Part 94

Animal diseases, Imports, Livestock, Meat and meat products, Milk, Poultry and poultry products, Reporting and recordkeeping requirements.

PART 94—RINDERPEST, FOOT-AND-MOUTH DISEASE, FOWL PEST (FOUL PLAGUE), EXOTIC NEWCASTLE DISEASE, AFRICAN SWINE FEVER, HOG CHOLERA, AND BOVINE SPONGIFORM ENCEPHALOPATHY: PROHIBITED AND RESTRICTED IMPORTATIONS

Accordingly, we are adopting as a final rule, without change, the interim rule that amended 9 CFR part 94 and that was published at 63 FR 71209–71210 on December 24, 1998.


Done in Washington, DC, this 23rd day of November 1999.

Craig A. Reed,
Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 99–31344 Filed 12–2–99; 8:45 am]

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Part 130

[Docket No. 98–052–2]

Veterinary Services User Fees; Biosecurity Level Three Laboratory Inspection Fee

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: We are amending existing user fees for the inspection for approval of biosecurity level three laboratories. Existing user fees require biosecurity level three laboratories to pay user fees for inspection based on hourly rates. We are replacing the hourly rates for this specific service with a flat rate user fee that would cover all the costs of inspection related to approving a laboratory for handling one defined set of organisms or vectors.


FOR FURTHER INFORMATION CONTACT: For information concerning program operations for Veterinary Services, contact Ms. Louise Lothery, Administrative Officer, Management Support Staff, VS, APHIS, 4700 River Road Unit 44, Riverdale, MD 20737–1231; (301) 734–7517.

For information concerning rate development of the proposed user fee, contact Ms. Donna Ford, Section Head, Financial Systems and Services Branch, Budget and Accounting Service Enhancement Unit, MRPBS, APHIS, 4700 River Road Unit 54, Riverdale, MD 20737–1232; (301) 734–8351.

SUPPLEMENTARY INFORMATION:

Background

User fees to reimburse the Animal and Plant Health Inspection Service (APHIS) for the costs of providing veterinary diagnostic services and import- and export-related services for live animals and birds and animal products are contained in 9 CFR part 130. Section 130.8 lists miscellaneous flat rate user fees. Section 130.9 lists the hourly rate user fees charged for APHIS’ import or entry services, including inspection of laboratories within the United States. On July 14, 1999, we published in the Federal Register (64 FR 37903–37905, Docket No. 98–052–1) a proposal to amend the existing user fees for the inspection of biosecurity level three laboratories. Existing user fees require biosecurity level three laboratories to pay user fees for inspection based on hourly rates. We proposed to replace the hourly rates for this specific service with a flat rate user fee that would cover all the costs of inspection related to approving a laboratory for handling one defined set of organisms or vectors.

We solicited comments concerning our proposal for 60 days ending September 13, 1999. We did not receive any comments. Therefore, for the reasons given in the proposed rule, 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.

In accordance with 5 U.S.C. 604, we have performed a final regulatory flexibility analysis, which is set out below, regarding the economic effects of this rule on small entities.

User fees to reimburse APHIS for the costs of providing veterinary diagnostic services and import- and export-related services for live animals and birds and animal products are contained in 9 CFR part 130. Prior to the effective date of this rule, APHIS charged user fees for the inspection of biosecurity level three laboratories under the hourly rate user fees contained in § 130.9.

APHIS inspects several laboratories in the United States that conduct biosecurity level three research on high-risk organisms and vectors. Under the hourly rate user fees, laboratories pay an average of $462 for inspections required to be approved to handle a defined set of organisms or vectors. The average actual cost of providing this service, including the cost of air travel and lodging necessary to inspect certain laboratories, is $977 per laboratory. APHIS has not been able to recover all costs of inspection associated with approving these laboratories under the hourly rate user fee structure because the regulations only provide for 6 hours of ground travel.

Therefore, we are amending the regulations in § 130.8 by establishing a flat rate user fee of $977 for this service, which would cover the average cost of inspection related to approving a laboratory to handle one defined set of organisms or vectors. The flat rate user fee will enable all laboratories to know in advance what costs they will incur.

We arrived at the flat rate user fee by using the average of the number of hours required for an APHIS inspector...
to complete an inspection, travel costs (including airfare and lodging, when appropriate), per diem, and miscellaneous travel expenses.

**Effects on Small Entities**

Under Small Business Administration (SBA) guidelines, a biosecurity level three laboratory with less than $5 million in annual sales is considered a small entity. All of the laboratories we inspect are small entities. We anticipate that the economic effects of this rule on these laboratories will be minimal. An informal survey of several of the affected laboratories revealed that in some cases inspection costs at laboratories are charged directly to the client if the client requested analysis of the particular organism or vector for which the inspection was undertaken. However, in most cases, laboratories pay for inspections with overhead funds from their operating budget. There are two types of biosecurity level three laboratories that we inspect. Some laboratories are privately owned, for-profit enterprises that charge clients fees to use the laboratory to research biosecurity level three organisms or vectors. These laboratories typically bill their clients for the cost of APHIS’ inspection service and, therefore, are not directly affected by the cost of inspections.

Other laboratories are publicly owned and are attached to universities or government agencies. These laboratories typically include anticipated APHIS inspection costs in their yearly budgets. We do not have the data to assess the effect of the rate change on these laboratories. On average, laboratories are inspected twice a year. However, a laboratory working with many different types of organisms could be subject to additional inspections.

In our proposal, we solicited comments on the potential effects of the proposed action on small entities. In particular, we sought data and other information to help us better determine what effects, if any, this rule would on the small entities mentioned above. We received no comments on the proposed rule.

**Alternatives Considered**

In developing this rule, we considered: (1) Making no changes to our existing method of recovering costs for inspecting biosecurity level three laboratories; (2) charging laboratories the exact costs incurred during each individual inspection, including costs of travel and lodging; or (3) charging a flat rate user fee for the inspection of biosecurity level three laboratories.

We rejected the first alternative because, if we made no changes to the regulations, we would continue to be unable to recover all of the costs associated with the inspection of biosecurity level three laboratories. All costs to APHIS for providing this service must be recovered solely through user fees; there is no other form of funding available to us that would cover this service.

We also rejected the second alternative, in which each laboratory would be charged the exact cost of inspection, including travel and lodging for APHIS personnel. We believe it is unfair to charge certain customers higher fees than others simply because a qualified APHIS inspector may not be stationed nearby. We believe that the fairest method of charging customers for this service is through a flat rate user fee.

This rule contains no new information collection or recordkeeping requirements.

**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 inconsistent with this rule; (2) has no retroactive effect; and (3) does not require administrative proceedings before parties may file suit in court challenging this rule.

**Paperwork Reduction Act**

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 Part 130**

Animals, Birds, Diagnostic reagents, Exports, Imports, Poultry and poultry products, Quarantine, Reporting and recordkeeping requirements, Tests.

Accordingly, we are amending 9 CFR part 130 as follows:

**PART 130—USER FEES**

1. The authority citation for part 130 continues to read as follows:


2. In §130.1, a definition for “biosecurity level three laboratory” is added in alphabetical order to read as follows:

   **§130.1 Definitions.**

   * * * *

   Biosecurity level three laboratory. A laboratory or production facility that works with foreign or domestic animal disease agents, organisms, or vectors that spread by aerosol route and that have serious or lethal effects, therefore requiring special biocontainment measures. 

   * * * *

3. In §130.8, paragraph (a), the table is amended by adding a new entry in alphabetical order to read as follows:

   **§130.8 User fees for other services.**

   (a) * * *

<table>
<thead>
<tr>
<th>Service</th>
<th>User fee</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inspection for approval of biosecurity level three laboratories.</td>
<td>$977.00 for all costs of inspection related to approving the laboratory for handling one defined set of organisms or vectors.</td>
</tr>
</tbody>
</table>

4. In §130.9, the introductory text of paragraph (a) is revised to read as follows:

   **§130.9 Hourly user fees for import or entry services.**

   (a) User fees for import or entry services listed in paragraphs (a)(1) through (a)(5) of this section, except those services covered by flat rate user fees elsewhere in this part, will be calculated at $56.00 per hour, or $14.00 per quarter hour, with a minimum fee of $16.50, for each employee required to perform the service. The person for whom the service is provided and the person requesting the service are jointly and severally liable for payment of these user fees in accordance with §§130.50 and 130.51.

   * * * *

   Done in Washington, DC, this 29th day of November 1999.

   **Bobby R. Acord,**

   Acting Administrator, Animal and Plant Health Inspection Service.

   [FR Doc. 99–31371 Filed 12–2–99; 8:45 am]

   BILLING CODE 3410–34–U
DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Part 130
[Docket No. 98–004–1]

Veterinary Services User Fees

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: We are making miscellaneous, nonsubstantive changes to the Veterinary Services user fee regulations. We are clarifying wording in the regulations to make the user fee regulations easier to understand and follow. We are also combining all pet bird user fees into one section in order to make them easier to find and consistently apply. These changes will make it easier to look up user fee rates and related information.

EFFECTIVE DATE: November 29, 1999.

FOR FURTHER INFORMATION CONTACT: For information concerning program operations for Veterinary Services, contact Ms. Louise Lothery, Director, Management Support Staff, VS, APHIS, 4700 River Road Unit 44, Riverdale, MD 20737–1231; (301) 734–7517.

For information concerning user fees, contact Ms. Donna Ford, Section Head, Financial Systems and Services Branch, Budget and Accounting Service Enhancement Unit, MRPBS, APHIS, 4700 River Road Unit 54, Riverdale, MD 20737–1232; (301) 734–8351.

SUPPLEMENTARY INFORMATION:

Background

The regulations in 9 CFR part 130 (referred to below as the regulations) specify user fees for services provided by the Animal and Plant Health Inspection Service (APHIS) for animals and birds, animal products, germ plasm, and organisms and vectors. We have reviewed the regulations and found some obsolete, redundant, and confusing items. We are updating and clarifying the regulations as explained below to resolve these problems. These editorial changes will not change the user fee rates.

Animal Quarantine Facilities

Section 130.2 of the regulations lists the user fees which must be paid for each animal or bird quarantined in an APHIS-owned or -operated animal import center or other quarantine facility. The current title, “User fees for individual animals and certain birds quarantined in APHIS Animal Import Centers,” implies that our charges are limited to those quarantine facilities specifically defined as animal import centers in 9 CFR 130.1. In order to clarify that APHIS’ user fees apply at all APHIS-owned or -supervised animal quarantine facilities, we are changing the title of § 130.2 to “User fees for individual animals and certain birds quarantined in APHIS-owned or -operated animal quarantine facilities, including APHIS Animal Import Centers.”

User Fees Along the United States-Mexico Border

Section 130.6 of the regulations lists user fees for import or entry services for live animals at land border ports along the United States-Mexico border. The categories for the different types of live animals are: feeder; slaughter; horses, other than slaughter; in-bond or in transit; and any ruminants not covered by the other categories listed. There has been some confusion among persons who receive services as to which category applies to breeder ruminants, such as breeding cattle. Breeder ruminants fall under the category of “Any ruminants not covered above.” To clarify this, we are amending § 130.6 by specifically adding breeder ruminants in the category of any ruminant not covered by the other categories listed.

Pet Bird User Fees

Section 130.8 of the regulations lists user fees for services that are not specifically addressed elsewhere in part 130. This list includes fees for pet birds, except pet birds of U.S. origin entering the United States from Canada. Section 130.10 lists the user fees for pet birds quarantined in APHIS-owned or -supervised quarantine facilities. We are consolidating all pet bird user fees into § 130.10. Moving the fees pertaining to pet birds from § 130.8 into § 130.10 will make it easier to find all the pet bird user fees. We are also changing the title of § 130.10 to “User fees for pet birds.”

Endorsing Export Health Certificates

Section 130.20 of the regulations lists the user fees we charge for endorsing export health certificates. The section currently lists user fees for endorsing certificates for various animals and animal products. It also has a user fee for “Other endorsements or certifications.” There has been confusion as to which user fee applies for certifications for nonanimal products. For example, if requested, we endorse export health certificates for grain shipments to certify that the grain shipments are free from specified plant diseases. We currently charge the same user fee—the “Animal products” fee—for endorsing an export health certificate for a nonanimal product as we do for endorsing a certificate for an animal product. Therefore, we are amending § 130.20 to clarify this by changing the user fee category “Animal products” to read “Animal and nonanimal products.”

The user fees listed in § 130.20 are broken down into two categories. In § 130.20, paragraph (a) lists user fees for endorsing export health certificates that do not require verification of tests or vaccinations; § 301.20(b)(1) lists user fees for endorsing export health certificates that do require verification of tests or vaccinations. Among the user fees listed in § 130.20(a) is a fee for endorsing export health certificates for “nonslaughter horses to Canada.” Nonslaughter horses being moved to Canada require only one test. However, that test needs to be verified. Therefore, we are amending § 130.20 to move the user fee for “nonslaughter horses to Canada” from § 130.20(a) to § 130.20(b)(1).

Miscellaneous

We are also making other miscellaneous, nonsubstantive changes throughout part 130 that will make it easier to look up user fee rates and related information.

Effective Date

This rule makes nonsubstantive changes to the Veterinary Services user fee regulations for clarity and consistency. Because the changes contained in this rule are nonsubstantive in nature, notice and other public procedure on this rule are unnecessary and contrary to the public interest. Therefore, pursuant to 5 U.S.C. 553, notice of proposed rulemaking and opportunity to comment are not required, and this rule may be made effective less than 30 days after publication in the Federal Register. Further, since this rule does not make a substantive change in the regulations, it is exempt from the provisions of Executive Orders 12866 and 12988. Finally, this action is not a rule as defined by the Regulatory Flexibility Act (5 U.S.C. 601) and, thus, is exempt from the provisions of that Act.

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 inconsistent with this rule; (2) has no retroactive effect; and (3) does not require administrative proceedings before parties may file suit in court challenging this rule.

Paperwork Reduction Act
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 Part 130
Animals, Birds, Diagnostic reagents, Exports, Imports, Poultry and poultry products, Quarantine, Reporting and recordkeeping requirements, Tests.

Accordingly, we are amending 9 CFR part 130 as follows:

PART 130—USER FEES
1. The authority citation for part 130 continues to read as follows:
2. In §130.2, the section heading is revised to read as follows:
§130.2 User fees for individual animals and certain birds quarantined in APHIS-owned or -operated animal quarantine facilities, including APHIS Animal Import Centers.
3. In §130.6, in the table in paragraph (a), the entry for “Any ruminants not covered above” is revised to read as follows:
§130.6 User fees for import or entry services for live animals at land border ports along the United States-Mexico border.
(a) * * *

<table>
<thead>
<tr>
<th>Type of live animal</th>
<th>User fee (per head)</th>
</tr>
</thead>
<tbody>
<tr>
<td>* * * * *</td>
<td>* *</td>
</tr>
</tbody>
</table>

Any ruminants (including breeders ruminants) not covered above .......................... 6.00

* * * * *

§130.8 [Amended]
4. In §130.8, the table in paragraph (a) is amended by removing the entire entry for pet birds.

5. Section 130.10 is amended as follows:
(a) The section heading is revised to read as set forth below.
(b) Paragraphs (a) through (c) are redesignated as paragraphs (b) through (d), respectively.
(c) A new paragraph (a) is added to read as set forth below.
(d) Footnote 4 in the redesignated paragraph (b) is removed.

§130.10 User fees for pet birds.
(a) User fees for pet birds of U.S. origin returning to the United States, except pet birds of U.S. origin returning from Canada, are as follows:
(1) $71.25 per lot if the birds have been out of the United States for 60 days or less;
(2) $169.75 per lot if the birds have been out of the United States for more than 60 days.

* * * * *

§130.14 [Amended]
6. In §130.14, footnote 5 is redesignated as footnote 4.
7. Section 130.20 is amended as follows:
(a) In paragraph (a), footnote 6 is redesignated as footnote 5.
(b) In paragraph (a), the table is revised to read.
(c) In paragraph (b)(1), the table is revised to read as follows:
§130.20 User fees for endorsing export health certificates.
(a) * * *

<table>
<thead>
<tr>
<th>Certificate categories</th>
<th>User fee</th>
</tr>
</thead>
<tbody>
<tr>
<td>Slaughter animals (except poultry) moving to Canada or Mexico ..........................</td>
<td>$24.50</td>
</tr>
<tr>
<td>Poultry, including slaughter poultry ..................................................</td>
<td>21.00</td>
</tr>
<tr>
<td>Hatching eggs ........................................</td>
<td>21.00</td>
</tr>
<tr>
<td>Animal and nonanimal products ............................................</td>
<td>21.50</td>
</tr>
<tr>
<td>Other endorsements or certifications .......................................</td>
<td>16.50</td>
</tr>
</tbody>
</table>

(b)(1) * * *

<table>
<thead>
<tr>
<th>Number of tests/vaccinations</th>
<th>Animals or birds on certificate</th>
<th>User fee</th>
</tr>
</thead>
<tbody>
<tr>
<td>1—2 ........................</td>
<td>Nonslaughter horses to Canada. Other animals or birds: First animal ..</td>
<td>$26.25</td>
</tr>
<tr>
<td>........................</td>
<td>Each additional animal.</td>
<td>52.50</td>
</tr>
<tr>
<td>........................</td>
<td>First animal ......</td>
<td>52.50</td>
</tr>
<tr>
<td>........................</td>
<td>Each additional animal.</td>
<td>5.00</td>
</tr>
<tr>
<td>3—6 ........................</td>
<td></td>
<td>64.75</td>
</tr>
</tbody>
</table>

Number of tests/vaccinations Animals or birds on certificate User fee
7 or more ........ First animal ..... 75.75 Each additional animal. 6.00

* * * * *

§130.50 [Amended]
8. In §130.50, paragraph (b)(3)(i), in the table, the first entry is amended by adding the words “or 7 CFR 354.3” immediately after “§97.1(a)”.

Done in Washington, DC, this 29th day of November 1999.

Bobby R. Acord,
Acting Administrator, Animal and Plant Health Inspection Service.

BILLING CODE 7590±01±P
DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 25

[Docket No. NM162; Special Conditions No. 25–154–SC]

Special Conditions: Bombardier Model DHC–8–400 Airplane; Automatic Takeoff Thrust Control System

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final special conditions.

SUMMARY: These special conditions are issued for the Bombardier Model DHC–8–400 airplane. This new airplane will have a novel or unusual design feature associated with an Automatic Takeoff Thrust Control System (ATTCS). The applicable airworthiness regulations do not contain appropriate safety standards for approach climb performance using an ATTCS. These special conditions contain the additional safety standards that the Administrator considers necessary to establish a level of safety equivalent to that established in the regulations.

Type Certification Basis

Under the provisions of Title 14, Code of Federal Regulations (14 CFR) §21.101, Bombardier must show that the Model DHC–8–400 meets the applicable provisions of the regulations incorporated by reference in Type Certificate No. A13NM or the applicable regulations in effect on the date of application for the change to the Model DHC–8–400. The regulations incorporated by reference in the type certificate are commonly referred to as the “original type certification basis.” The regulations incorporated by reference in Type Certificate No. A13NM are as follows: part 25, effective February 1, 1965, including Amendments 25–1 through 25–86, and §25.109 as amended by Amendment 92. The certification basis may also include later amendments to part 25 that are not relevant to these special conditions. In addition, the certification basis for the Model DHC–8–400 includes part 34, effective September 10, 1990, including Amendment 34–3 effective February 3, 1999, plus any amendments in effect at the time of certification; and part 36, effective December 1, 1969, including Amendments 36–1 through 36–21 and any subsequent amendments which will be applicable on the date the type certificate is issued. These special conditions form an additional part of the type certification basis. In addition, the certification basis may include other special conditions that are not relevant to these special conditions.

If the Administrator finds that the applicable airworthiness regulations (i.e., part 25, as amended) do not contain adequate or appropriate safety standards for the Bombardier Model DHC–8–400 because of a novel or unusual design feature, special conditions are prescribed under the provisions of §21.16. In addition to the applicable airworthiness regulations and special conditions, the Model DHC–8–400 must comply with the fuel vent and exhaust emission requirements of 14 CFR part 34 and the noise certification requirements of 14 CFR part 36. Special conditions, if appropriate, are issued in accordance with §11.49 after public notice, as required by §§11.28 and 11.29(b), and become part of the type certification basis in accordance with §21.101(b)(2).

Special conditions are initially applicable to the model for which they are issued. Should the type certificate for that model be amended later to include any other model that incorporates the same novel or unusual design feature, or should any other model already included on the same type certificate be modified to incorporate the same novel or unusual design feature, the special conditions would also apply to the other model under the provisions of §21.101(a)(1).

Novel or Unusual Design Features

The Model DHC–8–400 will incorporate the following novel or unusual design feature: the Automatic Takeoff Thrust Control System (ATTCS), referred to by Bombardier as uptrim, to show compliance with the approach climb requirements of §25.121(d). The Bombardier Model DHC–8–400 is a medium-sized airplane powered by two Pratt & Whitney Canada PW150A turbopropeller engines equipped with Full Authority Digital Engine Controls (FADEC) that, in part, protect against exceeding engine limits. The Model DHC–8–400 is also equipped with Dowty Aerospace Model R408 propellers as part of the propulsion package. The propellers incorporate a Propeller Electronic Control (PEC) that functions with the FADEC to control the engine/propeller system.

The Model DHC–8–400 incorporates a non-moving throttle system that functions by placing the throttle levers in detents for the takeoff and climb phases of flight, allowing the FADEC to schedule power settings based on flight phase. With the uptrim and associated systems functioning normally as designed, all applicable requirements of 14 CFR, part 25 and paragraph 23 of the Joint Aviation Requirements (JAR), will be met without requiring any action by the crew to increase power. Automatic takeoff power control on the Model DHC–8–400 involves uptrimming the remaining engine to Maximum Takeoff Power (MTO&P) and autofeathering the propeller on the failed engine. These actions will be controlled by the PEC. At takeoff when AUTOFEATHER (A/F) is selected and the power levers are set to Normal Takeoff Power (NTO&P), the engine display will show an “A/F ARM” message. This engine display will confirm to the pilot that the system is armed and autofeather and uptrim will occur without any further action by the crew if an engine fails. During go-around the uptrim will be automatically
arm as soon as the control (power) levers are set to the takeoff (go-around) configuration.

Engine power is set to NTOP, which is 90 percent of MTOP, to initiate the takeoff roll. The value of NTOP for the current ambient conditions will be calculated and set by the FADEC. Following an engine failure during takeoff or go-around, the ATTCS will change the power reference on the operating engine to achieve the MTOP rating if the engine power was originally set to NTOP. If the reduced power takeoff option is being used the ATTCS will increase the power of the operating engine from 90 percent to 100 percent of the corresponding set power.

The engine operating limits (turbine temperature and RPM) for NTOP are set and displayed to the pilot when that rating is selected. These limits are set such that the engine red line limits are not exceeded when an uptrim is applied. When MTOP rating is selected or triggered, the engine limits are reset automatically to reflect the engine red line limits.

When both Power Lever Angles (PLA) are high and both the Condition Lever Angles (CLA) are at maximum position (MAX), the system is armed. If the torque on one engine drops below 25 percent, the PEC on the failed engine sends an uptrim signal to the remaining engine. Other conditions that will trigger the uptrim are the reduction of prop speed (Np) below 80 percent or the automatic feathering of the prop. The power levers will continue to function normally should the ATTCS fail. The MTOP can also be selected by pressing the ‘“MTOP” switch on the engine control panel. The full MTOP is available if the pilot elects to push the PLA past the takeoff power detent into the over travel range.

To deactivate the uptrim, the PLA’s should be moved out of the rating detent to a position less than 60 degrees (PLA not high) or the CLA of the active engine should be moved out of the MAX/1020 takeoff detent.

The part 25 standards for ATTCS, contained in § 25.904 and appendix I, specifically restrict performance credit for ATTCS to takeoff. Expanding the scope of the standards to include other phases of flight, including go-around, was considered at the time the standards were issued, but flightcrew workload issues precluded further consideration. As stated in the preamble to Amendment 25–62: “In regard to ATTCS credit for approach climb and go-around maneuvers, current regulations is to ensure a higher thrust for the approach climb (§ 25.121(d)) than for the landing climb (§ 25.119). The workload required for the flightcrew to monitor and select from multiple in-flight thrust settings in the event of an engine failure during a critical point in the approach, landing, or go-around operations is excessive. Therefore, the FAA does not agree that the scope of the amendment should be changed to include the use of ATTCS for anything except the takeoff phase” (52 FR 43153, November 9, 1987).

The ATTCS incorporated on the Model DHC–8–400 allows the pilot to use the same power setting procedure during a go-around, regardless of whether or not an engine fails. In either case, the pilot obtains go-around power by moving the throttles into the forward (takeoff/go-around) throttle detent. Since the ATTCS is permanently armed, it will function automatically following an engine failure, and advance the remaining engine to the ATTCS thrust level. Therefore, this design adequately addresses the pilot workload concerns identified in the preamble to Amendment 25–62. Accordingly, these proposed special conditions would require a showing of compliance with those provisions of § 25.904 and appendix I that are applicable to the approach climb and go-around maneuvers.

The definition of a critical time interval for the approach climb case, during which time it must be extremely improbable to violate a flight path based on the § 25.121(d) gradient requirement, is of primary importance. The § 25.121(d) gradient requirement implies a minimum one-engine-inoperative flight path capability with the airplane in the approach configuration. The engine may have been inoperative before initiating the go-around, or it may become inoperative during the go-around. The definition of the critical time interval must consider both possibilities.

Discussion of Comments
Notice of Proposed Special Conditions No. 25–99–08–SC for the Bombardier Model DHC–8–400 series airplanes was published in the Federal Register on August 12, 1999 (64 FR 43943). Two commenters responded to the Notice.

Comment: One commenter states that the proposed special condition defines time periods for two different failure cases in an ATTCS go-around (not the same as critical time intervals) whose permitted duration is related to a period in the takeoff case (again, not the critical time interval). However, it is not clear how correlation with the takeoff case seems weak: in the takeoff case, the effect of an engine failure plus ATTCS failure in the critical time interval shall not result in a significant loss or reduction in thrust power, or must be shown to be an extremely improbable event. No changes were made to the proposed special condition as a result of this comment.

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Disposition: The time periods referring to the takeoff case in the definition of the critical time interval for go-around are associated with the minimum acceptable time period for the flightcrew to recognize the combined ATTCS and engine failure and to take corrective action by manually inserting go-around thrust. Using the time interval from the takeoff case for the time it takes the flightcrew to recognize and respond makes use of an accepted benchmark and ensures consistent treatment in the design and evaluation of the ATTCS for both takeoff and go-around. The intent of the special condition is to ensure a flight path implied by the part 25 approach climb gradient requirement is...
maintained when an automatic system is used to increase thrust on the operating engine when an engine fails. For both the takeoff and the go-around cases, the intent is for compliance with the applicable part 25 performance requirements to continue to be met, considering the potential for a concurrent ATTCS and engine failure. No changes were made to the proposed special condition as a result of this comment.

Comment: One commenter states there are no criteria directly associated with failures in the go-around critical time interval, noting that the “effect” is variable depending on go-around height, but surprisingly, the special condition deals only in terms of gradients. This is presumably by analogy with the basic go-around performance requirements, which are not tightly tied to obstacle clearance, but it does make it difficult to understand the objective of the special condition. Is it obstacle clearance or ground contact in the go-around?

Disposition: The Appendix I to part 25 requirements related to the critical time interval continue to apply for use of ATTCS in the go-around phase of flight. The part 25 approach climb gradient, which is the only applicable part 25 requirement for the use of ATTCS for go-around, is independent of the go-around initiation height. The objective of the special condition is to retain the performance capability associated with the part 25 approach climb requirement, which is not directly tied to either obstacle clearance or ground contact in the go-around. No changes were made to the proposed special condition as a result of this comment.

Comment: One commenter asks why the approach is assumed to be made on a 2.5 degree glidepath.

Disposition: Two and one-half degrees were selected to conservatively represent a normal approach glidepath, which is typically 2.5 to 3 degrees. No changes were made to the proposed special condition as a result of this comment.

Comment: One commenter notes that in the absence of any height constraints, the construction of the flight paths for setting the critical time interval could in theory involve flight below ground level, but still give a valid interval. Would this be acceptable?

Disposition: The special condition ensures that the existing part 25 requirements are met for an airplane incorporating an ATTCS. Under this special condition, the go-around flight path will not deviate below that required by part 25. The operating requirements address the relationship between this go-around flight path capability and the surrounding terrain. No changes were made to the proposed special condition as a result of this comment.

Comment: One commenter asks the purpose of the proposed special condition.

Disposition: The special condition ensures that the existing part 25 requirements are met for an airplane incorporating an ATTCS.

Comment: One commenter asks what regulatory effect the proposed special condition might have on design or performance scheduling.

Disposition: The special condition will affect the design of the ATTCS to the extent that the system meets the reliability requirements associated with the critical time interval for the go-around phase of flight. The special condition will provide the flightcrew with a means to verify, before beginning an approach for landing, that the ATTCS is in a condition to operate. There will be no effect on performance scheduling.

Comment: One commenter states that the absence of a defined point of origin for the go-around makes the possible effects and safety benefits of the proposed special condition hard to predict.

Disposition: The proposed special condition will ensure that the relevant part 25 requirement associated with go-around, § 25.121(d), will continue to be met when a system is installed that automatically increases power on the operating engine after an engine fails. Therefore, the level of safety provided by the special condition for an airplane with such a system installed is equivalent to that assured by part 25 for airplanes that do not have such a system. No changes were made to the proposed special condition as a result of this comment.

Applicability

As discussed above, these proposed special conditions would be applicable to the Bombardier Model DHC-8–400. Should Bombardier apply at a later date for a change to the type certificate to include another model incorporating the same novel or unusual design feature, these special conditions would apply to that model as well under the provisions of § 21.101(a)(1).

Under standard practice, the effective date of final special conditions would be 30 days after the date of publication in the Federal Register; however, as the certification date for the CASA Model C–295 is imminent, the FAA finds that good cause exists to make these special conditions effective upon issuance.

Conclusion

This action affects only certain novel or unusual design features on the Bombardier Model DHC–8–400 airplane. It is not a rule of general applicability and affects only the applicant who applied to the FAA for approval of these features on the airplane.

List of Subjects in 14 CFR part 25

Aircraft, Aviation safety, Reporting and recordkeeping requirements.

The authority citation for these proposed special conditions is as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701, 44702, 44704.

The Special Conditions

Accordingly, pursuant to the authority delegated to me by the Administrator, the following special conditions are issued as part of the type certification basis for the Bombardier Regional Aircraft Model DHC–8–400 airplane.

1. General. An Automatic Takeoff Thrust Control System (ATTCS) is defined as the entire automatic system, including all devices, both mechanical and electrical that sense engine failure, transmit signals, actuate fuel controls or power levers, or increase engine power by other means on operating engines to achieve scheduled thrust or power increases and furnish cockpit information on system operation.

2. ATTCS. The engine power control system that automatically resets the power or thrust on the operating engine (following engine failure during the approach for landing) must comply with the following requirements:

a. Performance and System Reliability Requirements. The probability analysis must include consideration of ATTCS failure occurring after the time at which the flightcrew last verifies that the ATTCS is in a condition to operate until the beginning of the critical time interval.

b. Thrust Setting. The initial takeoff thrust set on each engine at the beginning of the takeoff roll or go-around may not be less than:

(1) Ninety (90) percent of the thrust level set by the ATTCS (the maximum takeoff thrust or power approved for the airplane under existing ambient conditions);

(2) That required to permit normal operation of all safety-related systems and equipment dependent upon engine thrust or power lever position; or
(3) That shown to be free of hazardous engine response characteristics when thrust is advanced from the initial takeoff thrust or power to the maximum approved takeoff thrust or power.

   c. Powerplant Controls. In addition to the requirements of §25.1141, no single failure or malfunction, or probable combination thereof, of the ATTCS, including associated systems, may cause the failure of any powerplant function necessary for safety. The ATTCS must be designed to:

   (1) Apply thrust or power on the operating engine(s), following any one engine failure during takeoff or go-around, to achieve the maximum approved takeoff thrust or power without exceeding engine operating limits; and

   (2) Provide a means to verify to the flightcrew before takeoff and before beginning an approach for landing that the ATTCS is in a condition to operate.

3. Critical Time Interval. The definition of the Critical Time Interval in appendix I, §I25.2(b) shall be expanded to include the following:

   a. When conducting an approach for landing using ATTCS, the critical time interval is defined as follows:

   (1) The critical time interval begins at a point on a 2.5 degree approach glide path from which, assuming a simultaneous engine and ATTCS failure, the resulting approach climb flight path intersects a flight path originating at a later point on the same approach path corresponding to the part 25 one-engine-inoperative approach climb gradient. The period of time from the point of simultaneous engine and ATTCS failure to the intersection of these flight paths must be no shorter than the time interval used in evaluating the critical time interval for takeoff beginning from the point of simultaneous engine and ATTCS failure and ending upon reaching a height of 400 feet.

   (2) The critical time interval ends at the point on a minimum performance, all-engines-operating go-around flight path from which, assuming a simultaneous engine and ATTCS failure, the resulting minimum approach climb flight path intersects a flight path corresponding to the part 25 minimum one-engine-inoperative approach climb gradient. The all-engines-operating go-around flight path and the part 25 one-engine-inoperative approach climb gradient flight path originate from a common point on a 2.5 degree approach path. The period of time from the point of simultaneous engine and ATTCS failure to the intersection of these flight paths must be no shorter than the time interval used in evaluating the critical time interval for the takeoff beginning from the point of simultaneous engine and ATTCS failure and ending upon reaching a height of 400 feet.

   b. The critical time interval must be determined at the altitude resulting in the longest critical time interval for which one-engine-inoperative approach climb performance data are presented in the Airplane Flight Manual.

   c. The critical time interval is illustrated in the following figure:
The Model 20–C5/-D5/-E5/-F5 series of low wing airplanes are pressurized airplanes with twin, Garrett TRE731–5AR turbofans that are configured for 8–10 passengers and a crew of 2. The airplane has a maximum takeoff weight of 29,000 pounds, a maximum landing weight of 27,734 pounds, and a range of 1600 nautical miles. The overall length of the Falcon Model 20–C5/–D5/–E5/–F5 airplanes is 56 feet 3 inches, and the wing span is 53 feet, 6 inches.

The modification incorporates the installation of flat panel displays for display of critical flight parameters (altitude, airspeed, and attitude) to the crew. These displays can be susceptible to disruption to both command/response signals as a result of electrical and magnetic interference. This disruption of signals could result in loss of all critical flight displays and annunciations or present misleading information to the pilot.

**Type Certification Basis**

Under the provisions of 14 CFR 21.101, Garrett Aviation Services must show that the Dassault Aviation Falcon Model 20–C5/–D5/–E5/–F5 airplanes, as changed, continue to meet the applicable provisions of the regulations incorporated by reference in Type Certificate No. A7EU, or the applicable regulations in effect on the date of application for the change. The regulations incorporated by reference in the type certificate are commonly referred to as the "original type certification basis." The regulations incorporated by reference in Type Certificate No. A7EU are as follows:

The certification basis for the modified Dassault Aviation Falcon Model 20–C5/–D5/–E5/–F5 airplanes includes Civil Air Regulations (CAR) 4b, effective December 31, 1953. Amendments 4b-1 through 4b-12, Special Regulation SR422B, and provisions of FAR amendment 25–4 in lieu of CAR 4b.350(e) and (f).

If the Administrator finds that the applicable airworthiness regulations (i.e., CAR 4b, as amended) do not contain adequate or appropriate safety standards for the Dassault Aviation Falcon Model 20–C5/–D5/–E5/–F5 airplanes because of a novel or unusual design feature, special conditions are prescribed under the provisions of § 21.16.

In addition to the applicable airworthiness regulations and special conditions, the Model 20–C5/–D5/–E5/–F5 must comply with the fuel vent and exhaust systems requirements of 14 CFR part 34 and the noise certification requirements of 14 CFR part 36.

Special conditions, as appropriate, are issued in accordance with 14 CFR 11.49, as required by §§ 11.28 and 11.29(b), and become part of the type certification basis in accordance with § 21.101(b)(2).

Special conditions are initially applicable to the model for which they are issued. Should Garrett Aviation Services apply for a supplemental type certificate to modify any other model included on the same type certificate to incorporate the same novel or unusual design feature, the special conditions would also apply to the other model under the provisions of § 21.101(a)(1).

**Novel or Unusual Design Features**

The modified Dassault Aviation Falcon Model 20–C5/–D5/–E5/–F5 airplanes will incorporate the following new design feature: a new electronic flat panel display system, which was not available at the time of certification of these airplanes, that performs critical functions. This system may be vulnerable to HIRF external to the airplane.

**Discussion**

There is no specific regulation that addresses protection requirements for electrical and electronic systems from HIRF. Increased power levels from ground-based radio transmitters and the growing use of sensitive electrical and electronic systems to command and control airplanes have made it necessary to provide adequate protection. To ensure that a level of safety is achieved equivalent to that intended by the regulations incorporated by reference, special conditions are needed for the Dassault Aviation Falcon Model 20–C5/–D5/–E5/–F5 airplanes, which require that new electrical and electronic systems that perform critical functions, such as the flat panel displays for display of critical flight parameters (altitude, airspeed, and attitude) to the crew, be designed and installed to preclude component damage and interruption of function due to both the direct and indirect effects of HIRF.

**High-Intensity Radiated Fields (HIRF)**

With the trend toward increased power levels from ground-based transmitters, plus the advent of space and satellite communications coupled with electronic command and control of the airplane, the immunity of critical digital avionics systems to HIRF must be established. It is not possible to precisely define the HIRF to which the airplane will be exposed in service. There is also uncertainty concerning the effectiveness of airframe shielding for HIRF.
Furthermore, coupling of electromagnetic energy to cockpit-installed equipment through the cockpit window apertures is undefined. Based on surveys and analysis of existing HIRF emitters, an adequate level of protection exists when compliance with the HIRF protection special condition is shown with either paragraph 1 or 2 below:

1. A minimum threat of 100 volts rms per meter electric field strength from 10 kHz to 18 GHz.

   a. The threat must be applied to the system elements and their associated wiring harnesses without the benefit of airframe shielding.

   b. Demonstration of this level of protection is established through system tests and analysis.

2. A threat external to the airframe of the following field strengths for the frequency ranges indicated.

<table>
<thead>
<tr>
<th>Frequency</th>
<th>Field Strength (volts per meter)</th>
</tr>
</thead>
<tbody>
<tr>
<td>10 kHz–100 kHz</td>
<td>Peak 50, Average 50</td>
</tr>
<tr>
<td>100 kHz–500 kHz</td>
<td>Peak 50, Average 50</td>
</tr>
<tr>
<td>500 kHz–2 MHz</td>
<td>Peak 50, Average 50</td>
</tr>
<tr>
<td>2 MHz–30 MHz</td>
<td>Peak 100, Average 100</td>
</tr>
<tr>
<td>30 MHz–70 MHz</td>
<td>Peak 50, Average 50</td>
</tr>
<tr>
<td>70 MHz–100 MHz</td>
<td>Peak 50, Average 50</td>
</tr>
<tr>
<td>100 MHz–200 MHz</td>
<td>Peak 100, Average 100</td>
</tr>
<tr>
<td>200 MHz–400 MHz</td>
<td>Peak 100, Average 100</td>
</tr>
<tr>
<td>400 MHz–700 MHz</td>
<td>Peak 700, Average 700</td>
</tr>
<tr>
<td>700 MHz–1 GHz</td>
<td>Peak 700, Average 700</td>
</tr>
<tr>
<td>1 GHz–2 GHz</td>
<td>Peak 2000, Average 2000</td>
</tr>
<tr>
<td>2 GHz–4 GHz</td>
<td>Peak 3000, Average 3000</td>
</tr>
<tr>
<td>4 GHz–6 GHz</td>
<td>Peak 3000, Average 3000</td>
</tr>
<tr>
<td>6 GHz–8 GHz</td>
<td>Peak 1000, Average 1000</td>
</tr>
<tr>
<td>8 GHz–12 GHz</td>
<td>Peak 3000, Average 3000</td>
</tr>
<tr>
<td>12 GHz–18 GHz</td>
<td>Peak 2000, Average 2000</td>
</tr>
<tr>
<td>18 GHz–40 GHz</td>
<td>Peak 600, Average 600</td>
</tr>
</tbody>
</table>

The field strengths are expressed in terms of peak root-mean-square (rms) values.

The threat levels identified above are the result of an FAA review of existing studies on the subject of HIRF, in light of the ongoing work of the Electromagnetic Effects Harmonization Working Group of the Aviation Rulemaking Advisory Committee.

**Applicability**

As discussed above, these special conditions are applicable to Dassault Aviation Falcon Model 20–C5/–D5/–E5/–F5 airplanes modified by Garrett Aviation Services. Should Garrett Aviation Services apply at a later date for a supplemental type certificate to modify any other model included on the same type certificate to incorporate the same novel or unusual design feature, these special conditions would apply to that model as well under the provisions of §21.101(a)(1).

**Discussion of Comments**

Notice of proposed special conditions No. 25–99–07–SC was published in the Federal Register on August 12, 1999 (64 FR 43946). No comments were received.

**Conclusion**

This action affects only certain novel or unusual design features on Dassault Aviation Falcon Model 20–C5/–D5/–E5/–F5 airplanes modified by Garrett Aviation Services. It is not a rule of general applicability, and it affects only the applicant who applied to the FAA for approval of these features on the airplane.

**List of Subjects in 14 CFR Part 25**

Aircraft, Aviation safety, Reporting and recordkeeping requirements.

The authority citation for these special conditions is as follows:

**Authority:** 49 U.S.C. 106(g), 40113, 44701, 44702, 44704.

**The Special Conditions**

Accordingly, pursuant to the authority delegated to me by the Administrator, the following special conditions are issued as part of the type certification basis for Dassault Aviation Falcon Model 20–C5/–D5/–E5/–F5 airplanes modified by Garrett Aviation Services.

1. **Protection from Unwanted Effects of High-Intensity Radiated Fields (HIRF).** Each electrical and electronic system that performs critical functions must be designed and installed to ensure that the operation and operational capability of these systems to perform critical functions are not adversely affected when the airplane is exposed to high intensity radiated fields.

2. **For the purpose of these special conditions, the following definition applies:**

   **Critical Functions.** Functions whose failure would contribute to or cause a failure condition that would prevent the continued safe flight and landing of the airplane.

   Issued in Renton, Washington, on November 17, 1999.

   **Donald L. Riggin,**
   Acting Manager, Transport Airplane Directorate, Aircraft Certification Service, ANM–100.

[FR Doc. 99–31395 Filed 12–2–99; 8:45 am]

BILLING CODE 4910–13–P

**DEPARTMENT OF TRANSPORTATION**

**Federal Aviation Administration**

14 CFR Part 39

[Docket No. 99–ANE–18–AD; Amendment 39–11448; AD 99–25–05]

RIN 2120–AA64

Airworthiness Directives; Hartzell Propeller, Inc. Model HD–E6C–3( ) Propellers

**AGENCY:** Federal Aviation Administration, DOT.

**ACTION:** Final rule; request for comments.

**SUMMARY:** This amendment adopts a new airworthiness directive (AD) that is applicable to Hartzell Propeller, Inc.,
Model HD–E6C–3( ) series propellers, installed on Fairchild Dornier 328–110 series and 328–120 series airplanes. This action supersedes telegraphic AD T99–06–51 that currently requires initial and repetitive inspections of the propeller hub for cracks or grease leaks, and replacement of the hub if any cracks are found. This amendment requires an initial and repetitive inspections of Hartzell propeller hub, part number (P/N) D–5108–1, for cracks or grease leaks, replacement of the hub if any cracks are found, and allows the installation of propeller hub, P/N D–5108–5, as a terminating action for the inspection requirements. This amendment is prompted by the addition of propeller hub P/N D–5108–5 as a terminating action for the inspection requirements and by the removal of the inspection requirements for Hartzell propeller hub, P/N D–5108–5. The actions specified by this AD are intended to prevent severe vibration due to cracks in the propeller hub that could result in propeller blade loss, loss of control, and possible damage to the airplane.

DATES: Effective December 20, 1999. The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of December 20, 1999.

Comments for inclusion in the Rules Docket must be received on or before February 1, 2000.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), New England Region, Office of the Regional Counsel, Attention: Rules Docket No. 99–ANE–18–AD, 12 New England Executive Park, Burlington, MA 01803–5299. Comments may also be sent via the Internet using the following address: “9-ane-adcomment@faa.gov.” Comments sent via the Internet must contain the docket number in the subject line.

The applicable service information may be obtained from Hartzell Propeller, Inc., Technical Publications Department, One Propeller Place, Piqua, OH 45356; telephone (937) 778–4200, FAX (937) 778–4365. This information may be examined at the FAA, New England Region, Office of the Regional Counsel, 12 New England Executive Park, Burlington, MA; or at the Office of the Federal Register, 800 North Capitol Street, NW, Suite 700, Washington, DC.

FOR FURTHER INFORMATION CONTACT: Tomaso DiPaolo, Aerospace Engineer, Chicago Aircraft Certification Office, FAA, Small Airplane Directorate, 2300 East Devon Avenue, Des Plaines, IL 60018; telephone (847) 294–7031, FAX (847) 294–7834.

SUPPLEMENTARY INFORMATION: On March 2, 1999, the Federal Aviation Administration (FAA) issued telegraphic airworthiness directive (TAD) T99–06–51, applicable to Hartzell Propeller, Inc., Model HD–E6C–3( ), to require an initial and repetitive inspections of the propeller hub, regardless of propeller hub part number (P/N), for cracks or grease leaks, and replacement of the hub if any cracks are found. That action was prompted by a report of cracks in the propeller hub on a Hartzell Propeller, Inc. model HD–E6C–3B/E13890K propeller installed on a Fairchild Dornier 328–100 series airplane. Shortly after takeoff, the pilot reported severe vibration. The pilot turned back and landed at the departure airport, but an engine was not shut down in flight because the pilot could not determine which engine had a problem. During taxi back to the ramp, the pilot reported that the vibration was worse at ground idle. After shutdown, the propeller was removed and large cracks were discovered in both hub halves. That condition, if not corrected, could result in loss of control and possible damage to the airplane. Investigations have found that the cracks were propagating due to fatigue cycles. The nature or origin of the crack initiation flaw could not be determined due to the lack of physical evidence available in the post-failure hardware.

Events Since the Telegraphic AD

Since the issuance of that telegraphic AD, the FAA has determined that only Hartzell propeller hub, P/N D–5108–1, needs to be inspected. Also, the FAA has approved the replacement of Hartzell propeller hub, P/N D–5108–1 with an improved design Hartzell propeller hub, P/N D–5108–5, as terminating action for the inspection requirement. The improved design of the D–5108–5 hub addresses all determined possible causes of crack initiation.

Service Information

The FAA has reviewed and approved the technical contents of Hartzell Propeller, Inc. Alert Service Bulletin (ASB) HD–ASB–61–021, Revision 1, dated March 18, 1999, that describes procedures for visual inspections of propeller hubs for cracks and grease leaks and for replacing the propeller hub.

Required Actions

Since an unsafe condition has been identified that is likely to exist or develop on other propellers of the same type design, this AD supersedes telegraphic AD T99–06–51 to require an initial visual inspection of the Hartzell propeller hub, P/N D–5108–1, within 12 hours time-in-service after the effective date of this AD, and repetitive inspections at the start of each operational day and replacement of propeller hub P/N D–5108–1, with propeller hub P/N D–5108–5, within 600 hours TIS or three months after the effective date of this AD. The actions are required to be accomplished in accordance with the alert service bulletin described previously.

Immediate Action

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

Comments Invited

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

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

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this notice must submit a self-addressed, stamped postcard on which the following statement is made: “Comments to Docket Number 99–ANE–18–AD.” The
postcard will be date stamped and returned to the commenter. This proposed rule does not have federalism implications, as defined in Executive Order 13132, because it 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. Accordingly, the FAA has not consulted with state authorities prior to publication of this proposed rule. The FAA has determined that this regulation is an emergency regulation that must be issued immediately to correct an unsafe condition in aircraft, and is not a “significant regulatory action” under Executive Order 12866. It has been determined further that this action involves an emergency regulation under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979). If it is determined that this emergency regulation otherwise would be significant under DOT Regulatory Policies and Procedures, a final regulatory evaluation will be prepared and placed in the Rules Docket. A copy of it, if filed, may be obtained from the Rules Docket at the location provided under the caption ADDRESSES. List of Subjects in 14 CFR Part 39 Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety. Adoption of the Amendment Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration amends part 39 of the Federal Aviation Regulations (14 CFR part 39) as follows: PART 39—AIRWORTHINESS DIRECTIVES 1. The authority citation for part 39 continues to read as follows: Authority: 49 U.S.C. 106(g), 40113, 44701. §39.13 [Amended] 2. Section 39.13 is amended by adding the following new airworthiness directive: 99–23–05 Hartzell Propeller, Inc.: Amendment 39–11446; Docket 99–ANE–18–AD. Applicability: Hartzell Propeller, Inc., Model HD–E6C–5f; series propellers with propeller hub part number D–5108–1, installed on but not limited to Fairchild Dornier 328–110 and 328–120 series airplanes. Note 1: This airworthiness directive (AD) applies to each propeller identified in the preceding applicability provision, regardless of whether it has been modified, altered, or repaired in the area subject to the requirements of this AD. For propellers that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance in accordance with paragraph (e) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and, if the unsafe condition has not been eliminated, the request should include specific proposed actions to address it. Initial and Repetitive Inspection Requirements (a) Perform initial and repetitive visual inspections of the Hartzell propeller hub part number P/N D–5108–1 for cracks and grease leaks in accordance with paragraph 3.A. of the Accomplishment Instructions of Hartzell Propeller, Inc. ASB No. HD–ASB–61–021 Revision 1, dated March 18, 1999, as follows: (1) Within 12 hours time-in-service (TIS) after the effective date of this AD, perform an initial visual inspection. (2) Thereafter, perform a daily visual inspection. However, for airplanes that are not operated on a daily basis, inspect affected propeller hubs every operational day. Confirmation of Crack (b) If a crack is confirmed, before further flight, remove cracked hub from service and replace with a serviceable part in accordance with paragraph 3.B. of the Accomplishment Instructions of ASB No. HD–ASB–61–021, revision 1, dated March 18, 1999. Terminating Action (c) Replace propeller hub P/N D–5108–1 with propeller hub P/N D–5108–5 within 600 hours TIS or three months after the effective date of this AD, whichever occurs first. (d) Installation of propeller hub, P/N D–5108–5, constitutes terminating action for the inspection requirements of this AD. Alternative Methods of Compliance (e) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, Chicago Aircraft Certification Office (ACO), Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, ACO. Note 2: Information concerning the existence of approved alternative methods of compliance with this airworthiness directive, if any, may be obtained from the Chicago ACO. Special Flight Permits (f) Special flight permits may be issued in accordance with §§ 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the aircraft to a location where the requirements of this AD can be accomplished. Incorporation by Reference (g) The actions required by this AD shall be in accordance with Hartzell Propeller, Inc. ASB No. HD–ASB–61–021, Revision 1, dated March 18, 1999. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from Hartzell Propeller, Inc., Technical Publications Department, One Propeller Place, Piqua, OH 45356; telephone (937) 778–4200, FAX (937) 778–4365. Copies may be inspected at the FAA, New England Region, Office of the Regional Counsel, 12 New England Executive Park, Burlington, MA; or at the Office of the Federal Register, 800 North Capitol Street NW, Suite 700, Washington, DC. (h) This amendment becomes effective December 20, 1999. Issued in Burlington, Massachusetts, on November 24, 1999. David A. Downey, Assistant Manager, Engine and Propeller Directorate, Aircraft Certification Service. [FR Doc. 99–31172 Filed 12–2–99; 8:45 am] BILLING CODE 4910–13–U DEPARTMENT OF TRANSPORTATION Federal Aviation Administration 14 CFR Part 39 [Docket No. 98–ANE–76–AD Amendment 39–11446; AD 98–25–03] RIN 2120–AA64 Airworthiness Directives; International Aero Engines AG V2500–A1 Series Turbofan Engines AGENCY: Federal Aviation Administration, DOT. ACTION: Final rule. SUMMARY: This amendment supersedes two airworthiness directives (ADs) that apply to International Aero Engines AG (IAE) V2500–A1 series turbofan engines. The first superseded AD, AD 98–20–18, currently requires removal from service of affected high pressure turbine (HPT) disks, identified by part number and serial number in the applicability paragraph of that AD, and replacement with a serviceable part. The second superseded AD, AD 99–05–05, requires initial and repetitive inspections of certain HPT stage 1 and stage 2 disks utilizing an improved ultrasonic method when the disks are exposed during a normal shop visit, and if a subsurface anomaly is found, removal from service and replacement with a serviceable part. This supersede requires the initial
inspection mandated by AD 99–05–05 to be completed at the next shop visit regardless of the planned maintenance or the reason for shop removal. The repetitive inspection interval is redefined to eliminate the cyclic limit and thus be less restrictive. This superseding action is prompted by results from investigations subsequent to the publication of AD 98–20–18 that have revealed that the HPT disks affected by that AD are part of the population addressed by AD 99–05–05. These HPT disks can be safely reintroduced into service after completing the initial inspection requirements mandated by this proposed AD. This supersede is also prompted by further analysis that indicates a reduction in risk if the initial inspection required by AD 99–05–05 is completed sooner and the subsequent required inspections can be redefined to eliminate the cyclic limit, thereby creating less burden on operators. The actions specified by this AD are intended to prevent HPT disk fracture, which could result in an uncontained engine failure and damage to the airplane.


The incorporation by reference of International Aero Engines SB V2500–ENG–72–0344, dated December 18, 1998, as listed in the regulations, was approved by the Director of the Federal Register as of April 30, 1999 (64 FR 9910, March 1, 1999). The incorporation by reference of all other publications listed in the regulations is approved by the Director of the Federal Register as of January 7, 2000.

ADDRESSES: The service information referenced in this AD may be obtained from Rolls-Royce Commercial Aero Engine Limited, P.O. Box 31, Derby, England, DE2488J, Attention: Publication Services ICL-TP; telephone +44–1–33–22–46553, fax +44–1–33–22–46302. The information referenced in this AD may be obtained from the Rules Docket at the location provided under ADDRESSES.

FOR FURTHER INFORMATION CONTACT: Diane Cook, Aerospace Engineer, Engine Certification Office, FAA, Engine and Propeller Directorate, 12 New England Executive Park, Burlington, MA; or at the Office of the Federal Register, 800 North Capitol Street, NW, suite 700, Washington, DC.

SUPPLEMENTARY INFORMATION: A proposal to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) by superseding airworthiness directive (AD) 98–20–18, Amendment 39–10871 (63 FR 63398, November 13, 1998), and AD 99–05–05, Amendment 39–11053 (64 FR 9910, March 1, 1999), applicable to International Aero Engines AG (IAE) V2500–A1 series turbofan engines was published in the Federal Register on September 15, 1999 (64 FR 50020).

Supersede Requirements

This supersede requires that the initial inspection mandated by AD 99–05–05 be completed at the next shop visit regardless of the planned maintenance or the reason for shop removal. The repetitive ultrasonic inspection interval is redefined to eliminate the cyclic limit by requiring the repetitive inspection to be performed whenever the high pressure turbine (HPT) stage 1 or stage 2 disks are disassembled from the HPT module. In addition, this supersede allows the disks identified by serial number (S/N) that were retired by AD 98–20–18 to be reintroduced into service following an initial ultrasonic inspection specified by this AD.

Comment Received

Interested persons have been afforded an opportunity to participate in the making of this amendment. One favorable comment was received.

Conclusion

After careful review of the available data, including the comment noted above, the FAA has determined that air safety and the public interest require the adoption of the rule as proposed.

Cost Impact

Since this AD only adjusts the timing of inspections already required, there is no additional adverse economic impact.

Regulatory Impact

This rule does not have federalism implications, as defined in Executive Order No. 13132, because it does 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. Accordingly, the FAA has not consulted with state authorities prior to publication of this rule.

For the reasons discussed above, I certify that this action (1) is not a “significant regulatory action” under Executive Order 12866; (2) is not a “significant rule” under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A final evaluation has been prepared for this action and it is contained in the Rules Docket. A copy of it may be obtained from the Rules Docket at the location provided under the caption ADDRESSES.

List of Subjects in 14 CFR Part 39

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

Adoption of the Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

2. Section 39.13 is amended by removing amendment 39–10871 (63 FR 63398, November 13, 1998) and amendment 39–11053 (64 FR 9910, March 1, 1999) and by adding a new airworthiness directive to read as follows:


Applicability: International Aero Engines AG (IAE) V2500–A1 series turbofan engines, installed on but not limited to Airbus Industrie A320 series airplanes.

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

Compliance: Required as indicated, unless accomplished previously.

To prevent high pressure turbine (HPT) disk fracture, which could result in an uncontained engine failure and damage to the airplane, accomplish the following:
Return to Service of Certain Disks

(b) HPT stage 1 disks, part numbers (P/N’s) 2A1001, S/N’s P1000421, P1000430, P100618, and P100621, may return to service following a successful inspection in accordance with paragraph (a) of this AD.

Alternative Methods of Compliance

(c) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, Engine Certification Office (ECO). Operators shall submit their requests through an appropriate FAA Regional Maintenance Inspector, which may add comments and then send it to the Manager, ECO.

Note 2: Information concerning the existence of approved alternative methods of compliance with this airworthiness directive, if any, may be obtained from the ECO.

Ferry Flights

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

Incorporation by Reference

(e) The actions required by this AD shall be done in accordance with International Aero Engines Service Bulletin V2500–ENG–72–0344, dated December 18, 1998, or Revision 1, dated February 12, 1999. The incorporation by reference of IAE SB V2500–ENG–72–0344, dated December 18, 1998, was previously approved by the Director of the Federal Register as of April 30, 1999 (64 FR 9910, March 1, 1999). The incorporation by reference of IAE SB V2500–ENG–72–0344, Revision 1, dated February 12, 1999, was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from Rolls-Royce Commercial Aero Engine Limited, P. O. Box 31, Derby, England, DE2488F. Attention: Publication Services ICL–TP; telephone +44–1–33–22–46553, fax +44–1–33–22–46302. Copies may be inspected at the FAA, New England Region, Office of the Regional Counsel, 12 New England Executive Park, Burlington, MA; or at the Office of the Federal Register, 800 North Capitol Street, NW, suite 700, Washington, DC.

(i) This amendment becomes effective on January 7, 2000.

Issued in Burlington, Massachusetts, on November 22, 1999.

David A. Downey,
Assistant Manager, Engine and Propeller Directorate, Aircraft Certification Service.

[FR Doc. 99–31070 Filed 12–2–99; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39


[Note 2: Special flight permits may be issued in accordance with sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR part 21) to operate the aircraft to a location where the inspection requirements of this AD can be accomplished.]

A GyO: Federal Aviation Administration, DOT.

ACTION: Final rule.

SUMMARY: This amendment adopts a new airworthiness directive (AD), applicable to certain Lockheed Model 382 series airplanes, that requires a one-time visual inspection of the under floor to ring fittings at fuselage station 817E to verify installation of the correct sized fasteners; and follow-on corrective actions, if necessary. This amendment is prompted by notification from the manufacturer indicating that during production incorrect sized fasteners were installed on the under floor to ring fittings at fuselage station 817E. The actions specified by this AD are intended to prevent fatigue cracking of the fastener holes and adjacent fuselage structure due to installation of the incorrect sized fasteners, which could result in reduced structural integrity of the airplane.


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

ADDRESSES: The service information referenced in this AD may be obtained from Lockheed Martin Aeronautical Systems Support Company (LMASSC), Field Support Department, Dept. 693, Zone 0755, 2251 Lake Park Drive, Smyrna, Georgia 30063. This information may be examined at the Federal Aviation Administration (FAA), Transport Airplane Directorate, Rules Docket, 1601 Lind Avenue, SW., Renton, Washington; or at the FAA, Small Airplane Directorate, Atlanta Aircraft Certification Office, One Crowne Center, 1895 Phoenix Boulevard, suite 450, Atlanta, Georgia; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.


SUPPLEMENTARY INFORMATION: A proposal to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) to include an airworthiness directive (AD) that is applicable to certain Lockheed Model 382 series airplanes was published in the Federal Register on April 23, 1999 (64 FR 19938). That action proposed to require a one-time visual inspection of the under floor to ring fittings at fuselage station 817E to verify installation of the correct sized fasteners; and follow-on corrective actions, if necessary.

Comments

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

Request to Revise Compliance Time to Follow Alert Service Bulletin

One commenter requests that the compliance time be revised to read the same as the referenced service bulletin. While the notice of proposed rulemaking (NPRM) proposes a compliance time of 30 days after the effective date of the proposed AD, the service bulletin specifies 30 days after receipt of the service bulletin, which was issued January 30, 1997.

The FAA does not concur. The commenter’s request would result in retroactive rulemaking. The FAA does not have the legal authority to impose requirements that place operators in noncompliance based on past actions. Even if the commenter’s request was limited to future effect, as discussed in the preamble of the proposed AD, the FAA finds that a compliance time of 30 days after the effective date of this AD is adequate for accomplishment of the inspection and rework in that the FAA has determined that fatigue cracking originating at the fastener holes caused by the installation of incorrect sized fasteners could result in loss of pressurization, but not an “explosive
decompression” or severe structural degradation. In light of this, the FAA finds that it is not necessary to implement an immediate cabin pressurization limit of 8.75 in Hg (4.3 psi) for affected airplanes, which would result in immediate grounding of airplanes, to continue to operate without compromising safety.

**Explanation of Change Made to Proposal**

The FAA has clarified the inspection requirement contained in the proposed AD. Whereas the proposal specified a visual inspection, the FAA has revised this final rule to clarify that its intent is to require a general visual inspection. Additionally, a note has been added to the final rule to define that inspection.

**Conclusion**

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

**Cost Impact**

There are approximately 112 airplanes of the affected design in the worldwide fleet. The FAA estimates that 18 airplanes of U.S. registry will be affected by this AD, that it will take approximately 1 work hour per airplane to accomplish the required inspection, and that the average labor rate is $60 per work hour. Based on these figures, the cost impact of the AD on U.S. operators is estimated to be $1,080, or $60 per airplane.

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

**Regulatory Impact**

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

For the reasons discussed above, I certify that this action (1) is not a “significant regulatory action” under Executive Order 12866; (2) is not a “significant rule” under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A final evaluation has been prepared for this action and it is contained in the Rules Docket. A copy of it may be obtained from the Rules Docket at the location provided under the caption **ADDRESSES**.

**List of Subjects in 14 CFR Part 39**

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

**Adoption of the Amendment**

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

**PART 39—AIRWORTHINESS DIRECTIVES**

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

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

**§39.13 [Amended]**

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

   Docket 98–NM–371–AD.

   **Applicability:** Model 382 airplanes as listed in paragraph 1.A.(1) (“Effectivity”) of Lockheed Hercules Alert Service Bulletin A382–53–57, Revision 1, dated January 30, 1997, are considered acceptable for compliance with this AD.

   **Certification Office:** Certification Office (ACO), FAA, Small Airplane Directorate.

   **Action:**

   (i) For All Airplanes: Inspection and Corrective Action, If Necessary

   (b) [For all airplanes on which the distance between the fastener centers is greater than or equal to 0.57 inch, prior to further flight, accomplish the requirements of paragraph (b) of this AD.

   (ii) If the distance between the fastener centers is less than 0.57 inch, prior to further flight, perform a one-time visual inspection of the fuselage structure to detect discrepancies (damage, corrosion, or misdrilled or elongated fastener holes) in accordance with Lockheed Hercules Alert Service Bulletin A382–53–57, dated January 16, 1997, are considered acceptable for compliance with the applicable action specified by this AD.

   (1) If all fasteners are the correct size, no further action is required by this AD.

   (2) If any fastener is determined to be the incorrect size, prior to further flight, measure the distance between the fastener centers in accordance with the alert service bulletin.

   (i) If the distance between the fastener centers is less than 0.57 inch, prior to further flight, repair in accordance with a method approved by the Manager, Atlanta Aircraft Certification Office (ACO), FAA, Small Airplane Directorate.

   (ii) If the distance between the fastener centers is greater than or equal to 0.57 inch, prior to further flight, accomplish the requirements of paragraph (b) of this AD.

   **For All Airplanes: Inspection and Corrective Action, If Necessary**

   (a) Within 30 days after the effective date of this AD, perform a one-time general visual inspection of the under floor to ring fittings at fuselage station 817E to verify installation of the correct sized fasteners, in accordance with Lockheed Hercules Alert Service Bulletin A382–53–57, Revision 1, dated January 30, 1997.

   **Note 2:** For the purposes of this AD, a general visual inspection is defined as “A visual examination of an interior or exterior area, installation, or assembly to detect obvious damage, failure, or irregularity. This level of inspection is made under normally available lighting conditions such as daylight, hangar lighting, flashlight, or drop-light, and may require removal or opening of access panels or doors. Stands, ladders, or platforms may be required to gain proximity to the area being checked.”

   **Note 3:** Inspections, repairs, or replacements that have been accomplished prior to the effective date of this AD, in accordance with Lockheed Hercules Alert Service Bulletin A382–53–57, dated January 16, 1997, are considered acceptable for compliance with the applicable action specified by this AD.

   (i) If all fasteners are the correct size, no further action is required by this AD.

   (ii) If any fastener is determined to be the incorrect size, prior to further flight, measure the distance between the fastener centers in accordance with the alert service bulletin.

   (iii) If the distance between the fastener centers is greater than or equal to 0.57 inch, prior to further flight, accomplish the requirements of paragraph (b) of this AD.

   **For Certain Airplanes: Removal of Incorrect Sized Fasteners, Inspection, and Follow-On Actions**

   (b) For all airplanes on which the distance between the fastener centers is greater than or equal to 0.57 inch, prior to further flight, remove any incorrect sized fastener and perform a one-time visual inspection of the fastener holes and adjacent fuselage structure to detect discrepancies (damage, corrosion, or misdrilled or elongated fastener holes) in accordance with Lockheed Hercules Alert Service Bulletin A382–53–57, Revision 1, dated January 30, 1997.

   (1) If no discrepancy is detected, prior to further flight, redrill the fastener holes to the correct size and install correct sized fasteners in accordance with the alert service bulletin.

   (2) If any discrepancy is detected, prior to further flight, redrill the fastener holes to the correct size and perform an additional one-time visual inspection of the redrilled holes to detect remaining discrepancies (damage, corrosion, or misdrilled or elongated fastener holes) of the affected area, in accordance with the alert service bulletin.
DEPARTMENT OF TRANSPORTATION
Federal Aviation Administration
14 CFR Part 71

[Airspace Docket No. 99–AGL–50]
Modification of Class D Airspace and Establishment of Class E Airspace; Dayton, Wright-Patterson AFB, OH

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action modifies Class D airspace and establishes Class E airspace at Dayton, Wright-Patterson AFB, OH. This action amends the effective hours of the Class D surface area to coincide with the airport traffic control tower (ATCT) hours of operation for Wright-Patterson AFB. The purpose of this action is to clarify when two-way radio communication with the ATCT is required. This action also creates a Class E surface area for those times when the ATCT is closed.


FOR FURTHER INFORMATION CONTACT: Denis C. Burke, Air Traffic Division, AGL–520, Federal Aviation Administration, 2300 East Devon Avenue, Des Plaines, IL 60018, telephone (847) 294–7568.

SUPPLEMENTARY INFORMATION:

History

On Tuesday, September 14, 1999, the FAA proposed to amend 14 CFR part 71 to modify Class D airspace and establish Class E airspace at Dayton, Wright-Patterson AFB, OH (64 FR 49754). The proposal was to amend the effective hours to coincide with the ATCT hours of operation for Wright-Patterson AFB and to create controlled airspace when the ATCT is closed. Interested parties were invited to participate in this rulemaking proceeding by submitting written comments on the proposal to the FAA. No comments objecting to the proposal were received, Class D airspace designations are published in paragraph 5000, and Class E airspace areas designated as a surface area for an airport are published in paragraph 6002 of FAA Order 7400.9G dated September 1, 1999, and effective September 16, 1999.

The Rule

This amendment to 14 CFR part 71 modifies Class D airspace and establishes Class E airspace at Dayton, Wright-Patterson AFB, OH, by amending the hours of operation of the Class D airspace for Wright-Patterson AFB and by creating a Class E surface area during those times when the ATCT is closed. The area will be depicted on appropriate aeronautical charts.

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 DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a Regulatory Evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 71
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, CLASS B, CLASS C, CLASS D, AND CLASS E AIRSPACE AREAS; AIRWAYS; ROUTES; AND REPORTING POINTS

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


§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of the Federal Aviation Administration Order 7400.9G, Airspace Designations and Reporting Points, dated September 1, 1999, and effective September 16, 1999, is amended as follows:

Paragraph 5000 Class D airspace.

AGL OH D Dayton, Wright-Patterson AFB, OH [Revised]
Dayton, Wright-Patterson AFB, OH
AIRSPACE DESIGNATION: 
Patterson VORTAC 046 AFB, and within 1.3 miles each side of the 
Patterson VORTAC 046° radial extending 
from the 4.6-mile radius to 5.6 miles 
 northeaster of the VORTAC, excluding 
that airspace within the James M. Cox Dayton 
International Airport, OH, Class C airspace area. This 
Class D airspace area is effective during the 
specific dates and times established in advance by Notice to Airmen. 
The effective date and time will thereafter be 
continuously published in the Airport/ 
Facility Directory.

Class E airspace designated 
as a surface area.

AGL OH E2 
Dayton, Wright-Patterson AFB, 
OH [New]

Dayton, Wright-Patterson AFB, OH 
(Lat. 39°49′34″N., long. 84°02′54″W.) 
Patterson VORTAC 
(Lat. 39°49′06″N., long. 84°03′16″W.) 
That airspace extending upward from the 
surface to and including 3,400 feet MSL 
within an 4.6-mile radius of Wright-Patterson 
AFB, and within 1.3 miles each side of the 
Patterson VORTAC 046° radial extending 
from the 4.6-mile radius to 5.6 miles 
northeast of the VORTAC, excluding that 
airspace within the James M. Cox Dayton 
International Airport, OH, Class C airspace area. This 
Class E airspace area is effective during the 
specific dates and times established in advance by Notice to Airmen. 
The effective date and time will thereafter be 
continuously published in the Airport/ 
Facility Directory.


Christopher R. Blum, 
Manager, Air Traffic Division.
[FR Doc. 99–31401 Filed 12–2–99; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF TRANSPORTATION
Federal Aviation Administration

14 CFR Part 71
[Airspace Docket No. 99–AGL–42]

Modification of Class E airspace; 
Marquette, MI; Revocation of Class E 
Airspace; Sawyer, MI, and K.I. Sawyer, 
MI

AGENCY: Federal Aviation 
Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action modifies Class E 
airspace at Marquette, MI, and revokes 
the Class E airspace at Sawyer, MI, and 
K.I. Sawyer, MI. The legal description 
for the Class E airspace for Sawyer 
International Airport has been changed from 
Sawyer, MI, to Marquette, MI, and 
the legal description for Class E airspace 
for K.I. Sawyer, MI, is no longer valid 
because K.I. Sawyer Air Force Base 
(AF B) has been closed and renamed 
Sawyer International Airport. In 
addition, the closure of Marquette 
County Airport was made on September 
23, 1999. Finally, the Marquette, MI 
VHF Omnidirectional Range/Distance 
Measuring Equipment (VOR/DME) 
(MQT) navigational aid will be decommissioned and replaced with the 
new Gwinn, MI, VOR/DME (GWI), and 
will be located approximately 15 
nautical miles southeast of the existing 
MQT VOR/DME on the Sawyer 
International Airport. This action 
modifies Class E airspace for Marquette, 
MI, to correctly describe the Class E 
airspace required for Sawyer 
International Airport, to remove the 
reference to Marquette County Airport, 
and to incorporate the new GWI VOR/ 
DME location, and revokes the Class E 
airspace at Sawyer, MI, and K.I. Sawyer, 
MI.


FOR FURTHER INFORMATION CONTACT: 
Denis C. Burke, Air Traffic Division, 
Airspace Branch, AGL–520, Federal 
Aviation Administration, 2300 East 
Devon Avenue, Des Plaines, IL 60018, 
telephone (847) 294–7568.

SUPPLEMENTARY INFORMATION:

History

On Wednesday, August 4, 1999, the 
FAA proposed to amend 14 CFR part 71 
to modify Class E airspace at Marquette, 
MI, and to revoke Class E airspace at 
Sawyer, MI, and K.I. Sawyer, MI (64 FR 
42300). On Tuesday, October 5, 1999, 
the FAA extended the comment period 
for the proposal due to a minor 
modification to the legal description for 
the Class E airspace for Marquette, MI 
(64 FR 53057). The proposal was to 
modify controlled airspace extending 
upward from the surface to contain 
Instrument Flight Rules (IFR) operations in 
controlled airspace during portions of 
the terminal operation and while 
transiting between the enroute and 
terminal environments.

Interested parties were invited to 
participate in this rulemaking 
proceeding by submitting written 
comments on the proposal to the FAA. 
No comments objecting to the proposal 
were received. Class E airspace areas 
designated as surface area for an 
airport are published in paragraph 6002, 
and Class E airspace designations for 
airspace areas extending upward from 
700 feet or more above the surface of the earth are published in paragraph 6005, 
of FAA Order 7400.9C dated September 
1, 1999, and effective September 16, 
1999, which is incorporated by 
reference in 14 CFR 71.1. The Class E 
airspace designation listed in this 
document will be published 
subsequently in the Order.

The Rule

This amendment to 14 CFR part 71 modifies 
Class E airspace at Marquette, 
MI, and revokes Class E airspace at 
Sawyer, MI, and K.I. Sawyer AF B, MI, 
to accommodate aircraft executing 
instrument flight procedures at Sawyer 
International Airport. The area will be 
depicted on appropriate aeronautical 
charts.

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” 
derunder Executive Order 12866; (2) is not 
a “significant rule” under DOT 
Regulatory Policies and Procedures (44 
FR 11034; February 26, 1979); and (3) 
does not warrant preparation of a 
Regulatory Evaluation as the anticipated 
impact is so minimal. Since this is a 
routine matter that will only affect air 
traffic procedures and air navigation, it 
is certified that this rule will not have 
as a significant economic impact on a 
substantial number of small entities 
under the criteria of the Regulatory 
Flexibility Act.

List of Subjects in 14 CFR Part 71

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, 
CLASS B, CLASS C, CLASS D, AND 
CLASS E AIRSPACE AREAS; 
AIRWAYS; 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. 10884, 24 FR 95665, 3 CFR, 

§ 71.1 [Amended]

2. The incorporation by reference in 
14 CFR 71.1 of the Federal Aviation 
Administration Order 7400.9C, Airspace 
Designations and Reporting Points, 
dated September 1, 1999, and effective
DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

Establishment of Class E Airspace; Pine River, MN

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action establishes Class E airspace at Pine River, MN. A Nondirectional Beacon (NDB) Standard Instrument Approach Procedure (SIAP) to Runway (Rwy) 34 has been developed for Pine River Regional Airport.

Controlled airspace extending upward from 700 to 1200 feet above ground level (AGL) is needed to contain aircraft executing the approach. This action creates controlled airspace for Pine River Regional Airport.


FOR FURTHER INFORMATION CONTACT: Denis C. Burke, Air Traffic Division, Airspace Branch, AGL–520, Federal Aviation Administration, 2300 East Devon Avenue, Des Plaines, Illinois 60018, telephone (847) 294–7568.

SUPPLEMENTARY INFORMATION:

History

On Friday, August 27, 1999, the FAA proposed to amend 14 CFR part 71 to establish Class E airspace at Pine River, MN (64 FR 46871). The proposal was to add controlled airspace extending upward from 700 to 1200 feet AGL to contain Instrument Flight Rules (IFR) operations in controlled airspace during portions of the terminal operation and while transiting between the enroute and terminal environments.

Interested parties were invited to participate in this rulemaking proceeding by submitting written comments on the proposal to the FAA. No comments objecting to the proposal were received. Class E airspace designations for airspace areas extending upward from 700 feet or more above the surface of the earth are published in paragraph 6005 of FAA Order 7400.9G dated September 1, 1999, and effective September 16, 1999, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designation listed in this document will be published subsequently in the Order.

The Rule

This amendment to 14 CFR part 71 establishes Class E airspace at Pine River, NM, to accommodate aircraft executing the proposed NDB Rwy 34 SIAP at Pine River Regional Airport by creating controlled airspace. The area will be depicted on appropriate aeronautical charts.

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 DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a Regulatory Evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 71

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, CLASS B, CLASS C, CLASS D, AND CLASS E AIRSPACE AREAS; AIRWAYS; ROUTES; AND REPORTING POINTS

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


§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of the Federal Aviation Administration Order 7400.9G, Airspace Designations and Reporting Points, dated September 1, 1999, and effective September 16, 1999, is amended as follows:

* * * * * Paragraph 6005 Class E airspace areas extending upward from 700 feet or more above the surface of the earth. * * * * *

AGL MN E5 Pine River, MN [New]
Pine River Regional Airport, MN (Lat. 46° 43′ 29″ N, long. 94° 22′ 34″ W) Pine River NDB (Lat. 46° 43′ 37″ N, long. 94° 23′ 04″ W) That airspace extending upward from 700 feet above the surface within a 6.3-mile radius of Pine River Regional Airport and within 1.3 miles each side of the 154° bearing from the Pine River NDB, extending from the 6.3-mile radius to 7.0 miles southeast of the airport.

* * * * *

Issued in Des Plaines, Illinois on November 6, 1999.
Christopher R. Blum, Manager, Air Traffic Division.

[FR Doc. 98–31402 Filed 12–2–99; 8:45 am]
BILLING CODE 4910–13–M
DEPARTMENT OF TRANSPORTATION
Federal Aviation Administration

14 CFR Part 71
[Airspace Docket No. 99–AGL–49]

Modification of Class E Airspace; Caledonia, MN

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action modifies Class E airspace at Caledonia, MN. A Global Positioning System (GPS) Standard Instrument Approach Procedure (SIAP) to Runway (Rwy) 31 has been developed for Houston County Airport. Controlled airspace extending upward from 700 to 1200 feet above ground level (AGL) is needed to contain aircraft executing the approach. This action removes the extension to the existing controlled airspace for this airport.


FOR FURTHER INFORMATION CONTACT: Denis C. Burke, Air Traffic Division, Airspace Branch, AGL–520, Federal Aviation Administration, 2300 East Devon Avenue, Des Plaines, Illinois 60018, telephone (847) 294–7568.

SUPPLEMENTARY INFORMATION:

History

On Tuesday, September 14, 1999, the FAA proposed to amend 14 CFR part 71 to modify Class E airspace at Caledonia, MN (64 FR 49755). The proposal was to modify controlled airspace extending upward from 700 to 1200 feet AGL to contain Instrument Flight Rules (IFR) operations in controlled airspace during portions of the terminal operation and while transiting between the enroute and terminal environments. Interested parties were invited to participate in this rulemaking proceeding by submitting written comments on the proposal to the FAA. No comments objecting to the proposal were received. Class E airspace designations for airspace areas extending upward from 700 feet or more above the surface of the earth are published in paragraph 6005 of FAA Order 7400.9G dated September 1, 1999, and effective September 16, 1999, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designation listed in this document will be published subsequently in the Order.

The Rule

This amendment to 14 CFR part 71 modifies Class E airspace at Caledonia, MN, to accommodate aircraft executing the proposed GPS Rwy 31 SIAP for Houston County Airport by modifying the existing controlled airspace. The area will be depicted on appropriate aeronautical charts.

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 DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) Does not warrant preparation of a Regulatory Evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 71

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, CLASS B, CLASS C, CLASS D, AND CLASS E AIRSPACE AREAS: AIRWAYS; ROUTES; AND REPORTING POINTS

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


§71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of the Federal Aviation Administration Order 7400.9G, Airspace Designations and Reporting Points, dated September 1, 1999, and effective September 16, 1999, is amended as follows:

* * * * *

Paragraph 6005 Class E airspace areas extending upward from 700 Feet or more above the surface of the earth.

* * * * *

AGL MN E5 Caledonia, MN [Revised]

Caledonia, Houston County Airport, MN (Lat. 43° 35’ 47” N., long. 91° 30’ 14” W.)

That airspace extending upward from 700 feet above the surface within a 6.3-mile radius of Houston County Airport.

* * * * *


Christopher R. Blum,
Manager, Air Traffic Division.

[FR Doc. 99–31403 Filed 12–2–99; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF TRANSPORTATION
Federal Aviation Administration

14 CFR Part 71
[Airspace Docket No. 99–ASO–22]

Removal of Class E Airspace; Fulton, MS

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action removes Class E airspace at Fulton, MS, by revoking the airspace for the Fulton-Itawamba County Airport. The County of Itawamba, MS, has closed the Fulton-Itawamba County Airport. Therefore, the Class E airspace for the Fulton-Itawamba County Airport must be revoked.


FOR FURTHER INFORMATION CONTACT: Nancy B. Shelton, Manager, Airspace Branch, Air Traffic Division, Federal Aviation Administration, P.O. Box 20636, Atlanta, Georgia 30320; telephone (404) 305–5627.

SUPPLEMENTARY INFORMATION:

History

The Fulton-Itawamba County Airport is within the Fulton, MS, Class E5 airspace area. The County of Itawamba, MS, has elected to close the Fulton-Itawamba County Airport. Therefore, the Class E5 airspace must be revoked. This rule will become effective on the date specified in the “DATE” section. Since this action removes the Class E5 airspace, and as a result, eliminates the impact of Class E5 airspace on users of the airspace in the vicinity of the Fulton-Itawamba County Airport, notice and public procedure under 5 U.S.C. 553(b) are unnecessary.

Class E airspace designations for areas extending upward from 700 feet or more above the surface of the earth are published in paragraph 6005 of FAA Order 7400.9G dated September 1, 1999, and effective September 16, 1999, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designation listed in this document will be removed subsequently from the Order.
The Rule

This amendment to Part 71 of the Federal Aviation Regulations (14 CFR part 71) removes Class E5 airspace at Fulton, MS.

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. It, therefore, (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) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 71

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, CLASS B, CLASS C, CLASS D AND CLASS E AIRSPACE AREAS; AIRWAYS; ROUTES; AND REPORTING POINTS

§ 71.1 [AMENDED]

The incorporation by reference in 14 CFR 71.1 of Federal Aviation Administration Order 7400.9G, Airspace Designations and Reporting Points, dated September 1, 1999, and effective September 16, 1999, is amended as follows:

Paragraph 6005  Class E Airspace Areas Extending Upward From 700 Feet or More Above the Surface of the Earth

* * * * *

ASO MS E5  Fulton, MS  [Remove]

* * * * *
proposed rulemaking setting forth revised reporting requirements for the BE–10, Benchmark Survey of U.S. Direct Investment Abroad—1999. No comments on the proposed rules were received. Thus, these final rules are the same as the proposed rules.

These final rules amend 15 CFR part 806 to set forth revised reporting requirements for the BE–10, Benchmark Survey of U.S. Direct Investment Abroad—1999. The Bureau of Economic Analysis, U.S. Department of Commerce, will conduct the survey under the International Investment and Trade in Services Survey Act (22 U.S.C. 3101–3108), hereinafter, “the Act.” Section 4(b) of the Act requires that with respect to United States direct investment abroad, the President shall conduct a benchmark survey covering year 1982, a benchmark survey covering year 1989, and benchmark surveys covering every fifth year thereafter. In conducting surveys pursuant to this subsection, the President shall, among other things and to the extent he determines necessary and feasible—

1. Identify the location, nature, and magnitude of, and changes in total investment by any parent in each of its affiliates and the financial transactions between any parent and each of its affiliates;
2. Obtain (A) information on the balance sheet of parents and affiliates and related financial data, (B) income statements, including the gross sales by primary line of business (with as much product line detail as is necessary and feasible) of parents and affiliates in each country in which they have significant operations, and (C) related information regarding trade, including trade in both goods and services, between a parent and each of its affiliates and between each parent or affiliate and any other person;
3. Collect employment data showing both the number of United States and foreign employees of each parent and affiliate and the levels of compensation, by country, industry, and skill level;
4. Obtain information on tax payments by parents and affiliates by country; and
5. Determine, by industry and country, the total dollar amount of research and development expenditures by each parent and affiliate, payments or other compensation for the transfer of technology between parents and their affiliates, and payments or other compensation received by parents or affiliates from the transfer of technology to other persons.

In section 3 of Executive Order 11961, the President delegated authority granted under the Act as concerns direct investment to the Secretary of Commerce, who has redelegated it to BEA.

The benchmark surveys are BEA’s censuses, intended to cover the universe of U.S. direct investment abroad in terms of value. U.S. direct investment abroad is defined as the ownership or control, directly or indirectly, by one U.S. person of 10 percent or more of the voting securities of an incorporated foreign business enterprise or an equivalent interest in an unincorporated foreign business enterprise, including a branch.

The purpose of the benchmark survey is to obtain universe data on the financial and operating characteristics of, and on positions and transactions between, U.S. parent companies and their foreign affiliates. The data are needed to measure the size and economic significance of U.S. direct investment abroad, measure changes in such investment, and assess its impact on the U.S. and foreign economies. The data will provide benchmarks for deriving current universe estimates of direct investment from sample data collected in other BEE surveys in nonbenchmark years. In particular, they will serve as benchmarks for the quarterly direct investment estimates included in the U.S. international transactions and national income and product accounts, and for annual estimates of the U.S. direct investment position abroad and of the operations of U.S. parent companies and their foreign affiliates.

The survey consists of an instruction booklet, a claim for not filing the BE–10, and the following report forms:

1. Form BE–10A—Report for U.S. Reporters that are not banks;
2. Form BE–10A BANK—Report for U.S. Reporters that are banks;
3. Form BE–10B(LF) (Long Form)—Report for majority-owned nonbank foreign affiliates of nonbank U.S. parents with assets, sales, or net income greater than $100 million (positive or negative);
4. Form BE–10B(SF) (Short Form)—Report for majority-owned nonbank foreign affiliates with assets, sales, or net income greater than $7 million, but not greater than $100 million (positive or negative), minority-owned nonbank foreign affiliates of nonbank parents with assets, sales, or net income greater than $7 million (positive or negative); and
5. Form BE–10B BANK—Report for foreign affiliates that are banks.

Although the survey is intended to cover the universe of U.S. direct investment abroad, in order to minimize the reporting burden, foreign affiliates with assets, sales, and net income each equal to or less than $7 million (positive or negative) are exempt from being reported on Form BE–10B(SF) or BE–10B BANK (but must be listed, along with selected identification information and data, on Form BE–10A SUPPLEMENT or BE–10A BANK SUPPLEMENT).

Executive Order 12612

These final rules do not contain policies with Federalism implications sufficient to warrant preparation of a Federalism assessment under E.O. 12612.

Executive Order 12866

These final rules have been determined to be not significant for purposes of E.O. 12866.

Paperwork Reduction Act

The collection of information required in these final rules has been approved by OMB (OMB No. 0608–0049) under the Paperwork Reduction Act. Notwithstanding any other provisions of the law, no person is required to respond to, nor shall any person be subject to a penalty for failure to comply with, a collection-of-information subject to the requirements of the Paperwork Reduction Act unless that collection displays a currently valid Office of Management and Budget control number.

The survey is expected to result in the filing of reports from about 3,500 respondents. The respondent burden for this collection of information is estimated to vary from 14 to 8,500 hours per response, with an average of 130 hours per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Thus the total respondent burden of the survey is estimated at 458,000 hours (3,500 respondents times 130 hours average burden).

Comments regarding the burden estimate of any aspect of this collection of information should be addressed to: Director, Bureau of Economic Analysis (BE–1), U.S. Department of Commerce, Washington, DC 20230; and to the Office of Management and Budget, O.I.R.A., Paperwork Reduction Project 0608–0049, Washington, DC 20503 (Attention PRA Desk Officer for BEA).

Regulatory Flexibility Act

The Chief Counsel for Regulation, Department of Commerce, has certified to the Chief Counsel for Advocacy,
Small Business Administration, under the provision of the Regulatory Flexibility Act (5 U.S.C. 605(b)), that these final rules will not have a significant economic impact on a substantial number of small entities. A BE–10 report is required of any U.S. company that had a foreign affiliate—that is, that had direct or indirect ownership or control of at least 10 percent of the voting stock of an incorporated foreign business enterprise, or an equivalent interest in an unincorporated foreign business enterprise—at any time during the U.S. company’s 1999 fiscal year. Companies that have direct investment abroad tend to be quite large. To minimize the reporting burden on smaller U.S. companies, U.S. Reporters with total assets, sales or gross operating revenues, and net income less than or equal to $100 million (positive or negative) are required to report only selected items on the BE–10A form for U.S. Reporters in addition to forms they may be required to file for their foreign affiliates.

List of Subjects in 15 CFR Part 806

Balance of payments, Economic statistics, U.S. investment abroad, Penalties, Reporting and recordkeeping requirements.

Dated: November 17, 1999.

J. Steven Landefeld,
Director, Bureau of Economic Analysis.

For the reasons set forth in the preamble, BEA amends 15 CFR part 806 as follows:

PART 806—DIRECT INVESTMENT SURVEYS

1. The authority citation for 15 CFR part 806 continues to read as follows:


2. Section 806.16 is revised to read as follows:


A BE–10, Benchmark Survey of U.S. Direct Investment Abroad will be conducted covering 1999. All legal authorities, provisions, definitions, and requirements contained in §§ 806.1 through 806.13 and § 806.14(a) through (d) are applicable to this survey. Specific additional rules and regulations for the BE–10 survey are given in paragraphs (a) through (e) of this section. More detailed instructions are given on the report forms and instructions.

(a) Response required. A response is required from persons subject to the reporting requirements of the BE–10, Benchmark Survey of U.S. Direct Investment Abroad—1999, contained in this section, whether or not they are contacted by BEA. Also, a person, or their agent, who is contacted by BEA about reporting in this survey, either by sending them a report form or by written inquiry, must respond in writing pursuant to § 806.4. They may respond by:

(1) Certifying in writing, within 30 days of being contacted by BEA, to the fact that the person had no direct investment within the purview of the reporting requirements of the BE–10 survey;

(2) Completing and returning the “BE–10 Claim for Not Filing” within 30 days of receipt of the BE–10 survey report forms;

(3) Filing the properly completed BE–10 report (comprising Form BE–10A or BE–10A BANK and Forms BE–10B(LF), BE–10B(SF), and/or BE–10B BANK) by May 31, 2000, or June 30, 2000, as required.

(b) Who must report. (1) A BE–10 report is required of any U.S. company that had a foreign affiliate—that is, that had direct or indirect ownership or control of at least 10 percent of the voting stock of an incorporated foreign business enterprise, or an equivalent interest in an unincorporated foreign business enterprise—at any time during the U.S. person’s 1999 fiscal year.

(2) If the U.S. person had no foreign affiliates during its 1999 fiscal year, a “BE–10 Claim for Not Filing” must be filed within 30 days of receipt of the BE–10 survey package; no other forms in the survey are required. If the U.S. person had any foreign affiliates during its 1999 fiscal year, a BE–10 report is required and the U.S. person is a U.S. Reporter in this survey.

(3) Reports are required even though the foreign business enterprise was established, acquired, seized, liquidated, sold, expropriated, or inactivated during the U.S. person’s 1999 fiscal year.

(c) Forms for nonbank U.S. Reporters and foreign affiliates.—(1) Form BE–10A (Report for the U.S. Reporter). A BE–10A report must be completed by a U.S. Reporter that is not a bank. If the U.S. Reporter is a corporation, Form BE–10A is required to cover the fully consolidated U.S. domestic business enterprise.

(i) If for a nonbank U.S. Reporter any one of the following three items—total assets, sales or gross operating revenues excluding sales taxes, or net income after provision for U.S. income taxes—was greater than $100 million (positive or negative) at any time during the Reporter’s 1999 fiscal year, the U.S. Reporter must file a complete Form BE–10A and, as applicable, a BE–10A SUPPLEMENT listing each, if any, foreign affiliate that is exempt from being reported on Form BE–10B(LF), BE–10B(SF), or BE–10B BANK. It must also file a Form BE–10B(LF), BE–10B(SF), or BE–10B BANK, as appropriate, for each nonexempt foreign affiliate.

(ii) If for a nonbank U.S. Reporter no one of the three items listed in paragraph (c)(1)(i) of this section was greater than $100 million (positive or negative) at any time during the Reporter’s 1999 fiscal year, the U.S. Reporter is required to file on Form BE–10A only items 1 through 27 and items 30 through 35 and, as applicable, a BE–10A SUPPLEMENT listing each, if any, foreign affiliate that is exempt from being reported on Form BE–10B(LF), BE–10B(SF), or BE–10B BANK. It must also file a Form BE–10B(LF), BE–10B(SF), or BE–10B BANK, as appropriate, for each nonexempt foreign affiliate.

(2) Form BE–10B(LF) or (SF) (Report for nonbank foreign affiliate). (i) A BE–10B(LF) (Long Form) must be filed for each majority-owned nonbank foreign affiliate of a nonbank U.S. Reporter, whether held directly or indirectly, for which any one of the three items—total assets, sales or gross operating revenues excluding sales taxes, or net income after provision for foreign income taxes—was greater than $100 million (positive or negative) at any time during the affiliate’s 1999 fiscal year.

(ii) A BE–10B(SF) (Short Form) must be filed:

(A) For each majority-owned nonbank foreign affiliate of a nonbank U.S. Reporter, whether held directly or indirectly, for which any one of the three items listed in paragraph (c)(2)(i) of this section was greater than $7 million but for which no one of these items was greater than $100 million (positive or negative), at any time during the affiliate’s 1999 fiscal year, and

(B) For each minority-owned nonbank foreign affiliate of a nonbank U.S. Reporter, whether held directly or indirectly, for which any one of the three items listed in paragraph (c)(2)(i) of this section was greater than $7 million (positive or negative), at any time during the affiliate’s 1999 fiscal year, and

(C) For each nonbank foreign affiliate of a U.S. bank Reporter, whether held directly or indirectly, for which any one
of the three items listed in paragraph (c)(2)(i) of this section was greater than $7 million (positive or negative), at any time during the affiliate’s 1999 fiscal year.

(iii) Notwithstanding paragraphs (c)(2)(i) and (c)(2)(iii) of this section, a Form BE–10B(LF) or (SF) must be filed for a foreign affiliate of the U.S. Reporter that owns another nonexempt foreign affiliate of that U.S. Reporter, even if the foreign affiliate parent is otherwise exempt, i.e., a Form BE–10B(LF), (SF), or BANK must be filed for all affiliates upward in a chain of ownership.

(d) Forms for U.S. Reporters and foreign affiliates that are banks or bank holding companies. (1) For purposes of the BE–10 survey, “banking” covers a business entity engaged in deposit banking or closely related functions, including commercial banks, Edge Act corporations engaged in international or foreign banking, foreign branches and agencies of U.S. banks whether or not they accept deposits abroad, savings and loans, savings banks, and bank holding companies, i.e., holding companies for which over 50 percent of their total income is from banks that they hold. If the bank or bank holding company is part of a consolidated business enterprise and the gross operating revenues from nonbanking activities of this consolidated entity are more than 50 percent of its total revenues, then the consolidated entity is deemed not to be a bank even if banking revenues make up the largest single source of all revenues. (Activities of subsidiaries of a bank holding company that may not be banks but that provide support to the bank parent company, such as real estate subsidiaries set up to hold the office buildings occupied by the bank parent company, are considered bank activities.)

(2) Form BE–10A BANK (Report for a U.S. Reporter that is a bank). A BE–10A BANK report must be completed by a U.S. Reporter that is a bank. For purposes of filing Form BE–10A BANK, the U.S. Reporter is deemed to be the fully consolidated U.S. domestic business enterprise and all required data on the form shall be for the fully consolidated domestic entity.

(i) If a U.S. bank had any foreign affiliates at any time during its 1999 fiscal year, whether a bank or nonbank and whether held directly or indirectly, for which any one of the three items—total assets, sales or gross operating revenues excluding sales taxes, or net income after provision for foreign income taxes—was greater than $7 million (positive or negative) at any time during the affiliate’s 1999 fiscal year, the U.S. Reporter must file a Form BE–10A BANK and, as applicable, a BE–10A BANK SUPPLEMENT listing each, if any, foreign affiliate, whether bank or nonbank, that is exempt from being reported on Form BE–10B (SF), or BE–10B BANK. It must also file a Form BE–10B (SF) for each nonexempt nonbank affiliate and a Form BE–10B BANK for each nonexempt bank foreign affiliate.

(ii) If the U.S. bank reported had no foreign affiliates for which any one of the three items listed in paragraph (d)(2)(i) of this section was greater than $7 million (positive or negative) at any time during the affiliate’s 1999 fiscal year, the U.S. Reporter must file a Form BE–10B BANK and a BE–10A BANK SUPPLEMENT, listing all foreign affiliates exempt from being reported on Form BE–10B (SF) or BE–10 BANK.

(3) Form BE–10B BANK (Report for a foreign affiliate that is a bank). (i) A BE–10B BANK report must be filed for each foreign bank affiliate of a bank or nonbank U.S. Reporter, whether directly or indirectly held, for which any one of the three items—total assets, sales or gross operating revenues excluding sales taxes, or net income after provision for foreign income taxes—was greater than $7 million (positive or negative) at any time during the affiliate’s 1999 fiscal year.

(ii) Notwithstanding paragraph (d)(3)(i) of this section, a Form BE–10B BANK must be filed for a foreign bank affiliate of the U.S. Reporter that owns another nonexempt foreign affiliate of that U.S. Reporter, even if the foreign affiliate parent is otherwise exempt, i.e., a Form BE–10B (LF), (SF), or BANK must be filed for all affiliates upward in a chain of ownership. However, a Form BE–10B BANK is not required to be filed for a foreign bank affiliate in which the U.S. Reporter holds only an indirect ownership interest of 50 percent or less and that does not own a reportable nonbank foreign affiliate, but the indirectly owned bank affiliate must be listed on the BE–10A BANK SUPPLEMENT.

(e) Due date. A fully completed and certified BE–10 report comprising Form BE–10A or 10A BANK, BE–10A SUPPLEMENT (as required), and Form(s) BE–10B (LF), (SF), or BANK (as required) is due to be filed with BEA not later than May 31, 2000 for those U.S. Reporters filing fewer than 50, and June 30, 2000 for those U.S. Reporters filing 50 or more, Forms BE–10B (LF), (SF), or BANK.

SPECIAL SUPPLEMENTARY INFORMATION: We use the Listings in appendix 1 to subpart P of part 404 at the third step of the sequential evaluation process to evaluate claims filed by adults and individuals under age 18 for benefits based on disability under the Social Security and SSI programs. The Listings are divided into parts A and B. We use the criteria in part A to evaluate the impairments of adults. We use the criteria in part B first to evaluate impairments of individuals under age 18. If those criteria do not apply, then the medical criteria in part A will be used.

When we published revised listings in 1985 and subsequently, we indicated that medical advances in disability evaluation and treatment and program experience would require that they be periodically reviewed and updated. Accordingly, we established dates
ranging from 3 to 8 years on which the various body system listings would no longer be effective unless extended by the Secretary of Health and Human Services or revised and promulgated again. Effective March 31, 1995, the authority to issue regulations was transferred to the Commissioner of Social Security by section 102 of Public Law 103–296, the Social Security Independence and Program Improvements Act of 1994.

In this final rule, we are extending the dates on which several body system listings will no longer be effective to July 2, 2001. These body systems are:

- Cardiovascular System (4.00 and 104.00).
- Digestive System (5.00 and 105.00).
- Genito-Urinary System (6.00 and 106.00).

We last extended the dates on which these body system listings would no longer be effective in final rules published as follows:


We believe that the requirements in these listings are still valid for our program purposes. Specifically, if we find that an individual has an impairment that meets or is medically equivalent in severity to an impairment in the Listings or functionally equivalent to the Listings in SSI claims based on disability filed by individuals under age 18 and also meets the statutory duration requirement, we will find that the individual is disabled at the third step of the sequential evaluation process. We are extending these dates because we do not expect to develop revised listings criteria for these body systems by the expiration dates currently shown in the regulations. However, we are reviewing the listings and we plan to publish proposed and final rules over the course of the next two years.

**Regulatory Procedures**

**Justification for Final Rule**

Pursuant to section 702(a)(5) of the Social Security Act, 42 U.S.C. 902(a)(5), as amended by section 102 of Public Law 103–296, SSA follows the Administrative Procedure Act (APA) rulemaking procedures specified in 5 U.S.C. 553 in the development of its regulations. The APA provides exceptions to its notice and public comment procedures when an agency finds there is good cause for dispensing with such procedures on the basis that they are impracticable, unnecessary, or contrary to the public interest. We have determined that, under 5 U.S.C. 553(b)(B), good cause exists for dispensing with the notice and public comment procedures in this case. Good cause exists because this regulation only extends the date on which these body system listings will no longer be effective. It makes no substantive changes to those listings. The current regulations expressly provide that listings may be extended, as well as revised and promulgated again. Therefore, opportunity for prior comment is unnecessary, and we are issuing this regulation as a final rule.

In addition, we find good cause for dispensing with the 30-day delay in the effective date of a substantive rule provided by 5 U.S.C. 553(d). As explained above, we are not making any substantive changes in these body system listings. However, without an extension of the expiration dates for these listings, we will lack regulatory guidelines for assessing impairments in these body systems at the third step of the sequential evaluation process after the current expiration dates of these listings. In order to ensure that we continue to have regulatory criteria for assessing impairments under these listings, we find that it is in the public interest to make this rule effective upon publication.

**Executive Order 12866**

We have consulted with the Office of Management and Budget (OMB) and determined that this final rule does not meet the criteria for a significant regulatory action under Executive Order 12866. Thus, it was not subject to OMB review. We have also determined that this final rule meets the plain language requirement of Executive Order 12866 and the President's memorandum of June 1, 1998 (63 FR 31885).

**Regulatory Flexibility Act**

We certify that this final regulation will not have a significant economic impact on a substantial number of small entities. Therefore, a regulatory flexibility analysis as provided in the Regulatory Flexibility Act, as amended, is not required.

**Paperwork Reduction Act**

This final regulation imposes no reporting/recordkeeping requirements necessitating clearance by OMB.

(Catalog of Federal Domestic Assistance Program Nos. 96.001, Social Security-Disability Insurance; 96.002, Social Security-Retirement Insurance; 96.004, Social Security-Survivors Insurance; 96.006, Supplemental Security Income)

**List of Subjects in 20 CFR Part 404**

Administrative practice and procedure, Blind, Disability benefits, Old-Age, Survivors and Disability Insurance, Reporting and recordkeeping requirements, Social Security.

Dated: November 24, 1999.

Kenneth S. Apfel,
Commissioner of Social Security.

For the reasons set forth in the preamble, part 404, chapter III of title 20 of the Code of Federal Regulations is amended as set forth below.

**PART 404—FEDERAL OLD-AGE, SURVIVORS AND DISABILITY INSURANCE (1950—)**

**Subpart P—[Amended]**

1. The authority citation for subpart P of part 404 continues to read as follows:

**Authority:** Secs. 202, 205(a), (b), and (d)–(h), 216(i), 221(a) and (i), 222(c), 223, 225, and 702(a)(5) of the Social Security Act (42 U.S.C. 402, 405(a), (b), and (d)–(h), 416(i), 421(a) and (i), 422(c), 423, 425, and 902(a)(5)); sec. 211(b), Pub. L. 104–193, 110 Stat. 2105, 2189.

2. Appendix 1 to subpart P of part 404 is amended by revising items 5, 6, and 7 of the introductory text before Part A to read as follows:

**Appendix 1 to Subpart P—Listing of Impairments**

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5. Cardiovascular System (4.00 and 104.00): July 2, 2001.

* * * * *

[FR Doc. 99–31322 Filed 12–2–99; 8:45 am]

BILLING CODE 4191–02–P

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

21 CFR Parts 203 and 205

[Docket Nos. 92N–0297 and 88N–0258]

**RIN 0910–AA08**

**Prescription Drug Marketing Act of 1987; Prescription Drug Amendments of 1992; Policies, Requirements, and Administrative Procedures**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing a final
rule to set forth procedures and requirements implementing the
Prescription Drug Marketing Act of 1987 (PDMA), as modified by the Prescription
Drug Amendments of 1992 (PDA) and the FDA Modernization Act of 1997 (the
Modernization Act). The final rule sets
forth requirements for the reimportation and wholesale distribution of
prescription drugs; the sale, purchase, or trade of, or the offer to sell, purchase, or trade, prescription drugs that were
purchased by hospitals or health care
entities, or donated to charitable
organizations; and the distribution of
prescription drug samples. FDA is also
amending certain sections of the
regulations entitled “Guidelines for
State Licensing of Wholesale
Prescription Drug Distributors” to make
them consistent with this final
regulation.
DATES: Submit written comments on
the collection of information provisions by
February 1, 2000. This regulation is
effective December 4, 2000.
ADDRESSES: Submit written comments
on the collection of information to the
Dockets Management Branch (HFA–
303), Food and Drug Administration,
5630 Fishers Lane, rm. 1061, Rockville,
MD 20857. All comments should be
found in brackets in the heading of this
document.
FOR FURTHER INFORMATION CONTACT:
For information on the PDMA and
regulations: Lee D. Korb, Center for
Drug Evaluation and Research
(HFD–7), Food and Drug
Administration, 5600 Fishers Lane,
Rockville, MD 20857, 301–594–
2041, e-mail address via Internet:
“Korb!@CDER.FDA.GOV”.
For information on compliance with
and enforcement of the regulations:
Margaret M. O’Rourke, Center for
Drug Evaluation and Research
(HFD–330), Food and Drug
Administration, 7500 Standish Pl.,
Rockville, MD 20855, 301–594–
0101, e-mail address via Internet:
“ORourke@CDER.FDA.GOV”.
For information on biologics: Steven
F. Falter, Center for Biologics
Evaluation and Research (HFM–17),
Food and Drug Administration,
1401 Rockville Pike, Rockville, MD
20852, 301–827–6210, e-mail
address via Internet:
“Falter@CBER.FDA.GOV”.
SUPPLEMENTARY INFORMATION:
I. Background
PDMA (Public Law 100–293) was
enacted on April 22, 1988, and was
modified by the PDA (Public Law 102–
PDMA, as modified by the PDA,
amended sections 301, 303, 503, and
801 of the Federal Food, Drug, and
Cosmetic Act (the act) (21 U.S.C. 331,
333, 353, 381) to establish restrictions
and requirements relating to various
aspects of human prescription drug
marketing and distribution. Among
other things, PDMA: (1) Banned the
sale, purchase, or trade of (or offer to
sell, purchase, or trade) drug samples
and drug coupons; (2) restricted
reimportation of prescription drugs to
the manufacturer of the drug product or
for emergency medical care; (3)
established requirements for drug
sample distribution and the storage and
handling of drug samples; (4) required
wholesale distributors of prescription
drugs to be State licensed and required
FDA to establish minimum
requirements for State licensing
schemes; (5) established requirements
for wholesale distribution of
prescription drugs by unauthorized
distributors; (6) prohibited, with certain
exceptions, the sale, purchase, or trade
(or offer to sell, purchase, or trade) of
drug samples that were purchased by
hospitals or health care entities, or
 donated or supplied at a reduced price
to charities; and (7) established criminal
and civil penalties for PDMA violations.
In the Federal Register of September
13, 1988 (53 FR 35325), FDA published a
proposed rule containing minimum
requirements for State licensing of
wholesale drug distributors. The final
rule on State licensing requirements
(part 205 [21 CFR part 205]) was
published in the Federal Register of
September 14, 1990 (55 FR 38012)
(hereinafter referred to as the State
licensing guideline final rule). The State
licensing regulations require that all
wholesale distributors be State licensed,
establish minimum qualifications for
licensees, and set forth minimum
requirements for the storage and
handling of prescription drugs and for
the establishment and maintenance of
records of drug distribution by
wholesale distributors.
In the Federal Register of March 14,
1994 (59 FR 11842), FDA issued a
proposed rule to set forth agency
policies and requirements for those
sections of PDMA not related to State
licensing of wholesale distributors
(hereinafter referred to as the March
proposal contained provisions on
prescription drug reimportation,
wholesale distribution of prescription
drugs by unauthorized distributors,
the resale of prescription drugs by hospitals,
health care entities, and charitable
institutions, and distribution of
prescription drug samples. The March
1994 proposal called for the submission
of comments by May 30, 1994. At the
request of certain individuals, the
comment period was extended, by
notice in the Federal Register of July 15,
After careful consideration of the
comments, the agency has revised and
finalized the March 1994 proposal. A
discussion of significant issues, the
comments received on the proposal, and
the agency’s responses to the comments
follows.
II. Significant Issues and Revisions to
the Proposal
A. Reimportation of Drugs Composed
Wholly or Partly of Insulin
On November 21, 1997, the
Modernization Act (Public Law 105–
115) was enacted. Section 125(a)(2)(D)
of the Modernization Act amended
section 801(d)(1) of the act to prohibit
the reimportation of a drug composed
wholly or partly of insulin, except by
the manufacturer of the drug or for
emergency care. In accordance with the
revised statutory requirement, the
agency has revised proposed §§ 203.10
and 203.12 (21 CFR 203.10 and 203.12)
in the final rule to include insulin-
containing drugs.
B. Blood and Blood Components
Intended for Transfusion
In the State licensing guideline final
rule, FDA excluded from the definition of
“wholesale distribution” the sale,
purchase, or trade of blood and blood
components intended for transfusion
(see § 205.3(f)(8)). Thus, persons
engaged in the distribution of blood or
blood components intended for
transfusion are not required to be State
licensed wholesale prescription drug
distributors or to comply with other part
205 requirements.
Concurrent with the State licensing
guideline final rule, FDA published a
proposed rule entitled “Applicability to
Blood and Blood Components Intended
for Transfusion; Guidelines for State
Licensing of Wholesale Prescription
Drug Distributors” (55 FR 38027)
(hereinafter referred to as the September
1990 proposal). In that proposal, FDA:
(1) Tentatively concluded that PDMA
does not apply to the distribution of
blood and blood components intended
for transfusion, (2) set forth its rationale
for its tentative conclusion, and (3)
solicited comments. The agency stated
that, if comments persuaded FDA that
PDMA should be interpreted as
applying to the distribution of blood
and blood components intended for
transfusion, FDA would amend the
State licensing guideline final rule.
Comments received on the proposal supported the exclusion, however, and no action has been taken by the agency to amend part 203.

FDA again tentatively concluded in the March 1994 proposal (59 FR 11842 at 11844) that the restrictions in and the requirements of PDMA do not apply to the distribution of blood and blood components intended for transfusion. Proposed §§ 203.1 and 203.3(v) (21 CFR 203.1 and 203.3(v)) specified that blood and blood components intended for transfusion are outside the scope of PDMA, and do not constitute “prescription drugs” for the purposes of part 203 (21 CFR part 203). In addition, proposed § 203.22(g) specifically excluded the sale, purchase, or trade of, or offer to sell, purchase, or trade blood or blood components intended for transfusion from the sales restrictions in proposed § 203.20. No comments opposing the proposed sections were received.

Based on the rationale set forth in the September 1990 proposal, the agency had made a final determination that blood and blood components intended for transfusion should be excluded from all of the restrictions in and the requirements of PDMA. Accordingly, proposed §§ 203.1, 203.3(v), and 203.22(g) are being finalized, and the September 1990 proposal (Docket No. 88N–0258) is not being adopted.

As discussed in section III.B of this document in conjunction with comments received on the proposed rule, blood and blood components intended for transfusion include whole blood, red blood cells, plasma, fresh frozen plasma, cryoprecipitated AHP, and platelets. Blood derivatives such as Factor IX, Factor IX Complex, and immune globulin, as well as recombinant products regulated as biological products, are not blood or blood components intended for transfusion and, therefore, are subject to the requirements and restrictions of PDMA.

C. Medical Gases

In the March 1994 proposal (59 FR 11842 at 11844), the agency clarified that oxygen, USP (United States Pharmacopeia), is a prescription drug subject to section 503(b) of the act and, therefore, within the scope of PDMA and the proposed regulations. Since the publication of the March 1994 proposal, questions have been raised about the applicability of PDMA to medical gases generally.

FDA advises that all medical gases (i.e., oxygen, USP; nitrogen, NF (National Formulary); nitrous oxide, USP; carbon dioxide, USP; helium USP; and medical air, USP) are prescription drugs within the scope of PDMA and the State licensing guideline final rule. Therefore, under § 205.4, all persons engaged in the wholesale distribution of medical gases must be State licensed. This includes all air separation plants and units, suppliers, welding firms, durable medical equipment suppliers, and home respiratory care companies that distribute medical gases, except for those entities that exclusively distribute medical gases to patients under a valid prescription (see § 205.3(f)(6)). In addition, distributors of medical gases are subject to all other restrictions and requirements under PDMA and this final rule, including the requirement under § 203.50 to provide a drug origin statement and the requirements for drug sample distribution. The agency notes, however, that because most distributors of medical gases qualify as manufacturers under § 203.3(s), the requirement to provide a drug origin statement will generally not apply to such distributors. In addition, the agency is unaware of the practice of providing samples of medical gases to licensed practitioners. Therefore, the drug sample provisions of PDMA and this final rule should have no practical applicability to the medical gas industry.

D. Revision to Proposed 203.3(e)

In proposed § 203.3(e), the term “bulk drug substance” was defined to mean:

Any drug or drug component furnished in other than finished dosage form that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or function of the body of humans.

In § 207.3(a)(4) (21 CFR 207.3(a)(4)), the term is defined to mean:

Any substance that is represented for use in a drug and that, when used in the manufacturing, processing, or packaging of a drug, becomes an active ingredient or a finished dosage form of the drug, but the term does not include intermediates used in the synthesis of such substances.

Although the definitions are similar, the agency has decided that it is appropriate to use identical definitions of bulk drug substance throughout the regulations. Accordingly, the final rule adopts the definition of bulk drug substance used in § 207.3(a)(4).

E. Revisions to Proposed § 203.3(d)

For drug samples delivered by representatives, PDMA provides that a manufacturer or distributor is required to conduct a complete and accurate inventory of drug samples in the possession of representatives at least annually (21 U.S.C. 353(d)(3)(C)). FDA proposed in § 203.3(d) to require that manufacturers and distributors conduct a “complete and accurate drug sample inventory” at least annually of all drug samples in the possession or control of each manufacturer’s and distributor’s representatives using “generally accepted inventory practices.” In addition, FDA proposed to require that the results of the inventory be “recorded in an inventory record and reconciliation report.”

Under proposed § 203.31(d)(1), the inventory record would identify all drug samples by the proprietary or established name, dosage strength, and number of sample units in stock. Under proposed § 203.31(d)(2), the reconciliation report would contain a report of the physical count of the most recently completed prior inventory, a record of each drug sample received since the most recently completed prior inventory, and an explanation for any significant loss. Under proposed § 203.31(d)(3), the inventory would be conducted, and the inventory and reconciliation reports would be prepared by persons other than the representatives being inventoried or supervisors or managers in their department, division, or branch, or in their direct line of supervision or command.

The agency has revised proposed § 203.31(d) in the final rule to clarify certain requirements. The introductory paragraph of § 203.31(d) has been revised to specify that a “physical inventory” of drug samples is required, rather than an inventory. The term “physical inventory” has been added to more clearly distinguish the inventory from the reconciliation process and to clarify that the required inventory consists of a physical count of stock on hand. The proposed requirement that the inventory be conducted “using generally accepted inventory practices” has been deleted in the final rule because the agency has determined that there are no generally recognized standards for conducting a physical count. The final rule has also been revised to clarify that the results of the physical count must be recorded in the inventory record, not in the inventory record and reconciliation report. The proposed requirements for the inventory record remain unchanged.

In contrast to the relatively simple task of conducting a physical count, the reconciliation process involves comparing the latest inventory to the most recent inventory and taking into account drug samples acquired and distributed in the interim, to determine
whether sample diversion by a representative has occurred. As discussed by the agency in the March 1994 proposal, Congress’ purpose in enacting the inventory requirement was to facilitate detection of diversion activity, and conducting a physical inventory without reconciling that inventory with the most recent prior inventory would not achieve this goal (59 FR 11842 at 11849). Thus, the introductory paragraph of proposed § 203.31(d) has been revised in the final rule to clarify that, in addition to a physical inventory, manufacturers and distributors are required to reconcile the results of the physical inventory with the most recently completed prior physical inventory and to document this process in a reconciliation report.

The agency has revised proposed § 203.31(d)(2)(i) in the final rule to require that the reconciliation report include the inventory record for the most recently completed prior inventory. This is the same as the requirement in proposed § 203.31(d)(2) for a “report of the physical count of the most recently completed prior inventory,” but the terminology is clearer and consistent with the terminology used in § 203.31(d)(1).

Proposed § 203.31(d)(2)(iii) has been revised in the final rule to clarify the types of transactions that the agency considers to be “distributions.” This clarification is necessary because a representative’s stock of drug samples may be affected by various types of dispositions other than distributions to health care practitioners or their designees, and it is necessary that the reconciliation report reflect these different types of dispositions so that an accurate assessment of potential drug diversion activity can be made. Section 203.31(d)(2)(iv), which requires a record of drug sample thefts or significant losses reported by the representative since the most recently completed prior inventory, has been added for the same reason.

Section 203.31(d)(2)(v), which requires a summary record of the information contained in § 203.31(d)(2)(ii) through (d)(2)(iv), has been added in the final rule. The summary record will permit manufacturers and authorized distributors of record and the agency to quickly review the information that is necessary to conduct a reconciliation and thus will help to facilitate checking the accuracy of reconciliations.

Finally, as discussed in section III.E of this document in conjunction with the comments, proposed § 203.31(d)(3) has been substantially revised in the final rule to eliminate the proposed requirement that the inventory and reconciliation functions be conducted by persons other than the representative or supervisors or managers in the representative’s department, division, or branch, or in the representative’s direct line of supervision. Instead, manufacturers and authorized distributors are required to take appropriate internal control measures to guard against error and possible fraud in the conduct of the physical inventory and reconciliation, and in the preparation of the inventory record and reconciliation report.

F. Elimination of § 203.31(f)

Proposed § 203.31(f) has been removed from the final rule. The proposed section contained the same requirement for a manufacturer or authorized distributor to notify FDA of any conviction of its representatives as proposed in § 203.37(c) and finalized in the rulemaking.

G. Revisions to Proposed § 203.34

Proposed § 203.34(b), (c), (d), and (g) have been revised and renumbered in the final rule as § 203.34(b)(1) through (b)(4). Proposed § 203.34(d) is being finalized as § 203.34(b)(1) and has been revised to clarify that a manufacturer or authorized distributor must have written policies and procedures detailing its methodology for reconciling sample requests and receipts and for determining if patterns of nonresponse exist that may indicate sample diversion. In addition, written policies and procedures must detail how a manufacturer or authorized distributor will initiate investigations or otherwise respond when patterns of nonreturns of sample receipts are found. Proposed § 203.34(c) is being finalized as § 203.34(b)(2) and has been revised to cover the preparation of the reconciliation report as well as the conduct of the physical inventory. Proposed § 203.34(b) is being finalized as § 203.34(b)(3) and has been revised to require manufacturers and distributors to establish and adhere to written policies describing their administrative systems for conducting random and for-cause audits of sales representatives. The necessity for such audits is discussed in conjunction with comments on proposed § 203.31(d).

H. Charitable Donations of Prescription Drug Samples

In the preamble to the March 1994 proposal (59 FR 11842 at 11853), the agency tentatively concluded that charitable donations of drug samples is permissible under PDMA, provided that a system of controls is in place to provide accountability and oversight over such donations and to minimize the potential for drug diversion. The agency proposed a system of drug sample donation controls in § 203.39.

Although no comments were submitted concerning the provisions in § 203.39, the agency has determined that some of the proposed requirements are burdensome and unnecessary to ensure accountability and oversight over donated drug samples. Accordingly, the agency has revised the proposed requirements as follows.

Proposed § 203.39(a)(1) and (a)(2), which required that charitable institutions that receive drug sample donations be licensed by the State, if required by State law, and enrolled with FDA, have been eliminated. Regarding the elimination of proposed § 203.39(a)(4), the agency notes that charitable institutions are still required to comply with applicable State law in their operations. However, the agency believes that it is appropriate to defer licensure or other State requirements to the States. Proposed § 203.39(b)(1), which required charitable institutions to provide documentation demonstrating that their agents are authorized to solicit or receive drug sample donations, and proposed § 203.39(b)(2), which required charitable institutions to maintain a list of agents authorized to solicit or receive drug sample donations, have also been eliminated.

Proposed § 203.39(b)(8), which required the donor of a drug sample to prepare a donation record for drug samples delivered by mail or common carrier, has been eliminated. Under § 203.39(e) of the final rule, the charitable institution to which a drug sample is donated must prepare a donation record for the sample regardless of the manner of delivery of the drug sample and must retain the record for at least 3 years. Proposed § 203.39(b)(9) has been revised to require that the donation record contain
only the name, address, and telephone number of the donating licensed practitioner or charitable institution; the manufacturer, brand name, quantity, and lot or control number of the drug sample donated; and the date of the donation.

Proposed § 203.39(b)(11) has been revised to eliminate the proposed requirement that the inventory of donated drug samples in the possession of a charitable institution be conducted using independent inventory personnel. Proposed § 203.39(b)(12), which required that a charitable institution provide written certification to the donating party that it is in compliance with part 203, has been eliminated in the final rule. Finally, proposed § 203.39(c) has been eliminated, but its requirements have been incorporated into the introductory paragraph of § 203.39 such that charitable institutions may donate donated drug samples to other charitable institutions as long as § 203.39 is followed.

I. Charitable Donations of Prescription Drugs Generally

Since the publication of the March 1994 proposal, the agency has received requests that raise questions about whether and how PDMA should be applied to charitable donations of prescription drugs generally, not just drug samples. Nonsample drug products may be donated to charitable institutions from many different sources, including manufacturers, wholesale distributors, retail pharmacies, for profit and nonprofit hospitals and health care entities, other charitable groups, and reverse distributors (i.e., wholesale distributors that handle returns). In addition, FDA is aware that drug salvagers may also be a source of donations.

The donation of nonsample drug products to charitable institutions raises similar concerns about the quality of the drugs being donated and potential drug diversion as the donation of drug samples. Moreover, such donations constitute distribution of a prescription drug to other than a consumer or patient and therefore could be considered “wholesale distribution” under section 503(e)(4)(B) of the act. Although the agency is not establishing controls for nonsample prescription drug donations at this time, the agency is carefully considering the relevant issues and may in the future propose an approach to drug donations that encompasses both prescription drug samples and nonsample prescription drug products.

J. Creation and Maintenance of Required Forms, Reports, Records, and Signatures

Proposed § 203.60 set forth standards for the creation and maintenance of sample request and receipt forms, reports, records, and other documents required under PDMA and part 203. Proposed § 203.60(a) permitted any required document to be created either on paper or on electronic media. Proposed § 203.60(b) permitted any required document created on paper to be maintained on paper or by photographic or electronic imaging, provided the security and authentication requirements in § 203.60(d) were met. Proposed § 203.60(c) permitted required documents created electronically to be stored using computer technologies, provided they met the requirements in § 203.60(d) were met. Proposed § 203.60(d) provided that required documents and signatures must be created, maintained, or transmitted in a form providing reasonable assurance of being: (1) Resistant to tampering, revision, modification, fraud, unauthorized use, or alteration; (2) preserved in accessible and retrievable fashion; and (3) visible or readily made visible for purposes of review by regulated industry and FDA.

In addition to the requirements in proposed § 203.60, proposed § 203.61 permitted signatures on required forms, reports, and records to be made by means of a writing or marking instrument such as a pen or indelible pencil. The section also permitted signatures to be made by electronic stylus on an electronic pad or by other electronic medium, provided the security requirements in § 203.61(b) were met.

In the Federal Register of March 20, 1997 (62 FR 13430), the agency issued final regulations on electronic records and electronic signatures in part 11 (21 CFR part 11). Because of the issuance of those regulations and the applicability of part 11 to part 203 document and signature requirements, the March 1994 proposal has been substantially revised. Under part 11, electronic records, electronic signatures, and handwritten signatures executed to electronic records that meet the requirements of that part may be used to meet requirements to create and maintain records and signatures under the act and agency regulations, unless specifically excepted by future regulations.

Therefore, sections of the March 1994 proposal setting forth requirements relating to creation and maintenance of electronic records, electronic signatures, and handwritten signatures, as those terms are defined in part 11, have been revised or eliminated in the final rule.

Proposed § 203.60(a) has been deleted and replaced in the final rule by revised § 203.60(a), which states that electronic records, electronic signatures, and handwritten signatures executed to electronic records may be used in lieu of paper records and handwritten signatures executed on paper to meet any of the record and signature requirements of PDMA or part 203, provided that the requirements of part 11 are met. Although electronic signatures, electronic records, and handwritten signatures executed on electronic records would be permitted to meet PDMA and part 203 records and signature requirements under the provisions of part 11 without further rulemaking in part 203 (see, e.g., § 11.1), this section has been included in the final rule for added clarity. The final rule also defines the terms electronic record, electronic signature, and handwritten signature in revised § 203.3(k), (l), and (p), respectively, to have the same meaning that these terms have in § 11.3(b)(6), (b)(7), and (b)(8).

Revised § 203.60(a) permits combinations of paper records and electronic records, electronic records and handwritten signatures executed on paper, and paper records and electronic signatures or handwritten signatures executed to electronic records to be used to meet PDMA record and signature requirements, provided that the requirements of part 11 are met for the electronic component. In addition, a reasonably secure link must exist between the paper-based and electronic components to ensure that the combined records and signatures are trustworthy and reliable and the signer cannot readily repudiate the signed record as not genuine. A reasonably secure link could consist of a physical link between the electronic and paper-based records (i.e., where the paper-based record(s) and a computer disk containing the electronic record(s) are sealed together in a container and a chain of controlled custody for the sealed container is established) or a technology-based link. The agency is planning to issue in the future further guidance on technology-based links in conjunction with its implementation of part 11.

Revised § 203.60(a)(3) clarifies that the “record and signature requirements” to which §§ 203.60(a)(1) and (a)(2) refer include drug sample request, receipt forms, reports, records, and any other types of documents and their associated...
signatures required by PDMA or part 203.

Because part 11 does not apply to the photographic imaging of paper records, proposed § 203.60(b) has been retained in the final rule. The section has been revised, however, to clarify that electronic scanning of paper records into a computer creates an electronic record that is subject to the requirements of part 11. The security and authentication requirements in proposed § 203.60(d) have been renumbered in the final rule as § 203.60(c) and revised such that the requirements in the section apply only to documents and signatures that are created on paper and that are maintained by photographic imaging or transmitted electronically. Minor revisions have also been made to the security and authentication requirements in revised § 203.60(d)(3).

The requirements for maintenance of documents created by electronic means in proposed § 203.60(c) and the signature requirements in proposed § 203.61 have been superseded by part 11 requirements. Therefore, these sections have been deleted in their entirety in the final rule. Proposed § 203.60(e) and (f) have been renumbered in the final rule as § 203.60(d) and (e).

K. Implementation of the Final Rule

The provisions in the final rule will become effective 1 year after the date of publication of the final rule in the Federal Register. The agency is providing this period to give industry sufficient time to implement systems for prescription drug sample distribution and wholesale distribution that are in compliance with the final rule.

III. Comments on the Proposed Rule

A. General Comments

FDA received 56 comments on the March 1994 proposal from prescription drug manufacturers, industry organizations, professional associations and organizations, law enforcement agencies, and others. Although most of the comments addressed only specific provisions of the rule, a few commented generally on the proposed rule, and those comments were mixed. For example, one comment stated that it “supports the controls on prescription drug samples sought through the passage of PDMA and feels that, in general, the proposed rule is a positive step in combating the market in diverted prescription drugs and ensuring consumers that drug products continue to remain safe and effective.” Another comment, however, stated that “finalization of the proposed rule will create unnecessary additional administrative burdens for companies and their sales representatives” and “would not improve significantly the industry’s ability to track sample distribution and reduce the possibility of diversion of samples.”

A large number of comments addressed the provisions of the proposed rule relating to sample distribution. In fact, comments were received on almost all of the sections of the proposed rule dealing with sample distribution. Most of these comments were critical of the manner in which the agency proposed to implement the sample distribution requirements contained in PDMA. In addition to comments on sample distribution, comments were received on sections of the proposed rule relating to reimportation of prescription drugs, resales of prescription drugs purchased by health care entities, recordkeeping and investigation requirements, and wholesale distribution. Specific issues raised by the comments and the agency’s responses follow.

B. Definitions

Blood component. Proposed § 203.3(d) defined “blood component” as “that part of a single-donor unit of blood separated by physical or mechanical means.”

1. One comment requested clarification on whether various plasma products and derivatives, including antihemophilic factor, Factor IX, Factor IX Complex, and immune globulin IV, are considered blood components or drugs. The comment also asked for clarification of whether the agency makes a distinction between human and recombinant products in deciding whether to categorize a blood component preparation as a blood component or drug.

The agency advises that blood components, as defined in § 203.3(d) of the final rule, include red blood cells, plasma, fresh frozen plasma, cryoprecipitated AHF, and platelets. Antihemophilic Factor, Factor IX Complex, and immune globulin products are derivatives of blood, not blood components. Both blood components and blood derivatives are regulated as biologics under the authority of the Public Health Service Act (the PHS Act) and are also drugs under section 201(g)(1) of the act (21 U.S.C. 321(g)(1)). Products manufactured through recombinant technology that mimic blood derivatives or other biological products are also regulated as biologics under the PHS Act and are drugs under section 201(g)(1) of the act. These products, like blood derivatives, are not blood components.

Distribute. Proposed § 203.3(h) defined “distribute” to mean to sell, offer to sell, deliver, or offer to deliver a drug to a recipient, except that the term “distribute” does not include the providing of a drug sample to a patient by:

(1) A practitioner licensed to prescribe such drug;

(2) A health care professional acting at the direction and under the supervision of such a practitioner, or

(3) The pharmacy of a hospital or of another health care entity that is acting at the direction of such a practitioner and that received such sample in accordance with the act and regulations.

On its own initiative, the agency is revising proposed § 203.3(h) in the final rule to specify that the term “distribute” does not include the delivery of drugs or offer to deliver drugs by a common carrier in the usual course of its business as a common carrier. This revision is necessary to permit common carriers that deliver drug samples, or perform duties incidental to delivery (i.e., delivery verification) for manufacturers or authorized distributors of record, to do so without being required to be authorized distributors of record. Such a requirement would be confusing and inconsistent with language in section 503(d) of the act, which distinguishes between sample distribution and delivery by mail or common carrier. However, comarketers, fulfillment houses, and other entities that perform some or all of the functions associated with sample distribution and promotion that would otherwise be performed by the drug manufacturer are not covered by this exception. Thus, entities that create and maintain required forms, reports, and records; have their own sales forces and representatives; solicit and fill requests for drug samples; or conduct other such activities are engaged in drug sample distribution and must be authorized distributors of record.

Health care entity. Proposed § 203.3(n) defined “health care entity” as “any person that provides diagnostic, medical, surgical or dental treatment, or chronic or rehabilitative care, but does not include any retail pharmacy or any wholesale distributor. A person cannot simultaneously be a ‘health care entity’...
and a retail pharmacy or wholesale distributor.”

2. Several comments noted that, under the proposed definition of health care entity, full-service blood centers that currently function both as health care entities and distributors of blood plasma derivatives would not be permitted to continue to operate in both of these capacities. The comments expressed concern that the ability of community health care entities to obtain plasma derivatives would be detrimentally affected if community blood centers were prohibited from distributing them.

One comment explained that plasma derivatives are unique prescription drugs that are largely distributed outside the typical drug distribution network. The comment stated that, historically, blood centers and hospital blood banks have provided plasma processing and distribution services for their local communities. Although the processing has become more complex and is now done largely by for-profit manufacturers, blood centers, hospital blood banks, and transfusion services still act as final distributors of plasma derivatives. The comment said that this arrangement enables the health care providers who receive blood derivatives to use the “expert consultative services” of these entities.

Several comments stated that the same reasons for excluding blood and blood components intended for transfusion from PDMA’s sales restrictions are applicable to blood derivatives. The comments contended that there is no indication in the legislative history that the types of abuses that lead to the restrictions in section 503(c)(3) of the act are present with blood derivatives or that Congress intended the restrictions in section 503(c)(3) of the act to apply to blood derivatives.

The comments suggested ways in which the proposed rule could be amended to allow blood centers to continue to function as wholesale distributors of plasma derivatives. Two comments suggested specifically excluding blood banks, transfusion services, and hospital blood banks from the prohibition against a health care entity simultaneously being a wholesale distributor. Another comment recommended that FDA eliminate entirely the prohibition against a health care entity simultaneously being a wholesale distributor with a clarification in the preamble to the final rule that health care entities engaging in “share arrangements” to avoid resale prohibitions remain subject to enforcement of resale prohibitions, even if licensed as a wholesaler. One comment suggested expanding the definition of “blood” or “blood components” to include plasma derivatives. The agency declines to revise the definition of health care entity or otherwise revise the proposed rule to permit health care entities to engage in the wholesale distribution of blood derivatives or other prescription drug products. The statutory restrictions in section 503(c)(3)(A) of the act prohibit the sale, purchase, or trade of, or offer to sell, purchase, or trade prescription drugs that are purchased by a public or private hospital or health care entity or donated or supplied at a reduced price to a charitable organization. Because blood derivatives are prescription drugs that are neither blood nor blood components, a hospital or health care entity that purchases these products from a manufacturer or distributor, or a charitable institution that receives these products through a donation or at a reduced price, may not sell or trade these products except as permitted under section 503(c)(3)(B) of the act and § 203.22 of the agency’s regulations.

The agency is unpersuaded by the comments that blood derivatives should, as a matter of public health policy, be grouped with blood and blood components intended for transfusion as products that Congress did not intend to cover under PDMA generally, or under section 503(c)(3)(A) of the act specifically. In the September 1990 proposal, the agency stated that if PDMA and, in particular, PDMA’s restrictions on the resale of prescription drugs were considered applicable to blood and blood components intended for transfusion, the result would be to seriously impede the present blood distribution system and thereby substantially interfere with, and reduce, the nation’s blood supply. Based largely on this “untenable result,” the agency stated its belief that Congress did not intend to subject blood and blood components to PDMA’s provisions (55 FR 3027).

The comments contend that, as with whole blood and blood components intended for transfusion, the supply of blood derivatives to the public would be impeded if blood banks were not permitted to distribute these products. However, unlike whole blood and blood components, blood derivatives are manufactured in large quantities by manufacturers that are independent of blood banks and blood centers, are packaged and stored similarly to other pharmaceuticals, and have relatively normal shelf lives. Moreover, blood derivatives need not be matched from a donor to a donee as do whole blood and blood components intended for transfusion. Thus, although in some instances blood derivatives are distributed by blood centers and hospital blood banks, they also are distributed by conventional drug wholesalers. There is no evidence before the agency at this time that a substantial percentage of the nation’s supply of blood derivatives is currently distributed by blood centers, hospital blood banks, or transfusion services, or that the nation’s supply of blood derivatives would be seriously impeded if these entities were prohibited from distributing these products.

Moreover, the comments’ assertion that blood derivatives, like blood and blood components, are not subject to the abuses Congress set out to remedy in PDMA is speculative and unsupported by facts. As discussed previously, blood derivatives are distributed through a normal wholesale distribution system, and they need not be matched to specific patients. Thus, the possibility of diversion of these products exists, and documented instances of diversion of these products have in fact occurred. The fact that blood derivatives were not specifically mentioned by Congress in the legislative history is in itself of little significance.

FDA recognizes that, in addition to selling blood derivatives to community hospitals, blood centers have traditionally provided advice and guidance on how to use the derivatives. The final rule does not prohibit the provision of information by a health care entity to another health care entity, but rather prohibits the selling of prescription drug products, including blood derivatives, that are purchased by a hospital or health care entity. Thus, blood centers or other entities that have traditionally provided information to hospitals or other health care centers are not precluded from doing so under PDMA or the final rule.

3. One comment stated that FDA’s definition of health care entity is “without factual or legal foundation.”

Two comments stated that FDA’s interpretation of section 503(c)(3) of the act as prohibiting a health care entity from simultaneously being a wholesale distributor is contrary to the plain language of the statute and to legislative intent, and places inappropriate restrictions on the legitimate operations of blood centers. These comments interpreted the last sentence in section...
503(c)(3)(A) of the act, which states in part that “[f]or purposes of this paragraph, the term ‘entity’ does not include a wholesale distributor of drugs or a retail pharmacy licensed under State law,” as creating an exemption to the sales restrictions in that section for health care entities that are State licensed as wholesale distributors. The comments stated that FDA’s proposed definition of “health care entity” contradicts the clear wording of the statute. The comments also stated that the proposed definition is inconsistent with legislative intent to permit health care entities acting as legitimate wholesalers to engage in wholesale distribution of prescription drugs.

The agency acknowledges that the first clause of the last sentence in section 503(c)(3) of the act could be read to make the restrictions in section 503(c)(3)(A) of the act inapplicable to hospitals or health care entities State licensed as wholesale distributors. However, the agency believes that the statutory language should be read to mean that health care entities subject to the restrictions in section 503(c)(3)(A) of the act cannot simultaneously be wholesale distributors or retail pharmacies. As noted by the agency in the proposed rule (59 FR 11842 at 11845), the former interpretation is inconsistent both with general rules of statutory construction and with legislative intent. If this interpretation were to be given effect, it would mean that a health care entity could circumvent the sales restrictions by obtaining a State wholesale distribution license. Such an interpretation would deprive the sales restrictions of any force or effect. Moreover, Congress expressly enumerated in section 503(c)(3)(B) of the act the circumstances under which drugs purchased by a health care entity may be sold. The agency believes that if Congress had intended to permit sales of prescription drugs purchased by health care entities that are State licensed wholesale distributors, it would have done so under section 503(c)(3)(B) of the act. Interpreting section 503(c)(3) of the act in the manner suggested by the comments would also be inconsistent with legislative intent as reflected in the congressional findings and legislative history. The statutory restrictions in section 503(c)(3)(A) of the act reflect the congressional finding in section 205(7) of PDMA that the resale of prescription drugs by health care entities at below wholesale prices had helped to fuel the diversion market and constituted an unfair form of competition to legitimate wholesalers and retailers paying prevailing market prices. These same concerns also were expressed by Congress in the legislative history. (See H. Rept. 100–76, pp. 12–13.) If health care entities were permitted to obtain State wholesale distributor licenses and engage in wholesale distribution of prescription drugs, as suggested by the comments, there would be no way of ensuring that the types of abuses that Congress sought to prevent in section 503(c)(3)(A) of the act would not occur.

Neither the requirements applicable to wholesale distributors in section 503(e) of the act nor the State licensing guidelines in part 205 contain requirements to deter a health care entity from reselling prescription drugs, or require or authorize FDA to keep track of the circumstances under which prescription drugs are bought and sold by wholesale distributors. Thus, if health care entities were permitted to be State licensed wholesale distributors, they could purchase drugs for their own use and sell them on the secondary wholesale market with impunity and without the knowledge of the agency or Congress. The agency does not believe that Congress intended such a result.

Licensed practitioner. Proposed § 203.3(o) defined “licensed practitioner” as “any person licensed by State law to prescribe drugs.” 4. One comment recommended that “or authorized” be added after “licensed” in the definition to allow nonphysician practitioners subject to State authorization schemes other than licensing to obtain drug samples. The agency has decided to follow the suggestion of the comment and revise the definition of “licensed practitioner” in the final rule to include practitioners authorized by State law to prescribe drugs. Congress stated in the legislative history (S. Rept. 100–303, p. 5) that “Drug samples may only be distributed to practitioners licensed or authorized by State law to prescribe such drugs.” Moreover, the use by Congress of the term “licensed practitioner” rather than “physician” in section 503(d)(2)(A) of the act shows congressional intent to allow nonphysician practitioners to obtain drug samples. Because a significant number of these practitioners are subject to different State authorization schemes than licensing, the agency finds that a strict interpretation of the word “license” would be inconsistent with congressional intent.

5. One comment stated that, in some States, advanced practical nurses are licensed to prescribe certain drugs, but are prohibited from obtaining samples of the drugs. The comment asserted that, under the proposed definition of “licensed practitioner,” such nonphysician practitioners would be permitted to obtain samples.

In developing the proposed definition of licensed practitioner, the agency was not aware that some States may permit practitioners to prescribe certain drugs, but prohibit them from obtaining samples of those drugs. Because the agency does not wish to interfere with States’ authority to determine who may request and receive drug samples, the agency clarifies that a practitioner who is prohibited by State law from receiving samples of certain types of drugs is not permitted to do so under PDMA even though he or she is licensed or authorized to prescribe those drugs.

Ongoing relationship. Proposed § 203.3(r) defined “ongoing relationship” as an association that exists when a manufacturer and a distributor enter into a written agreement under which the distributor is authorized to sell the manufacturer’s products for a period of time or for a number of shipments, at least one sale is made under that agreement, and the name of the authorized distributor of record is entered on the manufacturer’s list of authorized distributors of record.

6. One comment objected to a requirement for a written agreement between a manufacturer and a distributor. The comment stated that written agreements are not customary in the industry and that such a requirement would be burdensome because distributors distribute for large numbers of vendors. The comment recommended that, for the purposes of proving that an ongoing relationship exists, it should be sufficient to show that sales are made on a continuing basis and that the distributor’s name appears on the manufacturer’s list of authorized distributors.

Another comment objected both to the requirement for a written agreement and to the requirement that a distributor be on the manufacturer’s list of authorized distributors of record. The comment stated that neither of these requirements was previously required by the agency in compliance information provided to industry by the agency. The comment stated that both requirements would make it more difficult for distributors to become authorized distributors of record. In addition, the comment stated that the requirements would give prescription drug manufacturers the ability to deny authorized-distributor-of-record status to distributors with whom they have engaged in ongoing business relationships. The comment stated that by giving drug manufacturers the power to designate which wholesalers are authorized, the distribution requirements apply without oversight or review. FDA would be
delegating legislative power to the private sector in violation of separation of powers principles in the U.S. Constitution. The comment recommended that FDA adopt a definition of ongoing relationship that mirrors a definition set forth by the agency in a 1988 compliance letter.

PDMA defines the term “authorized distributors of record” as those distributors with whom a manufacturer has established an ongoing relationship to distribute the manufacturer’s products. PDMA does not, however, define what constitutes an “ongoing relationship.” In a 1988 letter issued by FDA (see Letter from Daniel L. Michaels, Director, Office of Compliance to Regulated Industry, Docket No. 88N–258L, August 1, 1988), the agency made its first attempt to interpret the term in the context of PDMA. FDA stated that “ongoing relationship” may be interpreted to mean a continuing business relationship in which it is intended that the wholesale distributor engage in wholesale distribution of a manufacturer’s prescription drug product or products. The agency stated that evidence of such intent could include, but would not be limited to, the existence of a written franchise, license, or other distribution agreement between the manufacturer and wholesale distributor and the existence of ongoing sales by the manufacturer to the distributor.

The agency continues to believe that the term “ongoing relationship” in the context of wholesale distribution infers a continuing business relationship between a distributor and a manufacturer where the intent exists to engage in wholesale distribution. Furthermore, the agency has determined that, to facilitate compliance with and enforcement of the act, it is necessary to have a formalized way of establishing that an ongoing relationship exists. A written agreement in which the manufacturer authorizes the distributor to distribute some or all of its products for a period of time or for a number of shipments will provide a clear and verifiable expression of the parties’ intent to engage in a continuing business relationship. The written agreement required by proposed § 203.3(r) (revised as § 203.3(u)) need not rise to the level of a contract or create legally enforceable obligations on the parties. Rather, the agreement need only state that the distributor is authorized to distribute a manufacturer’s products for a period of time or for a number of shipments and, if the distributor is not authorized to distribute all of the manufacturer’s products, identify those products to which the authorization extends. This latter requirement, although not included in the proposed rule, is consistent with the requirement in proposed § 203.50(c)(1) for manufacturers to maintain a list of authorized distributors that specifies whether distributors are authorized to distribute the manufacturer’s full product line or only particular products.

Given the relative ease with which the agreement required by § 20.3(u) can be created, the agency believes that it is highly unlikely that a manufacturer would refuse to enter into a written agreement with a distributor with whom it wishes to have a continuing business relationship. Moreover, it is clearly not the agency’s intent in requiring a written agreement to confer additional discretion on manufacturers, but rather to implement the requirement in the act for an ongoing relationship in a manner in which it can be efficiently enforced. This is consistent with the agency’s authority under section 701(a) of the act (21 U.S.C. 371(a)) to issue regulations for the efficient enforcement of the act. Accordingly, the agency declines to revise the definition of “ongoing relationship” to eliminate the requirement for a written agreement.

Finally, on its own initiative, the agency has revised the proposed definition of “ongoing relationship” in the final rule to eliminate the requirement that at least one sale be completed under the written agreement and that a distributor be entered on the manufacturer’s list of authorized distributors of record. The proposed requirement for a completed sale under the written agreement is unnecessary and, as discussed below, inconsistent with the use of the definition in the context of sample distribution. The proposed requirement that a distributor be entered on the manufacturer’s list of authorized distributors of record is unnecessary in light of the requirement, in section 503(e)(1)(B) of the act and revised § 203.50(d) of the final rule, that manufacturers keep an updated list of authorized distributors of record at their corporate offices.

7 Another comment stated that sample fulfillment houses, mailing services, comarketers, and similar entities clearly distribute samples within the meaning of “distribute” in proposed § 203.3(h), but cannot satisfy the requirements for an ongoing relationship in proposed § 203.3(r).

necessary to be considered authorized distributors of record. The comment recommended that the proposed definition of ongoing relationship be revised to permit these entities to be authorized distributors of record.

The comment raises a valid point. The proposed definition of ongoing relationship is inappropriate for sample distribution, and has been revised in the final rule to specify that an ongoing relationship exists when there is a written agreement between a manufacturer and distributor to distribute, rather than to sell, the manufacturer’s products for a period of time or for a number of shipments.

Prescription drug. Proposed § 203.3(v) defined “prescription drug” as any drug required by Federal law to be dispensed only by a prescription, including finished dosage forms, bulk drug substances, and active ingredients subject to section 503(b) of the act.

On its own initiative, the agency has removed “active ingredients” in the final rule. The term “bulk drug substance,” as defined under § 203.3(e), is synonymous with “active ingredient.”

Wholesale distribution. Proposed § 203.3(y) defined “wholesale distribution” as “distribution of prescription drugs to persons other than a consumer or patient, but does not include: (1) Intracompany sales * * *.”

8 One comment objected to the exemption of intracompany sales from wholesale distribution, stating that it “totally gets away from the original intent of the PDMA.” The comment said that this provision leaves a gap where diversion can occur between wholesalers and retail outlets owned by them.

The agency disagrees with the comment. Intracompany sales were expressly excluded by Congress from the definition of wholesale distribution in section 503(e)(4)(B) of the act. In addition, both the House and Senate reports referred to the exclusion. (See H. Rept. 100–76, S. Rept. 100–303.) The House report stated:

[i]t is the express intent of the Committee that the scope of [this section] include distribution by chain drug warehouses, wholesale drug warehouses, and all sellers of prescription drugs in wholesale quantities to persons or firms other than the consumer or patient. With respect to section 503(e)(1), intracompany sales, i.e., the distribution between divisions and companies having the same ownership, are excluded. (H. Rept. 100–76, p. 17.)

Thus, as expressed in the language of the act and the legislative history, Congress’ intent was to exclude intracompany sales from the requirements for wholesale distribution in section 503(e) of the act. In addition,
the agency advises that § 205.5 contemplates a licensing scheme for business entities with subsidiaries, affiliates, and more than one facility (see § 205.5(b)), and provides that State licensing authorities require each wholesale distributor to supply information on all facilities used by the licensee for the storage, handling, and distribution of prescription drugs (see § 205.5(a)(3)).

C. Reimportation

Proposed § 203.10 stated, in relevant part, that “no prescription drug that was manufactured in a State and exported from the United States may be reimported by anyone other than its manufacturer.”

9. One comment requested that the proposed rule be revised to state that a prescription drug may be reimported by any of a manufacturer’s subsidiary companies or contract manufacturers.

For the reasons discussed in the preamble to the proposed rule (59 FR 11842 at 11844), FDA is adopting the definition of manufacturer set forth in § 201.1 (21 CFR 201.1) of the agency’s regulations for the purposes of part 203. Accordingly, a manufacturer’s subsidiary companies or contract manufacturers may reimport the prescription drug product only if they also qualify as a manufacturer of the drug product under § 201.1.

10. One comment recommended that language be added to the section to include drugs that are sold by a manufacturer for exportation, but never leave the United States. The comment stated that a large proportion of the “export” drugs that are diverted never actually leave the United States.

Because the drugs referred to by the comment are not exported, they cannot be subject to the restriction on reimportation. However, the domestic distribution of such drugs is covered by PDMA and other applicable laws, which should help to reduce the potential for diversion.

D. Sales Restrictions

Proposed § 203.20 prohibited the sale, purchase, or trade of, or offer to sell, purchase, or trade, any prescription drug that was purchased by a public or private hospital or health care entity or donated or supplied at a reduced price to a charitable institution.

1. Section 203.22(e)

Proposed § 203.22(e) provided that § 203.20 does not apply to: “The sale, purchase, or trade of a drug, an offer to sell, purchase, or trade a drug, or the dispensing of a drug under a valid prescription.”

11. A health care organization requested that FDA clarify whether, under this section, its nonprofit affiliates may provide prescription drugs obtained at a nominal cost to patients under a prescription, where the amount charged for the drug varies depending on the patient’s ability to pay.

Section 203.20 does not prohibit a health care entity from obtaining prescription drugs at reduced cost. Rather, it prohibits reselling those drugs except in specified ways. Section 203.22(e) allows the resale of drugs by a health care entity under a valid prescription. The amount of profit derived from such a sale, or the lack thereof, is not addressed by § 203.22(e). Therefore, a health care entity may, subject to other applicable laws, resell prescription drugs to patients under a valid prescription at varying prices.

2. Section 203.22(f)

Proposed § 203.22(f) provided that § 203.20 does not apply to:

The sale, purchase, or trade of a drug or the offer to sell, purchase, or trade a drug by hospitals or health care entities owned or operated by Federal, State, or local governmental units to other hospitals or health care entities owned or operated by Federal, State, or local governmental units.

12. One comment opposed this exclusion. The comment argued that government employees are just as apt to engage in drug diversion activities as are private sector employees. The comment stated that the potential for drug diversion is even greater in the public sector because Federal and State hospitals and health care entities often receive more favorable pricing terms than private hospitals. The comment also stated that the exclusion “appears self serving” and is not supported by the legislative record.

FDA disagrees with this comment. As the agency explained in the preamble to the proposed rule (59 FR 11842 at 11847), any profits from legitimate sales of prescription drugs by government hospitals would accrue to government treasuries. Thus, no financial incentive exists for a government hospital or health care entity, or its representatives acting in an official capacity, to engage in diversion. Given the lack of financial incentive, the amount of profit that could be realized due to the prices at which government hospitals may receive prescription drugs is irrelevant. Moreover, although it is possible that individual employees may steal drugs or sell them by other criminal methods and sell them, criminal conduct by individual employees was not intended by Congress to be addressed by the sales restrictions. Rather, it was the legal resale of drugs obtained by hospitals and health care entities, and the potential profit accruing to those entities from such sales, with which Congress was concerned in enacting the sales restrictions.

Finally, the agency disagrees that the exclusion is not supported by the legislative record. As discussed previously and in the proposed rule (59 FR 11842 at 11846 and 11847), the prohibition against sales by hospitals or health care entities was prompted in part because of the temptation for such entities to sell for profit drugs acquired at below wholesale prices. Because no financial incentive exists for government hospitals to profit from sales to other government hospitals, it is unlikely that such sales would result in the kinds of abuses that PDMA sales restrictions were designed to prevent.

In addition, Congress expressly created exclusions permitting, among other things, sales between hospitals or health care entities under common control and emergency sales by hospitals or health care entities to retail pharmacies to allow for the provision of health care to patients. (See H. Rept. 100–76, 13). As discussed in the preamble to the proposal (58 FR 11842 at 11846 and 11847), permitting prescription drug sales between government hospitals and health care entities will help such entities to provide health care services in response to various needs, including the provision of health care to people with low incomes and the distribution of vaccines. Thus, the exception is consistent with Congress’ general objectives in enacting the sales restrictions and with the rationale supporting other exemptions expressly created by Congress.

3. Sections 203.23 and 203.24

Proposed §§ 203.23 and 203.24 set forth exemptions to the sales prohibition contained in proposed § 203.20. Proposed § 203.23 provided an exemption for the revocation of a sale and purchase transaction by a hospital, health care entity, or charitable institution because of a mistake in ordering or delivery and the reshipment of the prescription drug to a manufacturer or wholesale distributor for a credit or refund. The section required that the drug be shipped back to the manufacturer or distributor within 10 days and that the reshipment be made under proper conditions for storage, handling, and shipping. In addition, the section required that, if the drug is reshipped to a wholesale distributor, the hospital, health care entity, or charitable institution must provide written notice to the
manufacturer of the revocation and reshipment.

Proposed § 203.24 provided an exemption for the return of a prescription drug purchased by a hospital or health care entity, or acquired at a reduced price by or donated to a charitable institution, to the manufacturer or the wholesale distributor that sold, donated, or supplied the prescription drug. The section required that, if the drug is returned to a wholesale distributor, the hospital, health care entity, charitable institution, or distributor must notify the manufacturer that the drug has been returned. In addition, the hospital, health care entity, or charitable institution must prepare a credit memo for all returns. The returning entity must forward a copy of the memo to the manufacturer and retain a copy for its records. The section also required that returned drugs be kept under proper conditions for storage, handling, and shipping. Finally, the section required that the value of any credit, refund, or exchange not exceed the purchase price or, if a donation, the fair market price of the returned product.

13. One comment said that it generally supported the agency’s approach for allowing returns, but questioned the need for § 203.23 and recommended that it be deleted in the final rule. According to the comment, the agency’s purpose for calling a return a revocation of acceptance and reshipment was to address concerns that sales provisions in the Uniform Commercial Code (UCC) could make a return a prohibited resale under PDMA. The comment stated that by “expanding on this initial allowance of returned product and proposing § 203.24, FDA has shown that it has overcome UCC concerns and will not view a return as a prohibited resale.”

The agency agrees for the most part with the comment. Because proposed §§ 203.23 and 203.24 permit transactions and impose notification and documentation requirements that are similar, and because the situations in which returns would be permitted under § 203.23 would also be permitted by § 203.24, the agency has decided to withdraw proposed § 203.23 and redesignate proposed § 203.24 as new § 203.23 in the final rule. This will simplify the regulation and eliminate potential confusion about whether proposed § 203.23 or § 203.24 applies to a particular return. Under the revised regulation, all prescription drugs returned by a hospital, health care entity, or charitable institution to its supplier will be regarded as “returns” and will be subject to the same requirements for providing notice to the manufacturer, documenting the return, and maintaining proper storage, handling, and shipping conditions.

On its own initiative, the agency has decided not to include in revised § 203.23 the requirement in proposed § 203.24(a) that a hospital, health care entity, charitable institution, or distributor notify the manufacturer that a prescription drug product has been returned when the return is made to a wholesale distributor. Under revised § 203.23(a) and (b), the hospital, health care entity, or charitable institution is already required to fill out a credit memo documenting the return of a prescription drug and to forward a copy of that memo to the manufacturer. The agency believes that the receipt of the credit memo by the manufacturer should provide sufficient notice to it of the source of a return, and the additional notice that would have been required under proposed § 203.24(a) is not necessary.

14. One comment stated that the concerns addressed by the requirements for notification of the manufacturer and documentation of returns in the proposal is legitimate, but that health care entities should not be “held responsible for helping to police the wholesale drug industry.” The comment said that wholesalers should be required to develop mechanisms for documentation and recordkeeping that would achieve the desired goals of the regulation.

The agency believes that the comment misconstrues the purpose of the notice and documentation requirements. As the agency explained in the proposal, the purpose of requiring that a credit memo be forwarded to the manufacturer is to help ensure that any chargebacks or reduced prices will be factored into a credit or refund provided by the manufacturer to prevent windfall profits from the transaction (59 FR 11842 at 11847). There is a potential for such profits to be realized not only by wholesale distributors, but by hospitals, health care entities, and charities. Thus, the agency disagrees that the purpose of providing notice is limited to policing the wholesale drug industry. In addition, the agency believes that the returning hospital, health care entity, or charity is in the best position to provide the information required in the credit memo and, as the party that derives the benefit from any special pricing provided by the manufacturer, should be responsible for ensuring that returns are legitimate.

15. Another comment stated that the resale restrictions were not intended by Congress to cover normal and legitimate returns of prescription drugs and that FDA is therefore not required or authorized by PDMA to place requirements on returns. The comment said that the provision of notice to a manufacturer when drugs are returned to a wholesale distributor would constitute an unreasonable administrative burden on manufacturers who do not provide a refund or credit in such circumstances.

As discussed in the proposal (59 FR 11842 at 11847), proposed §§ 203.23 and 203.24 were included to address the concern that, subsequent to a completed sale, a return for cash, credit, or other consideration could be viewed as a new and prohibited sales transaction under section 503(c)(3)(A) of the act. Although the agency agrees that Congress did not intend to prohibit legitimate returns of prescription drugs, there is a potential for abuses to occur with returns. The notice and documentation requirements in revised § 203.23(a) and (b) are necessary to help ensure that the returning entity or entities do not profit unfairly from the return and that diversion of returned drugs does not occur. Both of these goals are consistent with Congress’ intent in enacting the sales restrictions. (See sec. 2(7), PDMA, H. Rept. 100–76, pp. 12–13.)

16. One comment stated that proposed §§ 203.23 and 203.24 should be clarified so that prescription drugs that are returned to the manufacturer for destruction are exempt from the restrictions in § 203.20, and thus need not adhere to the requirements in proposed §§ 203.23 and 203.24.

The agency declines to provide the clarification sought by the comment. Under § 203.20, the sale, purchase, or trade of a prescription drug purchased by a hospital or health care entity, or donated or supplied at a reduced price to a charitable institution, is prohibited unless the sale, purchase, or trade is exempt from § 203.20 under § 203.22 or revised § 203.23. When a prescription drug that is purchased by a hospital, health care entity, or charity is returned to the manufacturer for destruction and a credit or refund is given for the return, the return constitutes a sale that is prohibited by § 203.20, unless the requirements of § 203.23 are met. Similarly, the agency will consider the provision of destruction services by a manufacturer or distributor at no or reduced cost to the returning entity, relative to the fair market value for such services, to constitute consideration supporting a sale. Thus, returns of prescription drugs for destruction must meet the requirements of § 203.23, unless no credit or refund is given for the return and the returning entity pays...
the fair market value for the drugs’ destruction. The conclusion reached above is fully consistent with the policy underlying the requirements in §203.23. First, drugs that are returned for destruction have the same potential to be diverted as drugs that are returned for redistribution. The threat to the public health from diversion of such drugs could be particularly severe because they are presumably unsuitable for use. Therefore, it is essential that drugs returned for destruction be subject to documentation requirements that provide accountability over the return. Additionally, there may be situations in which a returned drug that is designated for destruction by a hospital, health care entity, or charity may be deemed suitable for sale by the distributor or manufacturer. For example, a drug returned because its outer packaging was damaged may, after examination or testing is conducted by the manufacturer as required by §205.50(e), prove to be fit for use. Thus, returned drugs must be maintained under proper conditions for storage, handling, and shipping, and written documentation reflecting the maintenance of proper conditions must be provided to help ensure that, if the returned drug is redistributed, it is safe and effective.

Section 203.23(c) requires that a drug returned to a manufacturer be stored and handled appropriately, according to its labeled storage requirements, both while it is in the possession of a hospital, health care entity, or charity, and during its return (i.e., during reshipment). Prior to reshipment, only the hospital, health care entity, or charity in physical possession of the drug knows and can document whether the drug has been stored and handled appropriately. However, because a common carrier or other third party may be used to reship the drug, this party may provide documentation that the drug was stored and handled properly during reshipment. Thus, if a returning hospital, health care entity, or charity uses a common carrier or other third party to reship drugs, the third party or carrier may create the required documentation, and provide the documentation to the manufacturer or distributor on delivery.

The agency clarifies that, regardless of whether a common carrier is used to reship the drug, the returning hospital, health care entity, or charitable institution is responsible for complying with the requirements of §203.23. Thus, if proper conditions were not maintained during reshipment and/or if written documentation showing that proper conditions were maintained during reshipment was not provided to the manufacturer or wholesale distributor to which the drugs are returned, the requirements of §203.23 would not be met and the returning hospital, health care entity, or charitable institution would be in violation of §203.20 of FDA regulations and section 503(c)(3)(A) of the act.

18. Proposed §203.24(d) required that the value of any credit or refund not exceed the purchase price or fair market price of the returned drug. One comment stated that the provision would be burdensome on manufacturers that currently calculate credits or refunds based on the purchase price of the drug as of the date of return. The comment also stated that it would be virtually impossible, without the implementation of a sophisticated system by the manufacturer, to attach a cost to a specific item when it is not known when the item was acquired. The comment recommended that the provision be revised to allow the value of the return to be based on the purchase price of the drug as of the date of the return.

The agency’s intent in proposing §203.24(d) was, as with the notice provisions, to prevent hospitals, health care entities, charities, or distributors from obtaining windfall profits from returns at the expense of manufacturers. Thus, as proposed, the provision would not make manufacturers responsible for ensuring that the amount of a credit, refund, or exchange given for a drug does not exceed the purchase price or, if a donation, the fair market value at the time the donation was made. Instead, the section would make the returning hospital, health care entity, or charitable institution responsible for ensuring that it did not accept a credit, refund, or exchange that exceeded the purchase price or fair market value at the time the drug was purchased or donated. Nevertheless, FDA recognizes that in order to comply with this provision, the returning institution would have to maintain records of the price paid for a drug at the time it was purchased.

Because maintaining such records does not appear to constitute customary industry practice and would impose additional costs and burdens on manufacturers, the agency has revised §203.23 in the final rule to eliminate the requirement that the value of any credit or refund not exceed the purchase price or fair market price of the returned product.

E. Samples

1. Sample Distribution by Mail or Common Carrier

Proposed §203.30(a)(2) required that the recipient of a drug sample distributed by mail or common carrier execute “a written receipt, as set forth in paragraph (c) of this section, when the drug sample is delivered.” Proposed §203.30(c) set forth the required contents of the receipt for samples distributed to licensed practitioners, and to designated pharmacies of health care entities. Proposed §203.30(c) provided:

* * * The receipt is to be on a form designated by the manufacturer or distributor, and is required to contain the following:

(1) If the drug sample is delivered to the licensed practitioner who requested it, the receipt is required to contain the name, address, professional title, and signature of the practitioner or the practitioner’s designee who acknowledges delivery of the drug sample; the proprietary or established name and strength of the drug sample, the quantity, and the lot or control number of the drug sample delivered; and the date of the delivery.

(2) If the drug sample is delivered to the pharmacy of a hospital or other health care entity at the request of a licensed practitioner, the receipt is required to contain the name and address of the requesting licensed practitioner, the name and address of the hospital or health care entity pharmacy designated to receive the drug sample; the name, address, professional title, and signature of the person acknowledging delivery of the drug sample; the proprietary or established name and strength of the drug sample, the quantity, and the lot or control number of the drug sample delivered; and the date of delivery.

19. Several comments stated that not all of the information required to appear on the sample receipt form under proposed §203.30(c) is necessary to confirm delivery of a sample. One comment stated that the act only requires information sufficient to verify that the sample received matches the sample requested and sent. Another comment asserted that FDA does not have the authority under PDMA to specify the content of the receipt, and that the only information required by PDMA is the signature of the licensed practitioner and any information
necessary to determine the identity of the sample and the recipients. The agency has determined that, with the exception of the proposed requirement for the lot or control number of the sample (discussed below in conjunction with comments on §§203.30 and 203.31), the information requirements in proposed §203.30(c) are necessary to ensure that samples that are requested are received by the intended recipient and that patterns of nondelivery of drug samples can be identified. Both of these objectives are consistent with legislative intent. (See H. Rept. 100–76 at 15.) The agency therefore declines to eliminate or modify these requirements in the final rule.

The information required under proposed §203.30(c) mirrors most of the information required to appear on the sample request form under proposed §203.30(b). This information is the minimum information necessary to identify the type and quantity of drug samples requested and distributed, the requesting practitioner, and, if applicable, the designated hospital or health care entity to which the drug samples are to be delivered. The only information required by proposed §203.30 to appear on drug sample receipt forms that is not required to appear on request forms is the name, address, professional title, and signature of the person acknowledging delivery of the drug sample. This information is necessary to establish accountability for receipt of drug samples when samples are delivered to the practitioner's office and the requesting practitioner does not physically receive the drug sample and sign the sample receipt or when samples are delivered to a hospital or health care entity at the request of a practitioner.

20. Several comments objected to the required information because electronic delivery verification systems currently used by delivery services and common carriers cannot accommodate the information. According to the comments, current electronic delivery verification systems are capable of recording some, but not all, of the required information. The comments stated that to capture all of the required information, a manufacturer or authorized distributor of record would have to use a paper system independent of common carriers’ delivery verification, such as a business reply mail card. Several comments said that paper systems involve more administrative costs and would result in less compliance by practitioners than electronic delivery verification. One comment stated that, using business reply mail cards, it would take two to three followup letters to achieve compliance within the 90 to 95 percent range. Another comment said that data may be accessed faster and easier with electronic verification systems than with business reply mail cards, since the data are stored electronically rather than manually. Several comments recommended revising the proposed rule to bring it into conformity with the specific electronic delivery verification system used by the commenter. Other comments recommended that the proposed rule be revised to state that receipts used by common carriers as part of their normal course of business are sufficient.

The agency recognizes that manufacturers and authorized distributors of record may not be able to comply fully with the sample receipt content requirements in proposed §203.30(c) using commercial carriers’ electronic delivery acknowledgment systems. Electronic delivery acknowledgment systems do not appear to be designed to meet the specific informational requirements for sample receipts under §203.30(c) at the present time. Thus, the use of business reply mail cards or other types of paper systems capable of recording the required information may be necessary. These systems may not be as convenient for health care practitioners receiving samples to use as electronic delivery acknowledgment systems and will probably be more expensive for manufacturers and authorized distributors of record. However, these disadvantages are not in themselves sufficient reason to eliminate the informational requirements in proposed §203.30(c), where no satisfactory alternatives exist to ensure that congressional objectives for establishing controls on sample distribution are met.

21. Two comments requested that FDA permit the use of combinations of electronic and paper media to create the required receipt form. Under the scenario presented by one of the comments, a receipt would be signed by the practitioner after delivery of the sample but before a manufacturer or authorized distributor of record distributes a drug sample to a licensed practitioner, it must receive a signed, written request form from the licensed practitioner. Proposed §203.31(a)(2) required that the recipient sign a receipt form containing the information required under proposed §203.31(c) when the drug sample is delivered. Proposed §203.31(a)(3) required that the receipt be returned to the manufacturer or distributor.

22. One comment requested clarification of whether the proposed rule would supplant the March 2, 1993, guidance letter recommendations on delivery confirmation of drug samples by common carriers. Any policy stated in that document, including the policy on delivery verification, is superseded by the policies set forth in the final regulation.

2. Sample Distribution by a Representative or Detailer

a. Section 203.31(a)(1) and (a)(2). Proposed §203.31(a)(1) required that before a manufacturer or authorized distributor of record distributes a drug sample to a licensed practitioner, it must receive a signed, written request form from the licensed practitioner. Proposed §203.31(a)(2) required that the recipient sign a receipt form containing the information required under proposed §203.31(c) when the drug sample is delivered. Proposed §203.31(a)(3) required that the receipt be returned to the manufacturer or distributor.

23. One comment requested that the proposed rule be revised to clarify that a single form may be used to satisfy the requirements of a request and receipt form.

FDA set forth its policy on the use of one form to satisfy the request and receipt form requirements for samples delivered by a representative in the preamble to the proposed rule (58 FR 11842 at 11849). The agency stated:
A sample request and receipt need not be on separate forms if delivery is by a representative. A single form could be devised and used containing all of the required information, which could be fully completed and executed with a single signature, if the request and delivery are simultaneous, or executed in part with a signature for the request at the time of the request, and executed in part with a second signature acknowledging receipt at the time of the delivery. The agency wishes to emphasize that, whether one form or separate forms are used, only a licensed practitioner may request a sample and sign the request form. A sample receipt, however, may be signed either by a licensed practitioner or that practitioner’s designee.

24. FDA received four comments that objected to any requirement for a receipt for representative-delivered samples. The comments stated that receipts for representative-delivered samples were not required by PDMA and that this requirement goes beyond the scope of the act. Two comments stated that most requests and deliveries take place on the same representative visit. One comment recommended that the rule be revised to cover only those situations where request and delivery of samples do not occur on the same visit. Another comment said that Congress required receipts for samples delivered by mail or common carrier, but not representatives because there are more opportunities for samples to be lost or diverted when the mail is used. The comment recommended that the manufacturer could use the information on the request form to do its own followups with licensed practitioners to see whether samples had been delivered.

Although Congress did not expressly require a receipt for representative-delivered samples in the act, FDA has concluded that additional requirements, including receipts, are necessary to help ensure effective enforcement, increased accountability and oversight of sample distribution, and to provide adequate safeguards against drug sample diversion. All of these goals are consistent with and further the legislative intent in enacting PDMA. Although samples delivered by a representative to a licensed practitioner may be requested and delivered simultaneously, this is not always the case. For example, the delivery of samples by a representative to a hospital or health care entity pharmacy designated by a physician may not occur at the same time a request for such samples is made. When the request for and delivery of a sample by a representative do not occur simultaneously, the potential for sample diversion and corresponding need for a sample receipt are as great as when samples are delivered by mail or common carrier. When the request for and delivery of a sample do occur simultaneously, the sample request and receipt form may be merged into one form with a single signature (see discussion above).

25. FDA received four comments related to the medium on which the required information for representative-delivered sample receipts may appear. Two comments assumed that proposed § 203.31(a)(2) and (c) required receipts to be in paper form and objected to that requirement. Two comments asked for clarification on whether receipts do, in fact, have to be in paper form or may be electronically created. All four comments assumed that the proposed regulations required that a paper receipt be left with the licensed practitioner even when receipts are electronically created, and objected to this requirement. One comment stated that neither PDMA guidelines nor the proposed regulations require licensed practitioners to keep records of drug samples received, thus a written receipt would serve no purpose.

It appears that the confusion over whether receipts must be written on paper came from the preamble discussion of proposed § 203.31 (59 FR 11842 at 11849). FDA stated that “the agency has tentatively concluded that the requirement for a written receipt should extend to all drug sample deliveries, and that requirement is included in proposed §§ 203.30 and 203.31.” Moreover, the word “written” does appear in conjunction with receipts in § 203.30, but not in § 203.31. As discussed in section II.J of this document, request and receipt forms, reports, records, and other documents and signatures required by PDMA and part 203 may be created on paper or on electronic media, provided that records created on electronic media meet the requirements of revised § 203.60 and part 11. In addition, although the final regulations require that a receipt be signed and returned to the manufacturer when a sample is received, they do not require that a receipt be left with the practitioner for his or her records or that practitioners maintain records of samples received.

b. Section 203.31(c)(2). Proposed § 203.31(c)(2) stated that if the drug sample is received by the pharmacy of a hospital or other health care entity at the request of a licensed practitioner, the receipt is required to contain, among other things, the name and address of the hospital or health care entity pharmacy designated to receive the drug sample.

26. One comment objected to the requirement that the name and address of the hospital or health care entity pharmacy designated to receive the drug sample appear on the receipt. The comment stated that this information is known by the requesting licensed practitioner.

The purpose of the receipt requirement is not to provide information to the licensed practitioner that requests the drug sample, but to provide manufacturers and authorized distributors with documentation that samples that were requested were in fact properly delivered. When a licensed practitioner requests that a drug sample be delivered to a hospital or health care entity pharmacy, it is necessary for the name of the hospital or health care entity pharmacy to appear on the sample receipt so that the person receiving the sample at the pharmacy can verify, through his or her signature on the sample receipt, that the sample was delivered as requested.

c. Section 203.31(d)(1) and (d)(2). Proposed § 203.31(d) required that drug manufacturers and authorized distributors of record conduct an inventory, using generally accepted inventory practices, of drug samples in the possession or control of each of their representatives. The inventory must be conducted at least annually, and the results of the inventory are required to be recorded in an inventory record and reconciliation report. The contents of the inventory record and reconciliation report were set forth in proposed § 203.31(d)(1) and (d)(2). Proposed § 203.31(d)(1) required the identification of each drug sample in a representative’s stock by the proprietary or established name and dosage strength, and the number of sample units. Proposed § 203.31(d)(2) required:

(i) A report of the physical count of the most recently completed prior inventory;

(ii) A record of each drug sample shipment received since the most recently completed prior inventory, including the sender and date of the shipment, and the proprietary or established name, dosage strength, and number of sample units received;

(iii) A record of drug sample distributions since the most recently completed inventory showing the name and address of each recipient of each sample unit shipped, the date of the shipment, and the proprietary or established name, dosage strength, lot or control number, and number of sample units shipped; and

(iv) An explanation for any significant loss.

As discussed in section II.E of this document, the agency’s own initiative revised proposed § 203.31(d) to more clearly distinguish between the
inventory and reconciliation functions and to clarify certain required elements of the reconciliation report.

27. Two comments requested clarification of the meaning of the phrase “generally accepted inventory practices.” Both comments cited the statement in the preamble of the proposed rule (59 FR 11842 at 11849) that “it is FDA’s preliminary view that such an inventory must go beyond a mere physical count, and that meaningful information and data can only be provided if the inventory is conducted utilizing generally accepted inventory practices * * *.” The comments said that if generally accepted inventory practices refers to more than a physical count, FDA must clarify what is required.

As discussed in section II.E of this document, the final rule has been revised to eliminate the use of the phrase “generally accepted inventory practices” in conjunction with the inventory requirement.

28. Several comments objected to the requirements in proposed § 203.31(d)(2)(ii) and (d)(2)(iii) because the required information duplicates information contained in sample request forms and corporate distribution records that are already on file. Two comments stated that the reconciliation report should contain a reconciliation of opening and closing inventories against sample allocations received and sample distributions, but not a statement of all individual allocations and distributions. Another comment questioned whether the inclusion of the information required under these sections in a single report is productive or merely an additional clerical burden.

The first comment correctly points out that the information required to be contained in the reconciliation report under revised § 203.31(d)(2)(ii) and (d)(2)(iii) will come from various sources, including drug sample request and receipt forms, distribution records required to be created and maintained under the current good manufacturing practice (CGMP) regulations (see, e.g., 21 CFR 211.196), and other records maintained by the representative or the firm. Nevertheless, the agency believes that the assimilation of information from these multiple records into a single report that concisely identifies and characterizes each type of transaction conducted with drug samples will aid industry in detecting discrepancies in inventory that may be indicative of drug sample diversion activity. In addition, it will permit FDA and other Federal and State agencies responsible for enforcing PDMA to effectively oversee a company’s conduct in performing its reconciliation and in initiating investigations of potential drug sample record falsifications and significant losses and thefts of drug samples under § 203.37.

29. One comment sought clarification on whether the reconciliation report may consist of several documents that, when taken together, contain all required information.

The reconciliation report for an individual sales representative may consist of several paper documents and/or electronic records. However, all documents or records are to be collected and maintained as a single reconciliation “report.”

30. Another comment stated that “PDMA does not require manufacturers to annually compile a report for each sales representative that summarizes in one place all aspects of each sample delivery in minute detail.”

Although PDMA does not explicitly require the information under § 203.31(d)(2), it does establish an extensive scheme for monitoring drug sample distributions by a representative that includes requirements for drug sample request forms, an annual inventory, and reporting of significant losses and known thefts of drug samples. As discussed previously, the agency believes that the requirements contained in § 203.31(d)(2)(ii) and (d)(2)(iii), including the requirement for identifying individual transactions conducted with drug samples in revised § 203.31(d)(2)(iii), are necessary to bring potential drug sample diversion activities to the attention of manufacturers and authorized distributors. This objective is consistent with legislative intent in PDMA.

31. Two comments recommended that manufacturers should be permitted to use bar coding that represents the proprietary or established name and dosage strength on the inventory record and reconciliation report instead of actual words. One of the comments said that such coding is “easily translated” into the required information.

The agency advises that it does not object to the use of bar coding that represents required information in the inventory record or reconciliation report provided that the information in such a form can be used by the firm to conduct the reconciliation process and to detect discrepancies in inventory and potential drug diversion. In addition, the bar coding must be capable of being translated into words and the record or report must be capable of being produced by the purchasing entity upon request by FDA or other Federal, State, or local law enforcement authorities.

32. Two comments objected to the requirement in proposed § 203.31(d)(2)(iii) to list the lot or control number in the reconciliation report. One of these comments stated that this requirement would not assist in diversion detection because the batches are so large that significant numbers of representatives in varying geographical areas will receive the same batch. The comment also stated that “existing PDMA records” make it possible to determine every physician called on by representatives who could have received the lot in question. The other comment stated that the requirement would “have little or no effect in assuring a meaningful inventory,” but would increase difficulty of conducting inventory and preparing the report.

The requirement in proposed § 203.31(d)(2)(iii) was intended to ensure that a manufacturer or authorized distributor maintains a record enabling it to track the distribution of sample units by lot or control number from a representative to a licensed practitioner. Although the agency agrees that such information would not necessarily enable manufacturers or distributors to pinpoint the representative responsible for distributing a sample unit that has been diverted, it would promote precision in tracking samples and facilitate the location of samples in the event of a recall or other public health emergency. Nevertheless, as discussed below, the agency has determined that manufacturers and authorized distributors of record should be free to choose the types of records used to track the distribution of drug sample lots to licensed practitioners. Therefore, the proposed requirement for inclusion of lot or control numbers in the reconciliation report has been eliminated in the final rule.

d. Section 203.31(d)(3). Proposed § 203.31(d)(3) stated: “The inventory and reconciliation reports shall be conducted and prepared by persons other than the representatives being inventoried or superiors or managers in their department, division, or branch, or in their direct line of supervision or command.”

33. Three comments stated that the proposed requirement represents a misinterpretation of PDMA and its legislative history regarding section 303(b)(4)(B)(ii) of the act. The comments stated that this section allows a manufacturer the option of performing an independent audit to protect itself from civil liability for the acts of its representatives, but that FDA has misconstrued the section to mean that...
PDMA requires a yearly, independent audit of every representative. The comments apparently misunderstand the terms “inventory” and “audit.” An inventory is an itemized list or catalog of goods or property, usually taken annually. An audit is a formal, periodic examination and checking of accounts or records to verify their correctness. (Webster’s New World Dictionary, 2d College Ed.) The comments correctly assert that section 303(b)(4)(B)(ii) of the act does not require an annual audit of all representatives. However, proposed § 203.31(d)(3) did not establish an audit requirement, but rather set forth requirements concerning which personnel are to conduct the inventory and reconciliation and prepare the inventory record and reconciliation report. The proposed requirement was therefore intended to implement the requirement in section 503(d)(3)(C) of the act for an annual inventory of drug samples in the possession of a representative, rather than section 303(b)(4)(B)(ii) of the act.

34. Several comments said that the proposed requirement is too costly, and the ends can be achieved through more cost-effective means. Several comments stated that since inventory must be completed onsite, it would be too costly to require personnel other than supervisors or managers within the geographic area of the representative to perform it. On the other hand, the comments said, reconciliation can be performed at a central location, thus it is more suitable to completion by independent personnel.

Two comments distinguished inventory from reconciliation by stating that the former is relatively simple and can be performed by sales management, while the latter is more complex and should be done by a person independent of sales and marketing. In contrast, another comment recommended allowing representatives to perform the reconciliation, but not the inventory function.

One comment recommended allowing anyone but the representative to perform the inventory or prepare the reconciliation report. Several comments recommended allowing a sales representative’s district manager to perform the inventory function. The objective of the proposed requirement was to guard against errors and possible fraud in the conduct of the physical inventory and reconciliation, and in the preparation of the inventory record and reconciliation report, by the representative or other interested parties. Although the agency continues to believe that this is a legitimate and important objective, the agency agrees that it can be achieved through less burdensome means than by requiring the inventory and reconciliation to be conducted by persons other than the representatives, their superiors or managers, or others in their direct line of supervision or command. Accordingly, the agency has revised the proposed requirement to permit manufacturers and distributors to take “appropriate internal control measures” to guard against error and possible fraud in the conduct of the physical inventory and reconciliation, and in the preparation of the inventory record and reconciliation report.

Under the revised requirement, representatives and their supervisory personnel may conduct the inventory and reconciliation functions and prepare inventory records and reconciliation reports. However, the agency expects that appropriate internal control measures will be taken that include implementation of a security and audit system that is controlled by independent personnel, i.e., personnel other than the representatives, their superiors or managers, or others in their direct line of supervision or command. Under revised § 203.34(b), such a security and audit system must follow a plan that ensures that random audits are conducted on representatives by personnel independent of the sales force. In addition, the plan must ensure that for-cause audits are initiated in response to reports, incidents, or findings identified by the firm as indicating possible drug sample diversion or falsification of sample distribution records. If necessary, the agency will issue additional guidance on audit plans and procedures under revised § 203.34(b).

35. Two comments stated that the word “apparent” should be changed to “significant.” One comment stated that since manufacturers are permitted, under § 203.37, to determine what constitutes a “significant loss,” they should also be allowed to determine which discrepancies merit investigation. Another comment recommended revising “apparent discrepancy” to read “potentially significant discrepancy.”

The agency is not requiring manufacturers and distributors to conduct an investigation every time there is an apparent discrepancy in a representative’s inventory, but rather that they evaluate all apparent discrepancies. It is only when an apparent discrepancy cannot be justified that an investigation is required. Investigations under these circumstances are reasonable and consistent with the requirement in revised § 203.37(a) to investigate when there is a reason to believe that any person has falsified drug sample records or is diverting drug samples.

Accordingly, the agency declines to amend the requirement.

3. Issues Related to Sample Distribution by Mail or Common Carrier or by a Representative or Detailer

a. Sections 203.30(a)(1) and 203.31(a)(1). Proposed §§ 203.30(a)(1) and 203.31(a)(1) required that a licensed practitioner execute and submit a written request to the manufacturer or authorized distributor of record to obtain drug samples. Proposed §§ 203.30(a)(1) and 203.31(a)(1) are permissible. However, they must contain all information required by PDMA and the final regulations, and must be signed by a licensed practitioner.

b. Sections 203.30(a)(3) and 203.31(a)(3). Proposed § 203.30(a)(3) required that the recipient of a drug sample delivered by mail or common carrier return the receipt to the manufacturer or distributor from which the drug sample was received. Proposed §
§ 203.31(a)(3) required that the receipt for samples distributed by means other than mail or common carrier be returned to the manufacturer or distributor.

38. Two comments requested clarification on whether, if a licensed practitioner fails to return a receipt, he or she is barred from receiving further samples from a manufacturer. Both comments argued that the intent of Congress in enacting PDMA was to detect patterns of nonreturns of receipts. The comments recommended that licensed practitioners should not be barred for isolated failures to return receipts, but rather, where a pattern of nonreturns exists, manufacturers should be required to investigate to see if the samples actually arrived.

The question of whether a licensed practitioner should be barred from receiving further drug samples for failing to return drug sample receipts was not addressed in the proposed rule, and was not addressed directly by Congress. In the legislative history of PDMA (see H. Rept. 100-76, p. 15), Congress stated: “Whether the distributions are made by carrier return receipt or business reply cards, manufacturers or distributors would not be expected to equate each and every delivery and receipt; however, an adequate monitoring system would necessarily need to detect instances where non-return patterns exist.” Thus, there is evidence that Congress was not primarily concerned with isolated failures to return drug sample receipts, but with patterns of nonreturns. Moreover, the overall structure of PDMA is not intended to penalize practitioners or prevent them from receiving samples, but rather to ensure that samples are properly distributed to licensed practitioners. Therefore, the agency believes that Congress did not intend for licensed practitioners to be barred from receiving samples for isolated failures to return sample receipts or for isolated instances where receipts are not received for reasons beyond the practitioner’s control. However, upon detecting a pattern of nonreturns by a practitioner, a manufacturer or authorized distributor should not distribute further samples until the matter is thoroughly investigated. Such an investigation may, depending on the circumstances, be required under § 203.37, since a pattern of nonreturns may indicate that a representative is falsifying drug sample requests, that other drug diversion activity is occurring, or that a significant loss or theft of drug samples has occurred.

c. Sections 203.30(b)(1)(i) and 203.31(b)(1)(ii). Proposed § 203.30(b)(1) and (b)(1)(ii) stated: “A written request for a drug sample to be delivered by mail or common carrier to a licensed practitioner is required to contain the following: * * * The practitioner’s State license number or Drug Enforcement Administration identification number.” Proposed § 203.31(b)(1) and (b)(1)(ii) set out the same requirement for requests for drug samples delivered by means other than mail or common carrier.

39. FDA received 15 comments on these requirements. Many of the comments supported the overall goal of these sections, i.e., to ensure that persons requesting drug samples are licensed practitioners. However, several comments stated that State license numbers are not always assigned to practitioners who are otherwise authorized by State law to prescribe drugs. The comments requested clarification as to what verification is appropriate for practitioners subject to different authorization mechanisms than physicians.

As was discussed in response to the comments on the definition of licensed practitioner, the agency has determined that practitioners authorized by State law to prescribe drugs may request and receive drug samples. Practitioners who are authorized by a State to prescribe drugs and have no State license number may use any number assigned to them by the State that represents that they are authorized to prescribe drugs. The agency is any State that does not assign some type of number to practitioners that it authorizes to prescribe drugs. However, if such a case arises, the agency will consider how to provide verification at that time.

40. Several comments cited potential problems with the use of DEA numbers for verification. Several comments said that not all licensed practitioners, but only those who prescribe controlled substances, are issued Drug Enforcement Administration (DEA) numbers. Other comments stated that, although DEA numbers can be accessed through a central data base, this practice is discouraged by DEA unless a controlled substance is involved. One comment stated that DEA numbers are often improperly accessed and illegally used to divert drugs and recommended that only State license numbers be used. The agency has consulted with the DEA on the appropriate use of DEA numbers for identification purposes. DEA policy is that registration numbers assigned to practitioners are to be used only to obtain scheduled drug products, not for general identification purposes. Accordingly, the agency has modified the requirement in the final rule to specify that State license or authorization numbers are to be used on sample request forms generally, and DEA numbers are to be used only when a sample of a scheduled drug product is requested.

41. Several comments asked for clarification on whether a manufacturer or authorized distributor would be required under this section to verify the State licensing or DEA number on the request form. One comment stated that the provision of a State license or DEA number, without verification, would not confirm that a practitioner is in fact licensed. Other comments opposed requiring the manufacturer or authorized distributor to verify the State licensing or DEA number. One comment recommended that the presence of the number on a sample request form be deemed acceptable on its face. Two comments recommended that instead of requiring the manufacturer to verify whether the requesting person is a licensed practitioner, the person requesting samples could be required to attest to being a licensed practitioner on the sample request form, i.e., with the inclusion of a preprinted line next to where his or her signature would go. Three comments recommended that an internal number established by the manufacturer after checking a requesting practitioner’s credentials be considered acceptable.

FDA has determined that verification by a manufacturer or authorized distributor of the State license or authorization number, or the DEA number as appropriate, is necessary and has codified the requirement in §§ 203.30(a)(2) and 203.31(a)(2) of the final rule. The agency does not believe that allowing a manufacturer to deem acceptable the number on a request form without verifying its authenticity would offer any assurance that a person requesting samples is in fact licensed or authorized to prescribe drugs. Similarly, an attesting signature on a request form offers little more assurance that a person is in fact licensed or authorized than an unverified license or authorization number. The agency does believe there is merit in the suggestion that, once a practitioner’s number is verified by a manufacturer or distributor with a State licensing board or the DEA, an internal number or other tracking system may be devised such that the number does not have to be reverified every time a sample is requested by the same practitioner. However, any list of verified State license or authorization numbers maintained by an authorized
distributor or manufacturer must be updated at least annually to reflect changes in license or DEA status.

42. Several comments stated that it would be difficult for manufacturers to verify State license numbers because there is no national database that contains all State licensing numbers. State licensing boards do not possess mechanisms to provide wide-scale verification services, and methods of verification vary from State to State.

As discussed in section IV.B of this document, the agency believes that cost-efficient systems for verifying State licensing numbers will be made available to manufacturers and authorized distributors of record in the near future. Until that time, State licensing boards do possess sufficient mechanisms to provide verification that individuals are licensed by them. The agency recognizes that there may be some difficulty associated with verifying State license or authorization numbers. However, State licensing numbers are the only reliable way of proving that a practitioner is actually licensed by a State to prescribe drugs.

43. One comment recommended that FDA require States to adopt uniform methods of assigning licensing numbers.

The power to set prescribing requirements and methods is one that has traditionally been vested in the States. The agency does not wish to interfere with this power by requiring that States adopt uniform methods of assigning State licensing numbers.

44. Several comments recommended that FDA add the American Medical Association’s Medical Education (ME) number to the list of permissible verification numbers. The comments stated that the advantages of this number are that it is centrally accessible, it is not subject to change as State license numbers may be, and it includes at least some nonphysician practitioners. Two comments also recommended that use of the Association of Physician’s Assistants file number be permissible.

The agency has concluded that where a practitioner has a State license number, that number must be used for verification purposes. As discussed above, nonphysician practitioners who are licensed, or who are not licensed but are authorized by State law to prescribe drugs, may use any number assigned to them by the State that represents that they are authorized to prescribe drugs. The agency does not believe that other types of identification, including numbers assigned to health professionals in military service with membership in professional associations, are reliable means of proving that a practitioner is licensed or authorized to prescribe drugs.

d. Sections 203.30(b)(1)(iii) and 203.31(b)(1)(iii). Proposed §§ 203.30(b)(1)(iii) and 203.31(b)(1)(iii) required that the proprietary or established name and strength of the drug sample requested appear on the sample request form.

45. Two comments requested that the proposed sections be revised to allow bar coding on the request form that represents the name and strength of the drug sample. Both comments indicated that bar coding would be translated into words on the form so that the doctor would know what he or she was requesting.

The agency has no objections to allowing bar coding representing information on preprinted sample request forms where that information is also translated into words on the form. However, the bar coding must not cover up or otherwise detract from the ability of practitioners to read the words on the form.

e. Sections 203.30(b)(1)(v) and 203.31(b)(1)(v). Proposed §§ 203.30(b)(1) and 203.31(b)(1) set forth the requirements for contents of written request forms for delivery of samples by mail or common carrier and by representative, respectively. Proposed §§ 203.30(b)(1)(v) and 203.31(b)(1)(v), which are identical, required that the request form contain “the name of the manufacturer and the authorized distributor of record, if the drug sample is requested from an authorized distributor of record.”

46. FDA received four comments on these sections. One comment objected to the requirement in § 203.31(b)(1)(v) that the names both of the manufacturer and of the distributor be included on the request form. The comment stated that this requirement is redundant since the manufacturer and authorized distributor of record are responsible for knowing each other, and if a diverted sample is found, the manufacturer will be able to trace the sample to the authorized distributor. Three comments objected to the requirement in both §§ 203.30(b)(1)(v) and 203.31(b)(1)(v). These comments stated that requiring the names both of the manufacturer and of the authorized distributor of record causes additional recordkeeping burdens, serves no useful purpose, and is contrary to the explicit language of section 503(d)(3)(A) of the act.

A distributor may distribute drug samples under section 503 of the act only if it is an authorized distributor of record under section 503(b). Since practitioners and authorized distributors should be free to use other types of records to accomplish its relationship with the manufacturer, the agency believes that it is reasonable to require that a sample request form for an authorized distributor of record include the name of the manufacturer that authorizes the distributor to distribute the samples. The requirement will help ensure that the parties involved in and responsible for sample distribution can be readily identified by FDA and other government agencies. This purpose is consistent with legislative intent to ensure that distributors of drug samples are authorized distributors of record, and the agency therefore adopts the requirement in the final rule.

f. Sections 203.30(c)(1) and (c)(2) and 203.31(c)(1) and (c)(2). Proposed §§ 203.30(c) and 203.31(c) set forth the requirement that drug sample receipts contain, among other things, the lot or control number of the drug sample delivered.

47. FDA received several comments that objected to the sample lot or control number requirement. Several comments argued that, under existing CGMP requirements, the requirement is not necessary because distribution of sample lots is tracked by the manufacturer to the representative, who keeps a record of the practitioners visited and the samples that are distributed. Two comments stated that recording lot numbers on sample receipts is an inefficient way of tracking sample lots to the practitioner level, and that the method of tracking should be left to manufacturers as long as they can provide accurate and timely lot specific records. Other comments argued that lots should only have to be tracked down to the representative level.

The agency believes that the tracking of sample distributions by lot to the level of the licensed practitioner is essential both to maintaining accountability and oversight over sample distribution and to facilitating recalls and, therefore, declines to eliminate the proposed requirements on the ground that samples need only be tracked to the representative level. The agency agrees, however, that recording lot numbers on drug sample receipts and other drug sample distribution records required under part 203 may not be the most efficient method of tracking sample lots and that manufacturers and authorized distributors should be free to use other types of records to accomplish...
this purpose. Accordingly, the agency has eliminated the requirement to include lot or control numbers on drug sample receipts in revised §§ 203.30(c)(1) and (c)(2) and 203.31(c)(1) and (c)(2) and on reconciliation reports in revised § 203.31(d)(2)(iii). Moreover, the requirement under proposed § 203.38(b) to include lot or control numbers on all drug sample distribution records has been substantially revised. Under revised § 203.38(b), manufacturers and authorized distributors of record are required to maintain drug sample distribution records containing lot or control numbers that are sufficient to permit tracking of drug sample units to the point of the licensed practitioner. Sample distribution records containing lot or control numbers must be maintained by manufacturers or authorized distributors whether the samples are distributed by the mail or through representatives.

4. Drug Sample Forms

Proposed § 203.33 stated:

A sample request or receipt form may be delivered by mail, common carrier, or private courier or may be transmitted photographically or electronically (i.e., by telephoto, wirephoto, radiophoto, facsimile transmission (FAX), xerography, or electronic data transfer) or by any other system, provided that the method for transmission meets the security requirements set forth in § 203.60(d).

Due to the publication of part 11, which supersedes portions of proposed § 203.60, the security requirements that apply to paper documents transmitted photographically or electronically, or by any other system have been modified and appear under § 203.60(c) in the final rule. Section 203.33 has been revised to refer to this section.

5. Policies and Procedures

Proposed § 203.34 stated:

Each manufacturer or authorized distributor of record that distributes drug samples shall maintain, and adhere to written policies and procedures describing its administrative systems for the following:

(a) Distributing drug samples by mail or common carrier, including methodology for reconciliation of requests and receipts;
(b) Distributing drug samples by means other than mail or common carrier including the methodology for their independent sample distribution security and audit system;
(c) Conducting its inventory of drug samples under § 203.31(d), including an inventory schedule;
(d) Auditing and detecting falsified or incomplete drug sample records;
(e) Identifying any significant loss of drug samples and notifying FDA of the loss;
(f) Monitoring any loss or theft of drug samples; and
(g) Storing drug samples by representatives.

As discussed in section II.G of this document, the requirements in proposed § 203.34 have been renumbered and revised in the final rule. Comments on the proposal are addressed in light of the revisions.

48. One comment stated that PDMA only requires manufacturers to develop adequate audit and security systems to detect and investigate losses and thefts, not to create and adhere to extensive written policies documenting all aspects of the drug sampling process. The comment stated that a manufacturer should not be subject to liability for failure to have a written corporate-wide policy on the subject matter covered by the proposed rule.

The agency believes that the creation of internal policies by a manufacturer or authorized distributor of record to achieve the statutory objectives is important to the attainment of those objectives. PDMA sets forth requirements that manufacturers and authorized distributors of record report significant losses and thefts of samples, that manufacturers’ and authorized distributors’ representatives be inventoried at least annually, and that drug samples be subject to proper storage conditions. In addition, PDMA’s legislative history indicates that Congress intended that manufacturers and authorized distributors have audit and security systems in place to detect losses and thefts, as well as falsified or incomplete drug sample records. (H. Rept. 100–76, p. 20, S. Rept. 100–202, p. 9.) Accordingly, the agency believes that it is authorized to implement specific requirements regarding procedures and systems to accomplish these legislative objectives. However, the agency believes that industry should have the flexibility to develop its own procedures and systems, as long as such procedures and systems are documented and followed.

49. One comment stated that, under PDMA, a manufacturer is already liable for failing to identify and report losses, thefts, or falsification of records, whether it has written policies or not. Thus, according to the comment, written procedures are not necessary to ensure that significant losses of samples are detected.

Section 301(t) of the act subjects manufacturers and authorized distributors to civil and criminal penalties for failure to report significant losses and thefts as required under section 503(d)(3)(C) of the act. While the agency recognizes that this provision provides incentive for a manufacturer or authorized distributor to identify and investigate potential cases of diversion, it does not ensure that effective written procedures and administrative systems are in place to do so.

50. Another comment requested that the requirement in proposed § 203.34(c) for an inventory schedule be flexible so that a procedure committing to conduct a field force inventory at least yearly would be sufficient.

Administrative procedures adopted by manufacturers and authorized distributors of record must be adequate to ensure compliance with PDMA and agency requirements. With respect to the requirement in revised § 203.34(b)(2) for written policies and procedures describing administrative systems for conducting the annual physical inventory, the administrative procedures must ensure that all representatives are inventoried at least once a year in accordance with the requirements of § 203.31(d) and section 503(d)(3)(C) of the act.

6. Use of Third Parties

a. Section 203.36(a). Proposed § 203.36(a) stated:

Any manufacturer or authorized distributor of record that uses a fulfillment house, shipping or mailing service, or other third party, or engages in a co-marketing agreement with another manufacturer or distributor to distribute drug samples or to meet any of the requirements of PDMA, PDA, or this part, remains responsible for creating and maintaining all requests, receipts, forms, reports, and records required under PDMA, PDA, and this part.

51. One comment supported the section as written. Several comments requested clarification on whether the manufacturer or authorized distributor must itself create and maintain forms and records or ensure proper compliance by the third party. Several comments objected to the former interpretation on the ground that it would require so much involvement by the manufacturer or authorized distributor in the day-to-day operations of the third party that it would effectively preclude companies from using third parties.

The agency clarifies that a manufacturer or authorized distributor of record that uses a third party to distribute drug samples or meet any requirements of PDMA or the final rule may have the third party create and maintain required requests, receipts, forms, reports, and records. For example, a shipping company that delivers samples would be permitted to use its own delivery verification receipts and to maintain those receipts for the manufacturer or authorized distributor. However, the manufacturer or authorized distributor is responsible...
for ensuring that the third party complies with all requirements under PDMA and the final rule. In the previous example, if all of the information required in § 203.30 is not contained on the shipping company’s receipt, the manufacturer or authorized distributor is responsible for compliance, and thus liable for noncompliance, with § 203.30.

Additionally, the agency is aware that some drug manufacturers contract with an “outside” promotional sales force rather than maintaining an “in-house” one. These representatives, known in the industry as “contract representatives,” qualify as third parties under this section. Since contract representatives may be paid according to the number of samples distributed, firms using their services should be particularly vigilant concerning the possibilities for sample diversion and sample request and receipt form falsification.

52. One comment requested clarification as to whether, if a manufacturer enters into a comarketing agreement with another manufacturer for the distribution of samples by its representatives, the comarketer would thereby become an authorized distributor of record and would thus be responsible for creating and maintaining its own reports, forms, and records. Another comment contended that comarketers could qualify as manufacturers or authorized distributors of record and recommended that the final rule be revised to make comarketers who are themselves manufacturers or authorized distributors responsible as such for compliance with PDMA.

As the agency explained under the comments on the definition of “ongoing relationship,” a comarketer, sample fulfillment house, or other entity that performs sample distribution functions other than delivery or functions that are incidental to delivery is engaged in “distribution” of drug samples and must, under section 503(d) of the act, be an authorized distributor of record. Authorized distributors of record are responsible for complying with all requirements for sample distribution under PDMA and the final rule, including creating and maintaining all required requests, receipts, forms, reports, and records. Thus, if a manufacturer or authorized distributor contracts with a third party which itself becomes an authorized distributor of record, the manufacturer or authorized distributor and the third party are both responsible for compliance with PDMA requirements.

b. Section 203.36(b). Proposed § 203.36(b) stated that a manufacturer or authorized distributor of record that contracts with a third party to maintain some or all of its records shall produce required documents within 48 hours of a request by an authorized representative.

53. Several comments stated that 48 hours is not enough time to produce required documents. Three comments recommended that the section be revised to allow 5 working days for production of records. One comment stated that a manufacturer should be excused from penalty when requested information in the storage of a third party is not produced within 48 hours by reason of “unanticipated events beyond the reasonable control of either the drug manufacturer or the contractor (i.e., a force majeure defense).” The comment stated that, at a minimum, the section should be amended to provide 48 business hours to comply.

In response to the comments, the agency has revised proposed § 203.36(b) to require the production of records maintained by a third party within 2 business days of a request, rather than 48 hours. The agency believes that this period should be sufficient given the fact that most records are maintained electronically and can be quickly and easily retrieved and transmitted to the location where they are requested.

7. Investigation and Notification Requirements

a. Section 203.37(a)(1) and (a)(2). Proposed § 203.37(a)(1) stated:

A manufacturer or authorized distributor of record that has reason to believe that any person has falsified drug sample requests, receipts, or records shall conduct a full and complete investigation, and shall notify FDA, by telephone or in writing, within 5 working days of becoming aware of a falsification and within 5 working days of the completion of an investigation.

Proposed § 203.37(a)(2) stated: “A manufacturer or authorized distributor of record shall provide FDA with a complete written report, including the reason for and the results of the investigation, not later than 30 days after the date of the initial notification.”

The agency, on its own initiative, has reformatted proposed § 203.37(a)(1) and (a)(2) into § 203.37(a)(1), with three subsections. The agency believes that the new format is clearer and easier to understand.

54. FDA received 10 comments on these sections addressing the following issues: (1) The circumstances under which a manufacturer or authorized distributor should be required to investigate, (2) the time period to complete investigation, (3) when and under what circumstances a manufacturer should be required to give notice to FDA, and (4) the form of the notice and reporting requirements.

Two comments addressed the level of suspicion of falsification that is necessary to trigger the investigation requirement. One comment said that the “reason to believe” language that appears in § 203.37(a)(1) creates a standard that is “vague and difficult to interpret.” Another comment stated that “reason to believe needs to be defined so that a manufacturer will not be second guessed.” Another comment stated that the proposed rule does not define what constitutes “falsification,” and that variances in a representative’s reported numbers do not usually give rise to a “reason to believe” that a falsification has occurred, requiring investigation and notice, but rather that a representative has poor work habits. The comment stated that requiring investigation of every variance would be unrealistic.

Instances of potential falsifications are most likely to come to the attention of manufacturers or authorized distributors through discrepancies that are uncovered during the required annual inventory and reconciliation. However, it is possible that other events or occurrences, some foreseeable and some not, may bring potential falsifications to the attention of a manufacturer or distributor. The agency has determined that the reason to believe standard, while not capable of precise definition, is flexible enough to cover the multiplicity of situations in which potential falsification is brought to light. Moreover, the standard is one that can be applied by manufacturers and authorized distributors using common sense and good judgment. While the agency does not expect manufacturers and authorized distributors to investigate every slight discrepancy, the agency would require investigation under this standard where a pattern of discrepancies exists or where other reliable information indicates that records have been falsified.

55. Another comment said that the circumstance that triggers the investigation requirement should be diversion, not falsification. That comment also stated that the investigation requirement should apply only to a manufacturer’s or authorized distributor’s employees’ misconduct, not to any person. The drug sample recordkeeping requirements were instituted to help ensure that drug diversion schemes could be detected. The agency believes that patterns of falsification of drug sample requests, receipts, or records,
while not conclusive, are highly probative that drug sample diversion is taking place. Thus, the agency declines to follow the recommendation that knowledge of diversion precede investigation.

The agency recognizes, however, that circumstances other than record falsification may be indicative that drug sample diversion is occurring. Accordingly, the agency has revised proposed § 203.37(a) to require notification, investigation, and reporting where a manufacturer or authorized distributor of record has reason to believe that any person is diverting prescription drug samples.

Finally, the agency believes that the manufacturer or authorized distributor of record is in the best position to detect potential diversion not only by its own employees, but by other persons, such as contract representatives. Accordingly, the agency has determined that manufacturers and authorized distributors must investigate when they have reason to believe that any person has falsified drug sample records or has diverted drug samples.

56. Two comments stated that PDMA statutory requirements did not make falsification of drug sample records reportable to FDA.

Although PDMA did not expressly make falsification of drug sample records reportable to FDA, the agency has determined that such notice is necessary and furthers the legislative intent in PDMA. Persons who falsify drug sample requests, receipts, or records may be criminally prosecuted under sections 301 and 303 of the act, and under Title 18 of the United States Code. Because FDA is responsible for enforcing PDMA, it is necessary that the agency have all pertinent information regarding such potentially criminal conduct. Moreover, Congress did explicitly make significant losses and known thefts reportable to FDA, presumably because such losses and thefts indicate possible sample diversion activity. (See S. Rept. 100–303, p. 6, H. Rept. 100–76, p. 16.) As discussed previously, the agency believes that falsifications of drug sample records are highly probative that drug diversion is taking place. Thus, the agency has determined that it is consistent with congressional intent that the agency be made aware of such falsifications, as well as other activity that is indicative of drug sample diversion, to enable FDA to monitor compliance with PDMA.

57. One comment noted that statements made in the preamble to the proposal (59 FR 11842 at 11851) conflicted with proposed § 203.37(a)(1).

The comment stated that the proposal’s preamble indicated that notice would be required to be provided to FDA when an investigation is initiated. However, proposed § 203.37(a)(1) does not require notice until “within 5 working days of becoming aware of a falsification.” According to the comment, the notice discussed in the preamble may precede the notice required under the proposed regulation.

The agency acknowledges that the notice discussed in the preamble of the proposal (59 FR 11842 at 11851) is different than the notice that would be required under the proposed regulation. The agency has revised proposed § 203.37(a)(1) and (a)(2) to require that a manufacturer or authorized distributor of record that has reason to believe that any person has falsified drug sample requests, receipts, or records, or is diverting drug samples must notify FDA within 5 working days, immediately initiate an investigation, and submit a written report to FDA within 30 days after the date of the initial notification. Thus, the requirement in proposed § 203.37(a)(1) that a manufacturer or distributor notify FDA within 5 working days of becoming aware of a falsification and within 5 working days of the completion of an investigation has been eliminated. The agency believes that the provision of a single notice to FDA near the time when an investigation is initiated is sufficient.

58. One comment said that firms should be required to provide notice to FDA only in “situations where substantial evidence of apparent attempts to conceal diversion of samples exists.” Another comment stated that notice should not be required until a “strong probability” of falsification is indicated by an investigation. Several comments stated that, except for a final written report submitted at the completion of an investigation revealing that falsification has in fact occurred, no notice should be required. One of these comments stated that it would be “improper and unfair” to implicate employees in falsification before all of the facts are known and an informed judgment can be made with respect to responsibility. One comment recommended that a written report should be made available, but not automatically submitted, to FDA.

The agency believes that the manufacturer or authorized distributor, through its own investigation, is in the best position to determine whether falsification has occurred. However, for enforcement purposes, it is necessary that FDA be notified when there is reason to believe that there has been a falsification to ensure that an investigation is actually undertaken. Moreover, the provision of notice to FDA at the initiation of an investigation will establish a point from which to judge whether the investigation is completed in a timely manner. Thus, the agency disagrees with the recommendation that notice should not be provided to FDA until an investigation is completed and a strong probability of records falsification exists or until records falsification is confirmed. In addition, submission of a final written report to FDA stating the results of an investigation is necessary, even where falsification has not been found, to permit FDA to determine whether the circumstances were adequately investigated and explained.

59. One comment stated that reports of some complex cases could require more than 30 days to complete and requested that the proposed rule be revised to allow for 30 days, except in “unusual circumstances.” Another comment recommended allowing completion of the investigation within a “reasonable time,” while another recommended that there should be no time restriction for the submission of a final report.

The final rule as revised gives manufacturers 30 days to complete an investigation of possible falsification and to submit a written report. The agency believes that this amount of time is more than adequate in all but the most complex cases. In such cases, a preliminary report may be submitted describing the investigative measures taken, a summary of the findings of the investigation up to that point, the nature of the ongoing investigation, and the reasons the investigation was not completed within the required time.

b. Section 203.37(b)(1) and (b)(2). Proposed § 203.37(b)(1) stated:

A manufacturer or authorized distributor of record that distributes drug samples or a charitable institution that receives donated drug samples from a licensed practitioner shall notify FDA, by telephone or in writing, within 5 working days of becoming aware of any significant loss or known theft of drug samples and within 5 working days of the completion of an investigation into a report of a significant loss or known theft.

Proposed § 203.37(b)(2) stated: “A manufacturer or authorized distributor of record shall provide FDA with a complete written report not later than 30 days after the date of the initial notification.”

On its own initiative, the agency has reformatted and revised these sections into a single section, § 203.37(b)(1), with three subsections. The revised section eliminates the requirement in proposed § 203.37(b)(1) for notice to be given to
the agency within 5 days of the completion of an investigation of significant loss or known theft, but otherwise retains and clarifies the requirements in proposed § 203.37(b)(1) and (b)(2).

60. Two comments recommended revision of proposed § 203.37(b)(1) to extend the time a manufacturer or authorized distributor has to notify FDA after becoming aware of a significant loss or theft, with no notification required if subsequent investigation reveals no loss or theft. One of the comments said that it would not be possible to differentiate insignificant accounting mistakes and actual losses within 5 days of learning of an inventory discrepancy and that the requirement would cause too many false alarms.

Unlike falsifications of drug sample records, the agency requires notice of significant losses and known thefts only when a manufacturer or authorized distributor “becomes aware” of such losses or thefts. Thus, the level of certainty under which notice and investigation are required is higher for losses and thefts than it is for falsifications. Consequently, a manufacturer or authorized distributor should have already differentiated insignificant accounting mistakes and actual losses before notice is given to FDA. Thus, the agency believes that 5 working days from the time that a manufacturer or authorized distributor becomes aware of losses or thefts is sufficient to provide notice to FDA of losses or thefts.

61. Two comments recommended allowing 45 days after becoming aware of significant losses during shipment before notice is required, because such apparent losses of drug samples often show up during that time period.

The agency declines to follow the recommendation of the comments. Potential significant losses that occur during shipping must be investigated and reported like other significant losses. When samples thought to be lost or stolen during shipping are later found, a followup report should be made to the agency describing the circumstances of the recovery and the quantity of samples that were recovered.

62. In the preamble to the proposed rule (59 FR 11842 at 11851), the agency stated: “The reporting of any significant loss of drug samples is critical to the success of diversion control.” * * * * FDA intends this requirement to mean that the agency is to be advised of actual, physical losses, but not insignificant accounting mistakes. FDA stated that it was aware of the difficulty of establishing a threshold for significant loss and solicited comment on how to distinguish between significant losses and minor accounting or inventory errors. The agency did not propose to establish a tolerance level for sample losses below which no report is required, and stated that each manufacturer or distributor is required to establish its own threshold for determining when inventory not accounted for is significant.

One comment stated that losses may occur in several ways, including losses of shipments in transit, loss by representatives, and unexplained inventory discrepancies. The comment stated that, for shipping losses, it may be appropriate for companies to set a dollar amount above which a single loss is considered significant. This amount would vary by company and would be dependent on the size of the company, number of representatives, and size and value of its total inventory. The comment suggested that shipping losses should also be viewed cumulatively over a fixed, rolling period to determine if there is a pattern of losses that might indicate diversion. Regarding unexplained inventory shortages, the comment stated that each company should be required to establish its own threshold for determining when inventory not accounted for is significant. Inventory discrepancies that can be shown to be caused by math or accounting errors or mistakes that can be reconciled should not be reported. The comment suggested that there are three significant loss scenarios that may indicate possible diversion: (1) A single loss that exceeds a company’s predefined threshold; (2) the number of loss events over a fixed, rolling period exceeds the company’s threshold; or (3) the volume of losses over a fixed, rolling period exceeds the company’s threshold.

One comment stated that loss of a certain quantity of one drug sample with a high potential for diversion may be significant, while the loss of the same quantity of another sample with a low potential for diversion may not be significant. Therefore, the comment asserted, no universally applicable threshold can be established and a case-by-case analysis must be employed.

One comment requested that FDA clarify that not all physical losses are significant.

The agency agrees with the first comment that different methods for determining whether a loss is significant may be used depending on the type of loss involved. For single loss events (i.e., “physical” losses) including losses by representatives (except for losses reported as thefts, which must all be reported and investigated) and losses of drug samples in transit, establishing a predefined threshold based on a set dollar amount or other criteria, such as a fixed number of sample units, may be appropriate. The size of the manufacturer or authorized distributor of record, the number of representatives, and size and value of a firm’s total inventory, as well as a firm’s past experience with sample losses, are relevant factors in determining the level of the threshold. However, the agency also agrees with the second comment that firms should remain responsive to the individual circumstances surrounding a single loss event, such as the loss of a drug with a particularly high potential for diversion, to determine whether a loss is significant even though the size of the loss does not meet the firm’s predefined threshold.

Regarding potentially significant losses that are revealed through unexplained inventory shortages, the agency stated in the preamble to the proposed rule that it does not seek to receive reports concerning minor mathematical errors that are caught and corrected in the normal course of business. The agency stated that firms are required to establish their own threshold for distinguishing between insignificant accounting mistakes and significant losses in inventory shortages based on the firm’s past experience in sample distribution and inventory and the level of accuracy of its internal audit and security system. The agency also stated that some manufacturers or distributors might be able to set a “historically validated statistical baseline” for minimal amounts of inventory shrinkage caused by routine accounting errors, mistakes, or losses, and a statistical baseline for the frequency of occurrences (59 FR 11842 at 11851). The views expressed by the second comment regarding discerning significant losses from inventory shortages thus appear to be consistent with those previously set forth by the agency.

63. One comment supported permitting manufacturers and distributors to establish their own thresholds for determining when inventory not accounted for is significant, but said that it was concerned about being second-guessed by the agency in determining what constitutes a significant loss. The comment recommended that FDA clarify within proposed § 203.37 that it would not challenge a manufacturer for following its own definition of significant loss.

The agency declines to revise the proposal to state that it will not...
challenge a manufacturer for following its own definition of significant loss. However, the agency advises that a firm can best ensure that no enforcement action will be taken against it for violation of §203.37(b) where it establishes a system for reporting and investigating significant losses that is consistent with the guidance provided in this notice and in the proposed rule. Additionally, where a manufacturer or distributor is unsure about whether a loss is significant, it should report and investigate the loss as if it were significant.

64. One comment stated that FDA should not give manufacturers or distributors any discretion to define what constitutes significant loss, but rather should define it for them.

As explained previously and in the proposal (59 FR 11842 at 11851), the threshold level of what constitutes a significant loss will necessarily vary depending on such factors as the size of a company and the value of its total inventory, the accuracy of a manufacturer’s or distributor’s system for tracking sample distribution, and the circumstances surrounding the loss. Thus, the agency declines to codify a definition of significant loss.

65. One comment expressed concern that virtually all losses would have to be reported under the significant loss standard as described by the agency in the proposal and recommended that significant loss be defined as a percentage of total sales or supplies.

The agency believes that it has provided sufficient guidance in the proposed rule and in this notice about how to distinguish between routine losses and significant losses that need to be reported and investigated. Thus, the agency disagrees that all or virtually all losses will have to be reported and investigated and declines to set a threshold based on percentage of total sales or supplies above which a loss will be considered significant.

c. Section 203.37(d). Proposed

§203.37(d) stated: “* * * A manufacturer or authorized distributor of record that distributes drug samples shall inform FDA in writing within 30 days of selecting the individual responsible for responding to a request for information about drug samples of that individual’s name, business address, and telephone number.”

66. One comment sought clarification on whether the information required by this section is “for a regulatory agency and PDMA information or information for a potential customer-doctor or patient.”

FDA clarifies that the information required by this section is to facilitate requests for drug sample information by FDA and Federal, State, and local regulatory and law enforcement officials.

8. Sample Lot or Control Numbers; Labeling of Sample Units

a. Section 203.38(a). Proposed

§203.38(a) stated: “The manufacturer or authorized distributor of record of a drug sample shall include in the labeling of the drug sample and the label of the sample unit an identifying lot or control number that will permit the tracking of the distribution of each drug sample unit.”

67. Two comments stated that the statement “identifying lot or control number that will permit the tracking of the distribution of each drug sample unit” could be interpreted to mean that each drug sample unit would require its own identifying number. The comments requested that the agency clarify that tracking is required only of lots, not of sample units.

FDA clarifies that the section is intended to require only the tracking of sample units by the lot from which they came, and does not require that each sample unit receive its own identifying number.

68. Several comments requested clarification on whether the lot or control number is required to appear only on the external packaging of sample units or on all labeling as defined in 21 CFR part 201, including inserts and circulars. Several comments objected to the latter interpretation on the grounds that such a requirement would be costly and would not aid in the prevention of drug diversion. One comment, for example, stated that package inserts would probably be discarded by individuals engaged in diversion. Several comments stated that inserts are currently not lot-specific and that customizing inserts to lots would be extremely expensive. One comment stated that requiring lot numbers on package inserts would not benefit recall procedures.

The section as proposed would require lot or control numbers to appear on both sample unit labels and on other drug sample labeling. Inserts and circulars are labeling as defined in section 201(m) of the act. However, the agency agrees with the comments that requiring lot or control numbers to appear on package inserts, circulars, or similar labeling is not necessary. The section has been revised to require that the lot or control number appear only on the label of the sample unit itself, and on the outside container or packaging of the sample unit, if any, in accordance with section 201(k) of the act.

b. Section 203.38(c). Proposed

§203.38(c) stated, in relevant part, that “each sample unit shall bear a label that clearly denotes its status as a drug sample, e.g., ‘sample,’ ‘not for sale,’ ‘professional courtesy package.’”

In the preamble to the proposed rule (59 FR 11842 at 11855), the agency identified “starter packs” as prescription drug products distributed without charge by manufacturers or distributors to pharmacists with the intent that pharmacists place the drugs in stock and sell them at retail. The agency stated that starter packs are intended for sale and therefore do not meet the statutory definition of a drug sample. Since the publication of the proposed regulations, the agency has become aware of the use of the terms “starter,” “starter samples,” and “patient starter pack” to refer to drug sample units. Because the agency does not consider starter packs (as described previously) to be drug samples, the use of the term “starter” on drug sample labeling is inappropriate and should not be used.

69. One comment stated that the proposed requirement goes beyond the intent of Congress in PDMA and it would not deter diversion because the contents may be removed from the drug package.

Designating a sample unit as a sample is the only way to distinguish drug products manufactured for sale from drug samples. Because Congress prohibited the sale, purchase, or trade of drug samples, or the distribution of samples in a manner that is inconsistent with section 503 of the act, the requirement clearly is consistent with and furthers legislative intent. Although the requirement does not provide a foolproof method of preventing diversion, the requirement will help deter sample diversion by denying diverters a market-ready product.

70. One comment recommended, as an alternative to isolating a manufacturing run of labels, that manufacturers be permitted to use adhesive stickers that could be placed on the outside containers of sample units otherwise labeled for retail.

The agency will not object to the use of stickers provided that a sticker is applied to both the label of the sample unit and the outside container or packaging of the sample unit, if any, in accordance with §203.38(a). However, to avoid giving diverters a market-ready product, any sticker should be difficult to remove and their removal should be evident. The agency recommends more
durable methods of identifying a sample product, such as overprinting.

71. Several comments opposed the requirement in proposed § 203.38(c) on the grounds that it would entail too much expense. It is the agency’s experience that the packaging of sample units currently used by the majority of manufacturers already identifies the units as samples through the use of terminology such as “not for sale” or “professional use only.” Such wording meets the intent of this section. Moreover, as discussed under the previous comment, manufacturers may place an adhesive sticker on the label of a retail unit and on the outside container or package of the unit, if any, designating the retail unit as a sample. Therefore, the agency is unconvinced that this requirement would impose a financial hardship on the majority of manufacturers.

72. One comment objected to the proposed rule as it relates to the distribution of radiopharmaceutical samples. The comment stated that prohibiting manufacturers from supplying radiopharmaceutical samples in retail packages would be unduly burdensome because of the small numbers of such samples that are distributed. The comment recommended that radiopharmaceuticals be exempt from the requirement.

As discussed previously, manufacturers may place an adhesive sticker on the label of a retail unit and on the outside container or package of the unit, if any, designating it as a sample. The agency believes that this is sufficient to address the concerns raised by the comment and declines to create the requested exemption.

73. One comment stated that the increased costs associated with the labeling requirement would affect the ability of manufacturers to provide drugs free of charge to indigent patients. As discussed in the proposal (59 FR 11842 at 11855), there are some circumstances in which prescription drugs that are provided free of charge will not be considered samples under section 503(c)(1) of the act and § 203.3(i). The example given was of prescription drugs provided at no charge to licensed practitioners for the treatment of indigent patients where the main object is to ensure that patients in need of prescription drugs have access to them (whatever their financial circumstances) and not to promote the drugs. According to information available to the agency, these manufacturer-sponsored indigent patient programs generally include appropriate controls, documentation, and verification of the distribution and use of these products. Therefore, such drugs would ordinarily not be required to be labeled in accordance with § 203.38(c). Moreover, even where drugs are distributed for a promotional purpose and § 203.38(c) applies, the agency does not believe, for the reasons discussed in response to comment 71, that the labeling requirement will impose a financial burden large enough to affect the ability of manufacturers to provide drugs free of charge to indigent patients.

74. One comment requested a 3-month grace period after the effective date of the regulations in which nonlabeled sample units already in the possession of manufacturers could be used. As discussed in section II.K of this document, the agency has determined that the provisions in the final rule will not become effective until 1 year after the date of publication of the final rule in the Federal Register. Thus, the agency believes that manufacturers and authorized distributors will have ample time from the publication of the final rule to its effective date to come into compliance.

75. One comment recommended that the proposed regulation be rewritten to require that a drug sample label include the terms “sample” or “professional sample” and to allow, in addition to these terms, such terms as “not for sale” or “professional courtesy package.” The wording used in proposed § 203.38(c) was intended to be illustrative only. Any wording that clearly designate a sample unit as a sample may be used. As discussed previously, the term “starter” does not designate a sample unit as a sample, and should not be used.

9. Retail Pharmacies and Drug Samples

In the preamble to the proposal (59 FR 11842 at 11853), the agency explained that by limiting the distribution of samples to licensed practitioners and to hospitals or health care entity pharmacies at the request of a licensed practitioner, but not to retail pharmacies, Congress clearly expressed its intent not to allow the distribution of samples to retail pharmacies. Under proposed § 203.40, the presence in a retail pharmacy of any drug sample would have been considered evidence that the drug sample was obtained by the retail pharmacy in violation of section 503(c)(1) of the act.

76. One comment opposed proposed § 203.40, stating that “there is no statutory or evidentiary basis for creating this presumption.” The comment also stated that FDA, as a Federal agency, lacks the authority to shift the burden of proof in an enforcement proceeding.

The agency has decided to withdraw proposed § 203.40 from the final rule. However, the agency continues to interpret the act to prohibit the distribution of drug samples by a manufacturer or distributor to a retail pharmacy and the receipt of a drug sample by a retail pharmacy from any person. Moreover, the agency believes that the presence of drug samples in a retail pharmacy is probative that samples are being sold, purchased, traded, or distributed in violation of the act. Therefore, the agency may investigate the presence of drug samples in a retail pharmacy to determine if other violations warranting enforcement action exist.

77. Three comments objected to the prohibition on the distribution of drug samples to or the receipt of drug samples by retail pharmacies. Two comments stated that the prohibition would prevent pharmacists from providing drug counseling to patients. One comment stated that counseling is important because physicians are not accustomed to counseling patients to whom they give drugs. Another comment asserted that pharmacist-patient counseling improves compliance with drug therapy and reduces overall health care costs. Two comments stated that retail pharmacies should be allowed to store and dispense samples at the direction of a physician because pharmacies are designed for drug storage and physicians’ offices are not.

The agency recognizes that proper storage and handling of prescription drugs and adequate counseling in connection with prescription drug use are important concerns. However, the agency believes that both of these goals can and must be accomplished within the system of sample distribution established by Congress in PDMA. As discussed previously, under this system, drug samples may not be distributed to retail pharmacies and retail pharmacies may not receive such samples.

78. One comment objected to the fact that physicians are not permitted to give samples to or to request that samples be sent to a retail pharmacy, although they are expressly permitted to request that samples be sent to hospital or health care entity pharmacies. The comment argued that, except in two States, all pharmacists receive the same type of license regardless of practice setting. The comment also stated that all pharmacists, regardless of practice setting, independently dispense drugs to patients in accordance with a written prescription. The comment
recommended either that all types of pharmacies should be permitted to receive samples at the direction of a licensed practitioner or none should be permitted.

The agency declines to follow the recommendation of the comment. PDMA expressly provided that hospital or health care entity pharmacies may provide drug samples to patients at the direction of a licensed practitioner. Moreover, PDMA provided that manufacturers and authorized distributors of record may distribute drug samples to hospital or health care entity pharmacies at the request of a licensed practitioner. Thus, Congress clearly expressed its intent to allow hospital or health care entity pharmacies to receive and dispense drug samples. No such intent is evident with respect to retail pharmacies.

79. One comment stated that not permitting retail pharmacies to store and to dispense samples at the direction of a physician is inconsistent with agency positions expressed in the preamble to the proposal, allowing distribution of prescription drugs through retail pharmacies to indigent patients.

The proposal (59 FR 11842 at 11855) did not address dispensing prescription drugs to indigent patients through retail pharmacies. It discussed the circumstances whereby manufacturers make arrangements to provide prescription drugs to licensed practitioners to prescribe and dispense at no cost or at reduced cost to indigent patients of those practitioners. As previously stated, such drugs will ordinarily not be considered samples. Therefore, a licensed practitioner may direct such drugs to be distributed to and dispensed by a retail pharmacy.

10. Permissible Uses of Drug Samples by Licensed Practitioners

In the preamble to the proposal (59 FR 11842 at 11852), the agency described the permissible uses of drug samples by licensed practitioners by stating:

FDA advises that PDMA and this proposed rule would permit a licensed practitioner to:

(1) Dispense the drug sample as set forth in section 503(d)(1) of the act; (2) donate the drug sample to a charitable institution as provided for in proposed § 203.39; (3) return the drug sample to the manufacturer or distributor; or (4) destroy the drug sample.

80. One comment requested that the proposed rule be revised to permit a licensed practitioner to give drug samples to a requesting manufacturer for stability testing and other quality testing. The comment stated that a manufacturer be allowed to request and retrieve both its own samples and the samples of other manufacturers for this purpose. According to the comment, allowing manufacturers to retrieve samples for testing would further the purposes of PDMA legislation by ensuring that drug samples in the possession of licensed practitioners are safe and effective. The comment stated that, under the proposed rule, there are no regulatory controls on the handling and storage of drugs in the possession of licensed practitioners. The comment stated that by obtaining and analyzing drug samples that have been stored in practitioners’ offices under actual conditions of use, manufacturers will be able to improve packaging design to ensure the stability of drug samples. The comment also stated that allowing manufacturers to obtain and analyze samples “raises minimal, if not nonexistent, risk of samples being diverted into secondary commerce.”

As stated in the proposal, the agency’s policy is to permit licensed practitioners to return drug samples to the manufacturer or distributor from which they were obtained. Although the agency had originally only considered the scenario in which the licensed practitioner would initiate such returns, the agency clarifies that a request by a manufacturer to a practitioner for return of its own samples for stability testing or other analysis would be permissible. The agency does not believe, however, that it is permissible under PDMA for licensed practitioners to distribute drug samples to manufacturers or authorized distributors who did not supply them. The agency believes that such distribution would serve no legitimate purpose and would unnecessarily increase the risk of sample diversion. The agency is not persuaded that manufacturers would expend the time and resources necessary to perform stability and quality testing on other manufacturers’ samples. Moreover, even if such testing were performed, it is unlikely that the results of such testing would be shared with the manufacturer of the sample. Thus, the sample quality would not be improved by licensed manufacturers to retrieve other manufacturers’ samples. Finally, the agency believes that a risk of diversion does exist with such distribution and that the risk is not offset by any appreciable health benefit.

11. Drug Sample Status of Free Distributions

In the preamble to the proposed rule (59 FR 11842 at 11855), the agency stated that because starter packs are intended to be sold, they are not samples and thus the sample distribution requirements do not apply to them. The agency cautioned, however, that because starter packs provide opportunities for diversion similar to those presented by drug samples, manufacturers and distributors should establish and maintain accounting, audit, and security systems for starter packs to guard against diversion.

81. One comment supported the agency’s position on starter packs, stating: “We applaud the FDA for clearing up misunderstandings about the difference between samples and starter packs.” Another comment agreed with the agency’s position, but stated that the cautionary language used by the agency in connection with starter packs implicitly regulates them as samples. The comment recommended that the proposed regulations be revised to include a definition of starter pack indicating that it is not a sample and to allow manufacturers to decide how to monitor the distribution of starter packs. As noted previously, the agency has concluded that starter packs do not meet the statutory definition of a drug sample and thus are not subject to PDMA requirements for sample distribution. This determination is consistent with the definition of “drug sample” in the act and final regulations and need not be codified. The agency also clarifies that manufacturers are not required to follow the agency’s recommendations for monitoring the distribution of starter packs. However, because of the potential for diversion of these products, the agency continues to recommend that their distribution be monitored in a manner designed to prevent and detect diversion.

82. One comment sought clarification of whether specific distributions of prescription drugs to indigent patients through retail pharmacies would constitute a sample or nonsample transaction. In the scenario presented by the comment, the patient would present a prescription and a “prescription drug card” to the retail pharmacist, who would fill the prescription from a stock bottle and be reimbursed for the cost of the drug and patient counseling services through a “pharmacy benefits company.” The comment stated that the manufacturer would have a contract with the pharmacy benefits company to handle all transactions for a drug under the manufacturer’s indigent drug program.

The agency advises that the prescription drug dispensed in the scenario presented by the comment would not be considered a sample for purposes of PDMA because the drug product comes from the stock of the
retail pharmacy and is intended to be sold.

83. One comment requested that the agency recognize that drugs distributed to a physician for use by his family do constitute samples because they are intended to promote the marketing of a drug. A licensed practitioner is clearly benefitted by the provision of free drugs for personal or family use. The agency believes that the benefit conferred on a practitioner in this manner by a manufacturer or authorized distributor is clearly intended to influence the physician’s decisionmaking process about what drugs to prescribe for patients in the future and is therefore intended to promote the sale of the drug.

12. Bid and Commercial Samples

In the preamble to the proposal (59 FR 11842 at 11856), the agency discussed “bid” and “commercial” samples. The agency stated that these include specimens of bulk drug ingredients, precursor specimens, or finished dosage forms that are distributed to a manufacturer in limited quantities for testing and evaluation purposes. As noted by the agency, specimens of bulk drug ingredients may be used by manufacturers to determine whether the bulk drug is compatible with the manufacturer’s production equipment or suitable for use in formulating drug products. Finished dosage forms may be used by repackers to determine if they are suitable for use with various packaging materials and equipment. Citing the definition of drug sample in section 503(c)(1) of the act and proposed § 203.3(l), the agency stated that, because of the statutory language and the threat of diversion, persons who distribute bid or commercial samples should follow the requirements for sample distribution set forth in the act and the proposal.

84. One comment asked if the agency intended for manufacturers providing materials for stability trials or for validation studies to follow sample distribution requirements. The comment also sought guidance on which distributions of prescription drugs would be covered by the terms “bid” and “commercial” samples.

The agency clarifies that the terms “bid” and “commercial” samples, as used by the agency in the proposal and in the final rule, refer to distributions of bulk drug substances or finished dosage forms by a manufacturer or distributor to a manufacturer at no cost for testing and evaluation purposes. Such distributions would also include free distributions of bulk drug substances to conduct stability, validation, or characterization studies, or for other purposes related to testing and evaluation of the bulk drug substance. Such distributions would also include the free distribution of a limited quantity of a finished dosage form to a repacker for testing with the repacker’s packaging equipment. As discussed in comment 85, the agency has determined that distributions of bid and commercial samples are not subject to requirements for sample distribution under PDMA or the final rule.

85. Several comments objected to subjecting bid and commercial samples to the same requirements as prescription drug samples on the grounds that bid and commercial samples are not intended to promote the sale of a drug and thus are not drug samples. Two comments stated that adhering to drug sample distribution requirements for bid and commercial samples would be burdensome to small companies and drug manufacturers such as repackers that do not have licensed practitioners on their staff. One of these comments stated that the burden would not be offset by any appreciable public health benefit. Several comments stated that the likelihood of diversion of commercial or bid samples is extremely small. Another comment stated that the potential for diversion of bid and commercial samples asserted by the agency is unsupported in either the congressional or administrative record. Several comments recommended applying existing recordkeeping requirements for prescription drugs to bid and commercial samples.

Although bid and commercial samples arguably meet the literal definition of a drug sample under section 503(c)(1) of the act, the agency believes that application of the statutory requirements for drug sample distribution to such drugs would be inconsistent with congressional intent. In PDMA’s legislative history, Congress stated that “pharmaceutical manufacturers and distributors have a long-established practice of providing samples of their prescription drugs to physicians and other practitioners licensed to prescribe such drugs who, in turn, provide them to their patients. The ostensible purpose is to acquaint the practitioner with the therapeutic value of the medications and thus encourage the written prescription of the drug.” (See H. Rept. 100–76 at p. 12.) Because bid and commercial samples are not provided to practitioners or their patients, the agency believes that Congress did not intend the drug sample provisions of PDMA to apply to them. Therefore, the agency is no longer recommending that the sample distribution requirements in PDMA and the final rule be followed for bid and commercial samples. However, because the potential for diversion exists, the agency recommends that manufacturers and distributors monitor their bid and commercial sample distribution to prevent and detect diversion.

F. Application of PDMA to Bulk Pharmaceutical Chemicals

In the preamble to the proposal (59 FR 11842 at 11843), the agency concluded that bulk drug substances that are subject to section 503(b) of the act (i.e., prescription) are covered under PDMA. 86. One comment objected to the application of any portion of PDMA, including the sample distribution requirements and wholesale distribution requirements, to bulk pharmaceutical chemicals (BPC’s). The comment argued that PDMA was intended by Congress to apply to finished dosage forms only and that the proposed regulations cannot be practically applied to BPC’s. The comment stated that the legislative history of PDMA indicates that Congress was concerned with the effects of diversion on consumers and that, since BPC’s are not sold to consumers, Congress did not intend for the act to apply to them. The comment also stated that BPC’s were not mentioned by Congress in either PDMA or its legislative history and the absence of legislative reference to BPC’s indicates that Congress did not even consider including BPC’s under PDMA. The comment argued that this reasoning is consistent with the agency’s decision to exclude blood and blood components from wholesale distribution requirements in PDMA. The comment also said that the proposed regulations dealing with wholesale distribution and drug samples cannot be practically applied to BPC’s. The comment stated, for example, that the proposed sample regulations would not allow a BPC manufacturer to furnish a finished dosage form manufacturer with BPC samples because a manufacturer is prohibited from distributing drug samples to anyone other than a licensed practitioner or a hospital or health care entity pharmacy designated by a licensed practitioner. The comment said that BPC manufacturers could not comply with wholesale licensing requirements in part 205 because BPC’s...
are distributed in an entirely different way than other prescription drugs. The comment recommended that if BPC’s are to be included under PDMA, the proposed regulations should be revised to “include regulations specific to and appropriate to BPC’s that address the problems of diversion and counterfeiting.”

The preamble to the proposed regulations (59 FR 11843) discussed the applicability of PDMA not to BPC’s, but to bulk drug substances (BDS’s). As discussed in section II of this document, the definition of bulk drug substance used in the final rule includes only those substances that become active ingredients when used in the manufacturing, processing, or packaging of a drug. It is the agency’s understanding that the term BPC, as used in the comment, includes substances that do not become active ingredients when used in the manufacturing, processing, or packaging of a drug (i.e., substances that are not pharmacologically active, do not furnish direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, and do not affect the structure or function of the body of humans) and thus are not bulk drug substances.

The statutory language of PDMA makes it applicable to all drugs (as defined under section 201(g)(1) of the act) that are subject to section 503(b)(1) of the act. Although components of finished drug products that are not bulk drug substances may meet the statutory definition of a drug under section 201(g)(1) of the act, such materials are not prescription drugs as described under section 503(b)(1) of the act. Accordingly, non-BDS components of finished drug products are not subject to PDMA requirements (e.g., drug sample or wholesale drug distribution). In addition, as discussed under the preceding comment, the drug sample distribution requirements of PDMA do not apply to specimens of BDS’s provided to finished dosage form manufacturers for testing and evaluation purposes.

The agency disagrees, however, that PDMA was not intended by Congress to apply to prescription BDS’s or that the distribution of prescription BDS’s is so different than that of finished dosage forms that the wholesale distribution requirements of PDMA cannot be practically applied to BDS’s. As noted previously, the statutory language of PDMA makes it applicable to all drugs subject to section 503(b)(1) of the act. A BDS that is intended to furnish pharmacological activity or other direct effect when it becomes a finished dosage form that is a prescription drug necessarily falls within the scope of section 503(b)(1) of the act. Thus, on its face PDMA applies to prescription BDS’s. Although Congress did not specifically refer to BDS’s in the legislative history of PDMA, it also did not specifically refer to finished dosage forms or otherwise indicate that the scope of PDMA is limited to finished dosage forms. Moreover, the agency disagrees with the assertion that because prescription BDS’s are not sold to consumers Congress did not intend for PDMA to apply to them. Prescription BDS’s are used as components of prescription drug products that are sold to consumers, and clearly any practices that adversely impact upon the quality of prescription BDS’s could ultimately harm consumers. Thus, the agency believes that PDMA was intended by Congress to apply to prescription BDS’s.

The agency also believes that the wholesale distribution provisions of PDMA should and must be applied to prescription BDS’s. Prescription BDS’s are distributed from the manufacturer of the BDS to the manufacturer or compounder of the finished dosage form of the drug. That process of distribution may be direct or, as is generally the case for prescription BDS’s manufactured by a foreign manufacturer, through one or more brokers/wholesalers. This system of distribution meets the definition of wholesale distribution under section 503(e)(2)(A) of the act and part 205 inapplicable; (5) regulation by FDA of the manufacture of radiopharmaceuticals; (6) existing regulations cover how radiopharmaceuticals are manufactured, packaged, labeled, stored, shipped, and controlled; and (7) radiopharmacies are licensed under State retail pharmacy laws that impose

interstate commerce must be licensed by the State from which the distribution occurs. For domestically manufactured prescription BDS’s, the BDS manufacturer must be licensed by the State where its facilities are located. Agents that subsequently distribute the prescription BDS must be licensed by the State from which the distribution of the BDS occurs.

In addition, any agent or distributor that is not an authorized distributor of record must provide a statement of origin before distributing the BDS. Thus, except for those prescription BDS distributors that have a written agreement with the BDS manufacturer to distribute the manufacturer’s products for a period of time or for a number of shipments, prescription BDS distributors must provide a statement of origin showing all prior sales and purchases of the prescription BDS being distributed and the names and addresses of the parties to such transactions. Under § 203.50(c) of the final rule, a manufacturer that subjects a prescription BDS to any additional manufacturing processes to produce a different drug is not required to provide to a purchaser a drug origin statement.

G. Application of PDMA to Radiopharmaceuticals

87. One comment requested that distributions of radiopharmaceuticals be exempt from the definition of wholesale distribution in proposed § 203.3(y) and part 205 such that State licensing and drug origin statement requirements would be inapplicable to these drugs. The comment made the following points about radiopharmaceuticals: (1) Radiopharmaceuticals differ from other prescription drugs in that their radioactive component causes them to lose clinical effectiveness within a few days of manufacture; (2) radiopharmaceuticals are prepared in small quantities, shipped overnight, and used the same day they are received; (3) neither manufacturers nor retailers can have inventory of these drugs for longer than a couple of days; (4) the unique properties of radiopharmaceuticals make many of the storage, handling, and accountability considerations of part 205 inapplicable; (5) regulation by FDA would be inappropriate and was not intended by Congress because it would duplicate existing regulations by several Federal, State, and local agencies; (6) existing regulations cover how radiopharmaceuticals are manufactured, packaged, labeled, stored, shipped, and controlled; and (7) radiopharmacies are licensed under State retail pharmacy laws that impose
requirements relating to facilities, security, storage, and recordkeeping.

The agency declines to adopt the exclusions recommended by the comment. The term radioactive drugs, as defined under 21 CFR 310.3(n), encompasses both radioactive and nonradioactive drug products. Radioactive drugs include drug products derived from by-product materials from nuclear reactors (i.e., radionuclide generators), cyclotron-produced products (i.e., Ga-67 Citrate, TI-201 Chloride, and In-111 Oxide), and positron emission tomography products (e.g., Rubidium-82 and fluordeoxyglucose). Nonradioactive reagent kits are also radioactive drugs and are compounded with radioactive substances by radiopharmacies or hospitals to make the final drug product.

As the comment points out, most radioactive drugs have a limited shelf-life which requires that they be distributed in a different manner than many prescription drugs. In addition, certain Federal and various State requirements for shipping, storage, handling, and recordkeeping apply to radioactive drugs. However, as discussed previously in conjunction with medical gases and the comments on bulk drugs, PDMA applies to all prescription drugs. Therefore, unless there is a clear indication in PDMA or its legislative history that Congress did not intend for PDMA to apply to a specific class of drugs, the agency does not believe that it is appropriate to exempt the class from PDMA requirements and restrictions. Except for the factors mentioned above, there is no indication in PDMA or its legislative history that Congress intended that radioactive drugs be treated differently than other types of prescription drug products. The agency does not believe that those factors, by themselves, indicate a clear congressional intent to exempt radioactive drugs from PDMA or to exclude radioactive drugs from specific PDMA requirements.

H. Wholesale Distribution

1. Section 203.50(a) and (a)(6)

Proposed § 203.50(a) and (a)(6) stated:

* * * Before the completion of any wholesale distribution by a wholesale distributor of a prescription drug for which the seller is not an authorized distributor of record to another wholesale distributor or retail pharmacy, the seller shall provide to the purchaser a statement identifying each prior sale, purchase, or trade of such drug. This identifying statement shall include:

* * * The business name and address of all parties to each prior transaction involving the drug, starting with the manufacturer. * * *.

8. One comment objected to § 203.50(a) and (a)(6) because it would require an unauthorized distributor to provide information about all prior sales, purchases, or trades of the drug, starting with the manufacturer, even in cases where the seller from whom the distributor received the drug was an authorized distributor of record and did not provide any pedigree for the drug. The comment stated that “the proposed regulation would make it impossible, as a practical matter, for authorized distributors to sell into the [prescription] specialty market without providing a pedigree.” which was not intended by Congress. The comment recommended revising the proposed rule to require that the drug origin statement (i.e., the “pedigree”) only go back to the last authorized distributor of record.

The agency declines to revise the proposal in the manner suggested by the comment. Section 503(e)(1)(A) of the act requires that, prior to completion of a wholesale distribution of a prescription drug by a person who is not the manufacturer or an authorized distributor of the drug, a statement must be provided to the recipient identifying each prior sale, purchase, or trade of the drug, including the date of the transaction and the names and addresses of all parties to the transaction. There is no indication in PDMA that Congress intended that the statement include only those sales, purchases, or trades since the drug was last handled by an authorized distributor. Thus, an unauthorized distributor is required to provide a full drug origin statement in accordance with PDMA and the final rule whether or not it has purchased a prescription drug from an authorized distributor of record. Although the agency encourages authorized distributors to provide a drug origin statement to unauthorized distributors, they are not required to do so under PDMA or the final rule.

89. In the preamble to the proposal (59 FR 11842 at 11856 and 11857), the agency discussed at length its views on the use of coding that represents required information on the drug origin statement. The agency stated that, since the enactment of PDMA, FDA’s position has been that the use of coded statements on the drug origin statement that make information unintelligible to purchasers without the intervention of a third party to decipher the code (e.g., “this shipment of drugs came from unauthorized distributor RS47GS2273”) does not provide purchasers with the information that Congress intended that they receive. Moreover, the PDA, which amended section 503(e)(1) of the act to require, among other things, that the drug pedigree contain the “names and addresses of all parties to the transaction,” made clear that product source codes may not be used on the drug pedigree as a substitute for required information.

One comment supported the agency’s position on the use of coding. The comment stated that the practice of using codes places a large burden on distributors and recommended that the agency go a step further and revise the proposed regulations to prohibit the use of product source codes on drug origin statements.

The agency believes that its position against the use of product source codes as a substitute for the name and address of buyers or sellers in drug origin statements was adequately addressed in the preamble to the proposal and restated here. Accordingly, the agency declines to codify a prohibition on the use of such codes in the final regulation.

2. Section 203.50(b)

The agency has added § 203.50(b) to clarify that the drug origin statement is subject to the revised record retention requirements of § 203.60(d) and must be retained by all wholesale distributors involved in the distribution of the drug product, whether authorized or unauthorized, for 3 years. The agency is providing this clarification in response to numerous inquiries that it has received since the proposed rule was published.

3. Section 203.50(c)

Proposed § 203.50(c) stated: “Each manufacturer shall maintain at the corporate offices a current written list of all authorized distributors of record.”

Proposed § 203.50(c)(3) stated: “Each manufacturer shall make its list of authorized distributors of record available on request to the public for inspection or copying. A manufacturer may impose reasonable copying charges for such requests from members of the public.”

90. One comment recommended that the list of distributors could be maintained at any company site and could be made available via electronic media or within 24 hours to other sites.

The rule does not require company records to be kept at every company site. As long as a company can produce the required information for review and copying by FDA or other Federal, State, or local law enforcement agencies at the site where they are requested within 2 business days, the company may maintain its records at a central location.
91. Several comments objected to the proposed requirement that manufacturers must make their list of authorized distributors of record available to the public. The comments stated that this information is proprietary in nature and should be kept confidential. One comment stated that FDA has acknowledged that this information was considered proprietary in the past.

Other comments stated that providing such information is unduly burdensome on manufacturers. One comment recommended adding a “reasonable hours of inspection and reasonable copying charges” provision to the section. Another comment recommended revising the section to require only that industry respond to individual inquiries about whether a specific wholesaler is an authorized distributor of record.

The requirement that manufacturers maintain a current list of authorized distributors of record appears at section 503(e)(1)(B) of the act. In the legislative history, Congress stated that this list must be made available for public inspection. (See S. Rept. 100–303, p. 7.) Thus, the agency believes that denying public access to lists of authorized distributors maintained by manufacturers would contradict Congress’ clearly expressed intent.

In addition, the agency disagrees that a manufacturer’s list of authorized distributors constitutes proprietary or confidential information. No provision of PDMA or the act designates such information as proprietary, and the agency is unaware of other laws or regulations that designate such information as proprietary. Moreover, the agency has not previously stated that this information is proprietary. In fact, in a 1988 letter to regulated industry (see Letter from Daniel L. Michels, Director, Office of Compliance to Regulated Industry, Docket No. 88N–258L, August 1, 1988), the agency specifically requested that manufacturers make lists of authorized distributors available at reasonable charge to any requesting person.

Finally, the final rule permits manufacturers to impose reasonable copying charges for requests. Such charges could include clerical time used to create copies, copying costs, and mailing costs, if the requested copies are mailed. Therefore, except for costs associated with creating, updating, and maintaining the authorized distributors lists themselves (a cost that has been evaluated solely by the agency in the “Paperwork Reduction Act of 1995” section under §203.50(d)), the cost to comply with revised §203.50(d)(3) should be reimbursed.

4. Sales to Licensed Practitioners by Retail Pharmacies

In the preamble to the proposal (59 FR 11842 at 11858), the agency stated: FDA believes that permitting the sale of small quantities of prescription drugs by retail pharmacies to licensed practitioners for office use without the requirement of a State wholesale distributor’s license satisfies a legitimate need and is consistent with the intent of the statute. Accordingly, the agency has included language in proposed §203.3(y) that would exclude the sale of minimal quantities of drugs by retail pharmacies to licensed practitioners for office use from the definition of “wholesale distribution.”

In this context, sales of prescription drugs by a retail pharmacy to licensed practitioners for office use will be considered to be minimal if the total annual dollar volume of prescription drugs sold to licensed practitioners does not exceed 5 percent of the dollar volume of that retail pharmacy’s annual prescription drug sales.

92. One comment supported the agency’s decision to exclude minimal sales of prescription drugs by retail pharmacies from the definition of wholesale distribution and recommended that the 5 percent threshold be codified in the final regulation under §203.3(y)(11). The agency believes that its position on what constitutes a minimal amount of prescription drugs for the purposes of revised §203.3(cc)(10) was adequately explained in the preamble to the proposal and need not be codified.

93. Another comment recommended that the 5 percent threshold be increased to 20 percent and should be based on annual, not monthly or weekly, sales of a retail pharmacy. According to the comment, the 5 percent threshold would disadvantage small, independent pharmacies because a large percentage of their sales is derived from supplying local practitioners with prescription drugs. The comment also said that the 5 percent threshold could be reached easily by a pharmacy that supplies expensive drugs, such as chemotherapy medications, to practitioners.

The distribution of prescription drugs to practitioners for office use constitutes wholesale distribution under section 503(e) of the act and proposed §203.3(y) (i.e., distribution to other than a consumer or patient). The agency excluded the sale of minimal quantities of drugs by retail pharmacies to licensed practitioners for office use from the definition of wholesale distribution to meet the needs of licensed practitioners who may not otherwise be able to easily obtain drugs for office use. Thus, the exemption was not created to confer a special benefit on retail pharmacies, but to meet the legitimate needs of licensed practitioners. The agency believes that the 20 percent threshold recommended by the comment is inconsistent with the purpose of the exemption and declines to follow the recommendation. The agency notes that a retail pharmacy is not precluded from making more than 5 percent of its annual sales to licensed practitioners. It must, however, obtain a State wholesale distributor license to do so.

I. Request and Receipt Forms, Reports, and Records

1. Section 203.60(e)(1)

Proposed §203.60(e)(1) stated: “Any person required to create or maintain reports, lists, or other records under PDMA, FDA, or this part shall retain them for at least 3 years after the date of their creation.”

94. One comment objected to the proposed requirement in §203.60(e)(1), stating that it conflicts with the 2-year retention period requirement under §205.50(f)(2). The comment said that changing the record retention time in the manner proposed would “require 44 states that adopted FDA’s 2-year standard to enact legislative and/or regulatory changes in order to have licensing programs that meet the minimum federal requirements.” The comment also said that changing to a 3-year record retention period would serve no apparent public health purpose, citing the agency’s rationale behind the 2-year requirement in the preamble to the final rule on State wholesale licensing guidelines. The comment recommended that the proposed section should be revised to require record retention for 2 years for all records kept by prescription drug wholesalers under PDMA.

Section 205.50(f)(1) requires that inventories and records of transactions regarding the receipt and distribution or other disposition of prescription drugs be created and maintained. Section 205.50(f)(2) requires that such records be “made available” to authorized Federal, State, or local law enforcement agencies for a period of 2 years following the disposition of the drugs to which the record relates. Because the requirement under proposed §203.60(e)(1) that records be retained for 3 years after the creation of the record would appear to exceed requirements required by §205.50(f)(1), the requirements could potentially be conflicting. This result
was not anticipated by FDA at the time the proposed rule was issued.

The agency agrees with the comment that it is appropriate to establish one record retention period for all wholesale distribution records required to be created and maintained under PDMA and parts 203 and 205. The agency has determined that because the shelf life of the majority of prescription drug products is longer than the 2-year period specified in §205.50(f)(2), that period is insufficient to facilitate recalls by manufacturers and to enable the agency to respond to public health emergencies related to prescription drug distribution. Moreover, certain records required to be created and maintained under part 203, such as drug origin statements and written authorization agreements between manufacturers and distributors, are not linked to the disposition of a particular drug product or drug products. Therefore, the agency has decided to adopt the record-retention period specified in proposed §203.60(e)(1) (renumbered §203.60(d)), which is 3 years from the time of creation of a record, for all wholesale distribution records required under PDMA, including those wholesale distribution records required under §205.50(f)(1). Section 205.50(f)(2) has been amended to incorporate the 3-year requirement.

2. Section 203.60(e)(2)

Proposed §203.60(e)(2) stated: “Any person required to create or maintain reports, or records relating to the distribution of drug samples shall retain them for at least 3 years after the date of their creation or 3 years after the date of expiration of a drug sample for which the record is being kept, whichever is later.”

95. Several comments contended that the additional burdens that would result from record retention requirements over 3 years outweigh the possible benefits. One comment stated that the proposed section would require drug sample records to be kept a minimum of 6 years. Two comments stated that it could require record retention for 8 years. One comment stated that “if a practitioner signs a receipt for two different drug samples with different expiration dates, a manufacturer has to go through line by line to see if a record has to be kept.” A similar comment stated that the proposed section would require either implementation of a complicated and expensive process for retaining records to make maximum effective use of storage space or storage of all records for the same length of time, taking into account the drug with the longest shelf life plus 3 years.

Two comments stated that section 503(d)(2)(C) and (d)(3)(C) of the act specifically require that records for drug samples be maintained for 3 years and that FDA has no authority to require retention for a longer period.

Several comments recommended that the proposed section be revised to require a maximum record retention period of 3 years. One comment recommended revising the section to require retention for the greater of 3 years from the time of creation or 1 year after the date of expiration. Another comment recommended allowing manufacturers and distributors to decide how to meet PDMA requirements, while still being accountable to provide a complete distribution history.

The agency agrees that the burdens associated with the record-retention requirement in proposed §203.60(e)(2) may outweigh its benefits. Although the use of the expiration date as a reference point would ensure that the record is kept for the full shelf life of the drug sample, drug sample distribution records may refer to different types of drugs from varying lots that have different expiration dates. Thus, as noted by the comments, requiring a record retention period based on expiration dating would necessitate maintaining different distribution records for different periods of time or maintaining all records for a period that is based on the drug or drugs with the longest shelf life. The agency believes that retention of records relating to drug samples for 3 years from the time of their creation is sufficient to facilitate recalls and to maintain accountability over sample distribution. Accordingly, the agency has eliminated proposed §203.60(e)(2) in the final rule. Under revised §203.60(d), all records under PDMA and part 203, including records relating to the distribution of drug samples, must be retained for 3 years from the date of their creation.

3. Section 203.60(e)(3)

On its own initiative, the agency is deleting proposed §203.60(e)(3) in the final rule. The proposed requirement would have required manufacturers and authorized distributors of record to maintain records of drug sample distribution identifying the drugs distributed, the recipients of the distributions, and all drug samples destroyed or returned to the manufacturer for 3 years. The agency believes that the final rule, as revised, contains recordkeeping provisions to ensure accountability over drug sample distribution.

4. Section 203.60(f)

Proposed §203.60(f) stated that any person required to create or maintain request and receipt forms, reports, lists, or other records under PDMA, PDA, or part 203 shall make them available upon request, in a form that permits copying or other means of duplication, to FDA or other Federal, State, or local regulatory and law enforcement officials for review and reproduction.

On its own initiative, the agency has revised proposed §203.60(f) (renumbered §203.60(e)) to specify that the records must be made available within 2 business days of a request. The agency believes that this constitutes a reasonable period of time to obtain records kept off-site and is consistent with other PDMA record production requirements.

J. Penalties and Rewards

In the preamble to the proposed rule (59 FR 11842 at 11860), the agency stated that “most violations of the act are punishable as misdemeanors.” The agency later stated that “most PDMA violations are felonies punishable by a prison term of not more than 10 years, a fine of not more than $250,000, or both * * *.”

96. One comment stated that the two statements made by the agency are conflicting and should be reconciled. The agency clarifies that the first statement (“most violations of the act are punishable as misdemeanors”) refers to the entire act (see sections 303(a)(1) and (a)(2) of the act), not the PDMA provisions. As stated in the preamble to the proposed rule (59 FR 11842 at 11860), most PDMA violations, except for the distribution of a drug sample in violation of section 503(d) of the act and the failure to comply with the drug origin statement requirement in section 503(e)(1)(A) of the act, are felonies.

K. Amendments to 21 CFR Part 205

In the proposal, the agency proposed an amendment to the introductory paragraph of §205.50(c) that would require that prescription drugs be stored by wholesale distributors at appropriate temperatures and under appropriate conditions in accordance with the labeling requirements of the drugs or with the requirements of USP XXII. The agency also proposed an amendment to §205.50(c)(1) that would require that, if no storage requirements are established for a prescription drug, the drug must be held at “controlled room temperature” as defined in USP XXII. Current §205.50(c)(1) states that, if no storage requirements are established for a prescription drug, the drug “may” be
The proposal are due to increased determination that the regulatory costs of recommendations. The agency PDMA's enactment, FDA's guidance, and regulated industry in response to the requirements in the proposed rule have been implemented by regulated industry, including small entities, the agency certified that the proposed rule would not have a significant economic impact on a substantial number of small entities.

98. One comment stated that "FDA's assessment of all costs and benefits of available regulatory alternatives and selected regulatory approaches does not prove that the proposed rule maximizes net benefits." The comment stated that the proposed rule will have a "significant negative effect on the industry, health care costs, the environment, and State licensing agencies." This impact, the comment states, is not outweighed by benefits in controlling, preventing, or detecting diversion, or by adding significantly to the safety of the consumer. Another comment stated that the proposed rule would add significant costs, including new systems costs, without corresponding benefits.

The agency believes that the final rule is consistent with the principles set forth under Executive Order 12866. The benefits of the final rule, including the public health and safety benefits, have been discussed extensively in the proposal and in this notice. The estimated costs to industry of the final regulations, which are due primarily to additional paperwork costs, are set forth in section IV.B of this document and have been substantially revised from the estimates provided in the proposal. The agency has attempted to accurately represent the benefits and costs of the final regulation, has carefully analyzed them, and believes that the regulatory approaches chosen for the final rule maximize net benefits.

99. One comment stated that the agency's financial impact estimates are "much too low." According to the comment, FDA has not considered costs associated with the proposed requirements, including travel and personnel expenses in conjunction with inventorying sales representatives and conducting investigations, increased paperwork in conjunction with comarketing agreements, and administrative and other costs in conjunction with longer record maintenance periods and tracking of bid and commercial samples.

100. Two comments disagreed with FDA's assertion that most of the proposed requirements have been implemented by the industry in response to PDMA's enactment, FDA's guidance, and industry trade associations' recommendations. One of the comments stated that the proposed rule contains items which are a "significant departure" from currently understood requirements. The comment cited the following specific proposed requirements and recommendations: The requirement under proposed § 203.60(e)(2) for retention of drug sample records for 3 years past the expiration date of the drug sample; the requirement under proposed § 203.37(b) for reporting possible falsifications of drug sample records; the requirement under proposed § 203.38(c) for labeling of sample units; the requirements under proposed §§ 203.30 and 203.31 for drug sample receipts; and the agency's recommendation in the proposal that bid or commercial samples be tracked using PDMA sample controls.

As discussed previously, many of the proposed requirements and recommendations cited by the comment have been deleted or substantially modified in the final rule in response to other comments or on the agency's initiative. Nevertheless, FDA acknowledges that some of the proposed requirements may not have been implemented by industry at the time the proposal was published and that too much reliance may have been placed by the agency on prior industry implementation in the "Analysis of Impacts" section of the proposal. The agency has significantly revised its analysis of impacts for the final rule.

M. Estimated Annual Reporting and Recordkeeping Burden

101. Several comments stated that the estimated burdens set forth under the "Paperwork Reduction Act of 1980" section of the proposed rule (59 FR 11842 at 11860 and 11861) were too low. One comment stated that FDA grossly underestimated the annual reporting and recordkeeping burden and that both industry and FDA will be burdened more than anticipated by implementation of many of the regulations. Another comment stated that "the agency's predicted time estimates to comply with the rule are so
unrealistic as to be arbitrary and capricious.”

One comment cited specific examples of estimates that it considered to be too low. The comment stated that the agency’s estimate of 30 minutes to comply with the recordkeeping requirements under proposed § 203.31(d) “grossly understates the time and expense to comply.” The comment stated that the estimate of 30 seconds to comply with §§ 203.30(c) and 203.31(c) takes into account only the time necessary to sign a sample receipt, but not the time necessary for a representative to fill out the receipt with the required information or the time that a representative will have to wait for a practitioner or his or her designee to sign the receipt. The comment stated that the agency’s estimate of 30 and 60 minutes to meet the recordkeeping requirements under proposed § 203.37(a) and (b), respectively, may accurately reflect the time necessary to write up the report, but not to initiate and complete a thorough investigation. According to the comment, the estimate of 24 hours to prepare policies and procedures under proposed § 203.34 underestimates the time it will take for a company to research its activities, prepare and revise draft guidance documents, type the material, and obtain management approval. The comment stated that the agency neglected to provide an estimate for the time it will take to comply with proposed § 203.60. Finally, the comment stated that FDA has ignored the burden the proposal will place on the agency.

Based upon the comments, the agency has significantly modified and increased its estimate of the reporting and recordkeeping burdens associated with the final rule under the section of this notice entitled “Paperwork Reduction Act of 1995.” Regarding the absence of a burden estimate for proposed § 203.60, the agency advises that it has included an estimate of the costs associated with the record retention requirement in revised § 203.60 in section IV.B of this document. Generally, the agency expects its administrative costs associated with oversight of the final rule to be minimal. As discussed below, the public has 60 days from the publication of the final rule to comment on the accuracy of FDA’s revised burden estimates, and the agency encourages interested parties to do so.

IV. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act (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 Regulatory Flexibility Act requires an analysis of regulatory options that would minimize any significant economic impact of a rule on small entities unless an agency certifies that a rule will not have a significant economic impact on a substantial number of small entities. The Unfunded Mandates Reform Act requires that agencies prepare an assessment of anticipated costs and benefits before proposing any rule that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million (adjusted annually for inflation) in any 1 year. The agency believes that this final rule is consistent with the regulatory philosophy and principles identified in the Executive Order, Regulatory Flexibility Act, and Unfunded Mandates Reform Act.

A. Regulatory Benefits

Through this regulation, the agency is establishing procedures and requirements implementing PDMA. As discussed extensively above and in the preamble of the proposed rule, the requirements in the final rule will, consistent with Congress’ intent in enacting PDMA, help to prevent the sale of subpotent, adulterated, counterfeit, or misbranded prescription drugs and drug samples to the American public. For example, the final rule establishes procedural and recordkeeping requirements for drug sample distribution that will help to prevent the diversion and sale of drug samples. The final rule also establishes wholesale distribution requirements that will permit the distribution chain of prescription drugs to be traced, and will make wholesale distributors more accountable. In sum, the final rule establishes controls over the distribution of prescription drugs and drug samples that will help to ensure that drugs are safe and effective not only when they leave manufacturers, but when they reach consumers.

B. Regulatory Costs

FDA estimates that the incremental costs that will result from the issuance of this rule will amount to about $43 million annually. Moreover, industry will continue to incur an estimated $39 million in annual costs for those activities initiated shortly after PDMA was enacted into law by Congress 10 years ago. Thus, the total cost of PDMA and this implementing rule is approximately $82 million. Almost all of the costs are associated with sample distribution, and most are related to paperwork requirements.

1. Cost of Sample Distribution Requirements

a. Paperwork costs. The paperwork section of this preamble shows the hourly reporting and recordkeeping burden estimates for all of the sample distribution requirements, including the following: Request and receipt forms, license verification, inventory of representatives, notification of FDA and investigation of losses and falsified information, representative lists and sample storage sites, representative conviction reports, written policies, assignment of individuals responsible for sample information, donation records, and inventory records and reconciliation reports. These costs will be shared by those manufacturers, distributors, and charities subject to the above requirements. These individuals should already possess the necessary professional skills to comply with these paperwork requirements. To determine the paperwork costs for the sample distribution requirements, FDA assumed that sales representatives would complete the majority of the request and receipt forms. In the case of sample distribution by mail or common carrier, the agency assumed that an administrator in the practitioner’s office would complete the request and receipt forms. Also, the agency believes that an individual in the office would be authorized to sign the receipt forms for the practitioner. Using 1995 hourly earnings of approximately $24 (including 40 percent for benefits) for sales representatives and executive, administrative, and managerial positions, the estimated total annual paperwork costs for the sample distribution requirements are $79 million. Approximately $36 million of these costs have been incurred annually since PDMA’s enactment. The remaining $43 million are sample paperwork costs that will go into effect as a result of this regulation. These additional costs include: $22.6 million for receipt recordkeeping, $2.6 million for license verification, $2.1 million for establishing written policies and

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procedures for sample distribution, and $15.6 million for the lot or control number requirements.

b. Other request and receipt form costs. Sample request and receipt forms are required under PDMA for samples delivered by mail or common carrier. Under the final rule, FDA is also requiring receipt forms to be used when samples are delivered by representatives. To minimize printing and storage costs, FDA believes companies will primarily use one combination request and receipt form for samples delivered by representatives and separate request and receipt forms for mail delivery. Therefore, a total of three forms will be used, one of which will be new with this rule. The agency estimates that the development and approval of each form may take approximately 2 hours of an administrator’s time. Taking into consideration the 2,208 manufacturers and distributors who distribute samples (691 manufacturers of pharmaceutical preparations plus 25 percent of the 6,069 establishments of wholesale distributors of drugs, drug properties, and druggists’ sundries), the total one-time cost of developing these forms is approximately $318,000 (2 hours x 3 forms x 2,208 x $24). Of this amount, the one-time cost of developing the additional form attributable to this regulation is approximately $106,000 (2 hours x 1 form x 2,208 x $24).

Manufacturers and distributors also incur annual printing costs associated with the distribution of these forms. After evaluating several printing estimates, the agency selected $0.025 per page as a reasonable printing cost. Based on the paperwork estimates of approximately 32.5 million request and receipt forms for delivery by representatives and 750,000 receipt forms for mail-delivery (20 percent of 309,807 offices and clinics of doctors of medicine and dentists x 12 per year), the agency estimates that manufacturers and distributors incur printing costs of approximately $831,000 annually ((32.5 million + 750,000) x 0.025). FDA does not include any printing costs for mail-requests, assuming that a paper exchange already occurred in the marketplace for this purpose. In addition, the agency believes that, in most cases, manufacturers and distributors will combine the receipt and request forms when samples are delivered by a representative. Therefore, none of the above printing costs are new to this regulation.

c. Other license verification costs. The final rule will require manufacturers and authorized distributors of record to verify with the State that the practitioner to whom samples are distributed is licensed or authorized by law to prescribe the drug product. To evaluate the cost of compliance with this requirement, the agency spoke with a representative of the Board of Physician Quality Assurance in Maryland. FDA found that it costs approximately $500 to purchase a list of all active practitioners with a license in the State of Maryland. Due to the high cumulative cost for each manufacturer to purchase a list from every State (or, from as many States as their distribution reaches), provide it to their distributors, and update it on a regular basis, it is likely that market forces will establish a more efficient process. For example, a third party could easily purchase the information and sell it to manufacturers. Considering the costs for third parties to purchase, manipulate, and disseminate this information, the agency believes that $500 to $1,000 would be a reasonable price range for charges by third parties to manufacturers for nationwide data. For the purpose of this analysis, FDA assumes that each of the 691 manufacturers would pay an average of $750 each year, yielding total annual costs of approximately $518,000 to meet the license verification requirement. The agency does not calculate any costs for manufacturers to disseminate this information, but instead assumes that the license numbers would be added to the list of physicians that is currently provided to sales representatives on a yearly basis.

d. Other sample distribution requirements. The other requirements of the rule entailed negligible costs, were already part of industry practice, or were attributable to the overall cost of doing business. For example, FDA assumes all charities that receive samples have a licensed practitioner on staff and that the cost of examining drug sample packaging is negligible. The final rule also permits the inventory of samples held by sales representatives to be conducted by the representatives themselves. Therefore, no travel expenses will be incurred for this purpose. The agency also assumes that most manufacturers and distributors and their representatives are currently following proper storage and handling requirements to prevent the distribution of adulterated samples. In addition, the agency believes that it is already part of company policy for manufacturers and distributors to investigate significant losses and known thefts of samples and common practice to label sample units so they may be tracked in recall situations.

2. Nonsample-Related Costs

To determine the costs associated with the nonsample-related requirements, the agency multiplied the $24 hourly rate¹⁰ for sales representatives and executive, administrative, and managerial positions by the burden hours estimated under the paperwork section of this preamble. These annual paperwork costs are grouped into the following categories: Reimportation, sales restrictions, and wholesale distribution. To calculate reimportation costs, the agency used the salary data for executive and managerial positions. As few requests for emergency reimportation are expected, the annual paperwork costs for all reimporters to fill out the emergency reimportation application total only $144. The annual cost of the credit memo and storage documentation required under “Sales Restrictions” is shared by hospitals, healthcare entities, and charities, and is estimated at $1.3 million. Wholesale distribution requirements, including the drug origin statement and distributor list, are estimated to impose recordkeeping costs of $258,000 per year on manufacturers and distributors. All of the previous costs were initiated by the enactment of PDMA and will not be significantly affected by the issuance of this rule.

3. Storage Costs for Sample and Nonsample-Related Requirements

The final rule requires that manufacturers and/or distributors retain records for at least 3 years, including the following documents: Drug return memos, request and receipt forms, drug sample inventory records and reconciliation reports, representative lists, and drug origin statements. In 1995, the average expected annual rent for space in commercial buildings equaled $9.43 per square foot.¹¹ For


⁷Data from IMS, 1996, as presented to FDA on May 27, 1997. Data included an estimated 18.1 million office calls, 8.1 million service calls, and 6.3 million hospital calls made in 1996.


¹⁰Employment and Earnings, pp. 205 and 206.

each of the first 3 years, the agency estimates that an additional 5 square feet of storage space per affected manufacturer and distributor will be needed to accommodate the record retention requirements. After the third year, each subsequent year’s records can replace the most previous year’s, indicating that no more than 15 square feet of storage space will be necessary. FDA estimates that up to approximately 2,500 manufacturers and distributors will be affected; therefore, average annual storage costs will amount to approximately $118,000 in year 1, $236,000 in year 2, and $354,000 in each year thereafter. Though retention of drug return memos is also required of hospitals and charities, the agency believes these costs are negligible. Some of these storage requirements were initiated by PDMA, but other storage requirements have been added by this regulation. The agency did not separate these storage costs for the purpose of this analysis.

C. Small Business Analysis

The agency has analyzed this rule in accordance with the Regulatory Flexibility Act to determine its effect on small entities.

1. Need for and Objectives of the Rule

As stated previously, PDMA was enacted by Congress to prevent the sale of subpotent, adulterated, counterfeit, or misbranded drugs. Through this regulation, the agency is establishing the procedures and requirements to implement PDMA. The final rule facilitates the goals of PDMA by establishing procedural and recordkeeping requirements for drug sample distribution that will help to prevent the diversion and sale of drug samples. In addition, the final rule establishes wholesale distribution requirements that will permit the distribution chain of prescription drugs to be traced, and will make unauthorized wholesale distributors more accountable.

2. Description and Estimate of the Number of Small Entities

According to the Small Business Administration (SBA), distributors of drugs, drug proprietaries, and druggists’ sundries with 100 or fewer employees or manufacturers of pharmaceutical preparations with 750 or fewer employees are considered small entities. The U.S. Census does not disclose data on the number of drug manufacturing firms by employment size, but between 92 percent and 96 percent of drug manufacturing establishments, or approximately 650 establishments, are small under this definition. Although the number of firms that are small would be less than the number of establishments mentioned above, FDA still concludes that the majority of pharmaceutical preparation manufacturing firms are small entities. In addition, the agency found that 94 percent of the distribution firms, or approximately 4,000 firms, are small. However, as stated previously, the agency believes that the majority of these do not distribute samples, and thus will not be affected by the rule. According to SBA’s definition, general medical and surgical hospitals, and the offices and clinics of dentists and doctors of medicine that are either not-for-profit or have $5 million or less in revenue are also considered small. Using this definition, FDA determined that approximately 96 percent of the hospitals (or approximately 4,000 hospitals) and 99 percent of the offices and clinics (or approximately 268,000 offices and clinics) are small. In addition, due to their nonprofit status, the agency assumes that the 3,112 charities expected to be affected by this rule (based on a portion of not-for-profit hospitals, doctors’ offices, and clinics) would be considered small by SBA. As noted in the paperwork section of this regulation, FDA believes that approximately 12 importers will be affected by this rule, and assumes that the majority of them are small. The agency notes that the great majority of the costs of this rule will be incurred by the manufacturers and distributors that distribute drug samples. The costs will not be evenly distributed, but directly related to the size of each company’s sales force. According to Census data, less than 10 percent of the manufacturing companies in the pharmaceutical preparations industry have 90 percent of the industry’s sales. Likewise, approximately 1 percent of the firms distributing drugs, drug proprietaries, and druggists’ sundries have 74 percent of the industry’s sales. Consequently, the largest firms will incur the majority of the drug sample-related costs of this regulation, and the smallest firms will incur relatively few of these costs. While some small reimporters will be affected by the reimportation restriction, this impact will be moderated because most also import non-U.S. drugs or other products. The cost impact on charities will be minimal.

3. Estimate of the Recordkeeping Burden

The majority of the costs of this regulation are derived from the paperwork requirements. The manufacturers, distributors, and charities involved in the sample distribution process are required to comply with the recordkeeping requirements specified earlier in this analysis. These individuals should already possess the necessary skills to establish written policies and procedures, complete forms and applications, and prepare the required documentation. The paperwork specified by this rule does not require any special professional training or skills to complete and would be of a type already being handled by regulatory affairs professionals who are employed by drug manufacturers and distributors.

4. Analysis of Alternatives

FDA could have implemented the rule as proposed, but instead, the agency took several steps to minimize the economic impact on small entities. Specifically, the agency reduced or eliminated several of the requirements under the proposed rule. Examples of this can be found under the requirements for sample inventory, lot or control numbers, sample unit identification, and sample record retention. Under the proposal, the inventory of drug samples held by sales representatives would be conducted by an executive other than the representative or the immediate supervisor. Comments emphasized the costliness of this requirement, indicating it was time consuming and entailed travel expenses to regional sales offices. In response to these comments, the final rule allows sales representatives and their supervisory personnel to conduct the inventory and reconciliation functions. Also, in response to comments on the proposal, FDA reduced the administrative burden.

associated with the donation of prescription drug samples to charity. Furthermore, FDA found it unnecessarily burdensome to require that lot or control numbers appear on drug sample records, receipts, and reconciliation reports, as proposed. Therefore, the final rule adds flexibility by allowing the recording of lot or control numbers on other types of records. Also, in response to comments, the agency is allowing the use of adhesive stickers on retail units to designate a sample unit as a sample. The final rule reduces the drug sample record retention period, which was proposed as 3 years from the sample expiration date. The agency decided that retention of drug sample records for 3 years from the date of their creation is sufficient for recall facilitation and proper accountability over sample distribution.

The agency considered minimizing the impact of this rule by not requiring manufacturers and authorized distributors to verify with the State that the practitioner to whom samples are distributed is licensed or authorized by law to prescribe the drug product. However, under the final rule, this license verification requirement was added in response to comments. The cost of this requirement is estimated at approximately $3.2 million per year. The agency determined that this requirement is the only reliable way of proving that the practitioner requesting samples is actually licensed by a State to prescribe drugs. The agency does not believe that allowing a manufacturer to deem acceptable a license or authorization number on a request form without verifying its authenticity would offer any such assurance.

The agency considered eliminating the receipt requirement for representative-delivered samples. This would reduce the cost of the final regulation by approximately $22.6 million per year. However, although Congress did not expressly require a receipt for representative-delivered samples, FDA concluded that this requirement is necessary to help ensure effective enforcement, increased accountability and oversight of sample distribution, and to provide adequate safeguards against drug sample diversion.

5. Response to Comments

Several of the comments indicated that the initial economic analysis understated the impact of the proposed rule. FDA reevaluated and significantly increased the paperwork estimates to more accurately reflect industry’s implementation of this final regulation. For example, the agency increased the estimated time for a manufacturer to conduct an annual inventory and complete a reconciliation report from 30 minutes to 40 hours per manufacturer. The agency also increased the amount of time estimated to generate a sample receipt from 1 minute to 3 and 5 minutes for distribution by mail and representative respectively, and the estimated time to investigate possible significant loss or theft of samples from 1 hour to 24 hours. In addition, the agency identified and estimated the burden associated with requirements other than recordkeeping that were not quantified under the proposed rule. For example, FDA allotted 2 hours for the development of each of the sample request and receipt forms. The annual printing costs associated with these forms have also been assessed. Storage costs have been added as necessitated by the paperwork requirements of this regulation.

D. Conclusion

FDA calculated both the incremental costs of this final rule and the costs initially imposed upon the enactment of PDMA, and determined that there are one-time costs of $318,000 for developing forms, and total annual costs of approximately $82 million. Approximately $39 million of these annual costs have been incurred by industry since the enactment of PDMA by Congress in 1988. An estimated additional $43 million per year will result from the new requirements in this regulation. This rule is not a significant regulatory action as defined by the Executive Order, and is therefore not subject to review under the Executive Order. This rule does not impose any mandates on State, local, or tribal governments, nor is it a significant regulatory action under the Unfunded Mandates Reform Act. Finally, the agency has analyzed this rule in accordance with the Regulatory Flexibility Act and provided each of the elements required for a final regulatory flexibility analysis.

V. Executive Order 13132: Federalism

FDA has analyzed this final rule in accordance with Executive Order 13132: Federalism. Executive Order 13132 requires Federal agencies to carefully examine actions to determine if they contain policies that have federalism implications or that preempt State law. As defined in the Order, “policies that have federalism implications” refers to regulations, legislative comments or proposals, and other policy statements or actions 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.

FDA is publishing this final rule to set forth agency policies and requirements and provide administrative procedures, information, and guidance for those sections of PDMA that are not related to State licensing of wholesale prescription drug distributors. Because enforcement of these sections of PDMA is a Federal responsibility, there should be little, if any, impact from this rule 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. In addition, this regulation does not preempt State law.

Accordingly, FDA has determined that this final rule does not contain policies that have federalism implications or that preempt State law.

VI. Paperwork Reduction Act of 1995

This final rule contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The title, description, and respondent description of the information collection provisions are shown 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.

Title: Prescription Drug Marketing Act of 1987; Policies, Requirements, and Administrative Procedures.

Description: The final rule provides for the collection of information from establishments engaged in the reimportation and wholesale distribution of prescription drugs; the sale, purchase, or trade of (or offer to sell, purchase, or trade) prescription drugs by hospitals, health care entities, and charitable institutions; the distribution of prescription drug samples; and the wholesale distribution of prescription drugs.

Description of Respondents: Businesses, hospitals, health care entities, charitable institutions, and other for-profit and not-for-profit organizations; small businesses or organizations.

Although the March 1994 proposal provided a 60-day comment period under the Paperwork Reduction Act of 1980, and this final rule responds to the comments received, FDA is providing
an additional opportunity for public comment under the Paperwork Reduction Act of 1995, which became effective after the expiration of the comment period and applies to this final rule. Therefore, FDA now invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology. Individuals and organizations may submit comments on the information collection provisions of this final rule by February 1, 2000. Comments should be directed to the Dockets Management Branch (address above).

At the close of the 60-day comment period, FDA will review the comments received, revise the information collection provisions as necessary, and submit these provisions to OMB for review. FDA will publish a notice in the Federal Register when the information collection provisions are submitted to OMB, and an opportunity for public comment to OMB will be provided at that time. Prior to the effective date of this final rule, FDA will publish a notice in the Federal Register of OMB's decision to approve, modify, or disapprove the information collection provisions. 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.

### Table 1.—Estimated Annual Reporting Burden

<table>
<thead>
<tr>
<th>21 CFR Section</th>
<th>No. of Respondents</th>
<th>Annual Frequency per Response</th>
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1 There are no capital costs or operating and maintenance costs associated with this collection of information.

### Table 2.—Estimated Annual Recordkeeping Burden

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1 There are no capital costs or operating and maintenance costs associated with this collection of information.

Section 203.38(c) is exempt from recordkeeping requirements because the information it requires to be placed on drug sample labeling is provided by the agency.

### VII. Environmental Impact

The agency has determined under 21 CFR 25.30(h) that this action is of a class of actions that do not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Subpart E—Wholesale Distribution

203.50  Requirements for wholesale distribution of prescription drugs.

Subpart F—Request and Receipt Forms, Reports, and Records

203.60  Request and receipt forms, reports, and records.

Subpart G—Rewards

203.70  Application for a reward.


Subpart A—General Provisions

§ 203.1  Scope.

This part sets forth procedures and requirements pertaining to the reimportation and wholesale distribution of prescription drugs, including both bulk drug substances and finished dosage forms; the sale, purchase, or trade of (or the offer to sell, purchase, or trade) prescription drugs, including bulk drug substances, that were purchased by hospitals or health care entities, or donated to charitable organizations; and the distribution of prescription drug samples. Blood and blood components intended for transfusion are excluded from the restrictions in and the requirements of the Prescription Drug Marketing Act of 1987 and the Prescription Drug Amendments of 1992.

§ 203.2  Purpose.

The purpose of this part is to implement the Prescription Drug Marketing Act of 1987 and the Prescription Drug Amendments of 1992, except for those sections relating to State licensing of wholesale distributors (see part 205 of this chapter), to protect the public health, and to protect the public against drug diversion by establishing procedures, requirements, and minimum standards for the distribution of prescription drugs and prescription drug samples.

§ 203.3  Definitions.

(a) The act means the Federal Food, Drug, and Cosmetic Act, as amended (21 U.S.C. 301 et seq.).

(b) Authorized distributor of record means a distributor with whom a manufacturer has established an ongoing relationship to distribute such manufacturer's products.

(c) Blood means whole blood collected from a single donor and processed either for transfusion or further manufacturing.

(d) Blood component means that part of a single-donor unit of blood separated by physical or mechanical means.

(e) Bulk drug substance means any substance that is represented for use in a drug and that, when used in the manufacturing, processing, or packaging of a drug, becomes an active ingredient or a finished dosage form of the drug, but the term does not include intermediates used in the synthesis of such substances.

(f) Charitable institution or charitable organization means a nonprofit hospital, health care entity, organization, institution, foundation, association, or corporation that has been granted an exemption under section 501(c)(3) of the Internal Revenue Code of 1954, as amended.

(g) Common control means the power to direct or cause the direction of the management and policies of a person or an organization, whether by ownership of stock, voting rights, by contract, or otherwise.

(h) Distribute means to sell, offer to sell, deliver, or offer to deliver a drug to a recipient, except that the term "distribute" does not include:

(1) Delivering or offering to deliver a drug by a common carrier in the usual course of business as a common carrier; or

(2) Providing of a drug sample to a patient by:

(i) A practitioner licensed to prescribe such drug;

(ii) A health care professional acting at the direction and under the supervision of such a practitioner; or

(iii) The pharmacy of a hospital or of another health care entity that is acting at the direction of such a practitioner and that received such sample in accordance with the act and regulations.

(j) Drug coupon means a form that may be redeemed, at no cost or at reduced cost, for a drug that is prescribed in accordance with section 503(b) of the act.

(k) Electronic record means any combination of text, graphics, data, audio, pictorial, or other information representation in digital form that is created, modified, maintained, archived, retrieved, or distributed by a computer system.

(l) Electronic signature means any computer data compilation of any symbol or series of symbols executed, adopted, or authorized by an individual to be the legally binding equivalent of the individual's handwritten signature.

(m) Emergency medical reasons include, but are not limited to, transfers of a prescription drug between health care entities or from a health care entity to a retail pharmacy to alleviate a temporary shortage of a prescription
drug arising from delays in or interruption of regular distribution schedules; sales to nearby emergency medical services, i.e., ambulance companies and fire fighting organizations in the same State or same marketing or service area, or nearby licensed practitioners, of drugs for use in the treatment of acutely ill or injured persons; provision of minimal emergency supplies of drugs to nearby nursing homes for use in emergencies or during hours of the day when necessary drugs cannot be obtained; and transfers of prescription drugs by a retail pharmacy to another retail pharmacy to alleviate a temporary shortage; but do not include regular and systematic sales to licensed practitioners of prescription drugs that will be used for routine office procedures.

(n) FDA means the U.S. Food and Drug Administration.

(o) Group purchasing organization means any entity established, maintained, and operated for the purchase of prescription drugs for distribution exclusively to its members with such membership consisting solely of hospitals and health care entities bound by written contract with the entity.

(p) Handwritten signature means the scripted name or legal mark of an individual handwritten by that individual and executed or adopted with the present intention to authenticate a writing in a permanent form. The act of signing with a writing or marking instrument such as a pen or stylus is preserved. The scripted name or legal mark, when conventionally applied to paper, may also be applied to other devices that capture the name or mark.

(q) Health care entity means any person that provides diagnostic, medical, surgical, or dental treatment, or chronic or rehabilitative care, but does not include any retail pharmacy or any wholesale distributor. A person cannot simultaneously be a “health care entity” and a retail pharmacy or wholesale distributor.

(r) Licensed practitioner means any person licensed or authorized by State law to prescribe drugs.

(s) Manufacturer means any person who is a manufacturer as defined by § 201.1 of this chapter.

(t) Nonprofit affiliate means any not-for-profit organization that is either associated with or a subsidiary of a charitable organization as defined in section 501(c)(3) of the Internal Revenue Code of 1954.

(u) Ongoing relationship means an association that exists when a manufacturer and a distributor enter into a written agreement under which the distributor is authorized to distribute the manufacturer’s products for a period of time or for a number of shipments. If the distributor is not authorized to distribute a manufacturer’s entire product line, the agreement must identify the specific drug products that the distributor is authorized to distribute.


(w) PDMA means the Prescription Drug Marketing Act of 1987.

(x) Person includes any individual, partnership, corporation, or association.

(y) Prescription drug means any drug (including any biological product, except for blood and blood components intended for transfusion or biological products that are also medical devices) required by Federal law (including Federal regulation) to be dispensed only by a prescription, including finished dosage forms and bulk drug substances subject to section 503(b) of the act.

(z) Representative means an employee or agent of a drug manufacturer or distributor who promotes the sale of prescription drugs to licensed practitioners and who may solicit or receive written requests for the delivery of drug samples. A detailer is a representative.

(aa) Sample unit means a packet, card, blister pack, bottle, container, or other single package comprised of one or more dosage units of a prescription drug sample, intended by the manufacturer or distributor to be provided by a licensed practitioner to a patient in an unbroken or unopened condition.

(bb) Unauthorized distributor means a distributor who does not have an ongoing relationship with a manufacturer to sell or distribute its products.

(cc) Wholesale distribution means distribution of prescription drugs to persons other than a consumer or patient, but does not include:

(1) Intracompany sales;

(2) The purchase or other acquisition by a hospital or other health care entity that is a member of a group purchasing organization of a drug for its own use from the group purchasing organization or from other hospitals or health care entities that are members of such organizations;

(3) The sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug by a charitable organization to a nonprofit affiliate of the organization to the extent otherwise permitted by law;

(4) The sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug among hospitals or other health care entities that are under common control;

(5) The sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug for emergency medical reasons;

(6) The sale, purchase, or trade of a drug, an offer to sell, purchase, or trade a drug, or the dispensing of a drug under a prescription executed in accordance with section 503(b) of the act;

(7) The distribution of drug samples by manufacturers’ and authorized distributors’ representatives;

(8) The sale, purchase, or trade of blood or blood components intended for transfusion;

(9) Drug returns, when conducted by a hospital, health care entity, or charitable institution in accordance with § 203.23;

(10) The sale of minimal quantities of drugs by retail pharmacies to licensed practitioners for office use.

(dd) Wholesale distributor means any person engaged in wholesale distribution of prescription drugs, including, but not limited to, manufacturers; repackers; own-label distributors; private-label distributors; jobbers; brokers; warehouses, including manufacturers’ and distributors’ warehouses, chain drug warehouses, and wholesale drug warehouses; independent wholesale drug traders; and retail pharmacies that conduct wholesale distributions.

Subpart B—Reimportation

§ 203.10 Restrictions on reimportation.

No prescription drug or drug composed wholly or partly of insulin that was manufactured in a State and exported from the United States may be reimported by anyone other than its manufacturer, except that FDA may grant permission to a person other than the manufacturer to reimport a prescription drug or insulin-containing drug if it determines that such reimportation is required for emergency medical care.

§ 203.11 Applications for reimportation to provide emergency medical care.

(a) Applications for reimportation for emergency medical care shall be submitted to the Director of the FDA District Office in the district where reimportation is sought (addresses found in § 5.115 of this chapter).

(b) Applications for reimportation to provide emergency medical care shall be reviewed and approved or disapproved by each district office.
§ 203.12 An appeal from an adverse decision by the district office.

An appeal from an adverse decision by the district office involving insulin-containing drugs or prescription human drugs, other than biological products, may be made to the Office of Compliance (HFD—300), Center for Drug Evaluation and Research, Food and Drug Administration, 7520 Standish Pl., Rockville, MD 20855. An appeal from an adverse decision by the district office involving prescription human biological products may be made to the Office of Compliance and Biologics Quality (HFM—600), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852.

Subpart C—Sales Restrictions

§ 203.20 Sales restrictions.

Except as provided in § 203.22 or § 203.23, no person may sell, purchase, or trade, or offer to sell, purchase, or trade any prescription drug that was:
(a) Purchased by a public or private hospital or other health care entity; or
(b) Donated or supplied at a reduced price to a charitable organization.

§ 203.22 Exclusions.

Section 203.20 does not apply to:
(a) The purchase or other acquisition of a drug for its own use by a hospital or other health care entity that is a member of a group purchasing organization from the group purchasing organization or from other hospitals or health care entities that are members of the organization.
(b) The sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug by a charitable organization to a nonprofit affiliate of the organization to the extent otherwise permitted by law.
(c) The sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug among hospitals or other health care entities that are under common control.
(d) The sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug for emergency medical reasons.
(e) The sale, purchase, or trade of a drug, an offer to sell, purchase, or trade a drug, or the dispensing of a drug under a valid prescription.
(f) The sale, purchase, or trade of a drug or the offer to sell, purchase, or trade a drug by hospitals or health care entities owned or operated by Federal, State, or local governmental units to other Federal, State, or local governmental units.

§ 203.23 Returns.

The return of a prescription drug purchased by a hospital or health care entity or acquired at a reduced price by or donated to a charitable institution is exempt from the prohibitions in § 203.20, provided that:
(a) The hospital, health care entity, or charitable institution documents the return by filling out a credit memo specifying:
(1) The name and address of the hospital, health care entity, or charitable institution;
(2) The name and address of the manufacturer or wholesale distributor from which it was acquired;
(3) The product name and lot or control number;
(4) The quantity returned; and
(5) The date of the return.
(b) The hospital, health care entity, or charitable institution forwards a copy of each credit memo to the manufacturer and retains a copy of each credit memo for its records;
(c) Any drugs returned to a manufacturer or wholesale distributor are kept under proper conditions for storage, handling, and shipping, and written documentation showing that proper conditions were maintained is provided to the manufacturer or wholesale distributor to which the drugs are returned.

Subpart D—Samples

§ 203.30 Sample distribution by mail or common carrier.

(a) Requirements for drug sample distribution by mail or common carrier.
A manufacturer or authorized distributor of record may distribute a drug sample to a practitioner licensed to prescribe the drug that is to be sampled or, at the written request of a licensed practitioner, to the pharmacy of a hospital or other health care entity, by mail or common carrier, provided that:
(1) The licensed practitioner executes and submits a written request to the manufacturer or authorized distributor of record, as set forth in paragraph (b) of this section, before the delivery of the drug sample;
(2) The manufacturer or authorized distributor of record verifies with the appropriate State authority that the practitioner requesting the drug sample is licensed or authorized under State law to prescribe the drug product;
(3) The recipient executes a written receipt, as set forth in paragraph (c) of this section, when the drug sample is delivered; and
(4) The receipt is returned to the manufacturer or distributor from which the drug sample was received.

(b) Contents of the written request form for delivery of samples by mail or common carrier.
(1) A written request for a drug sample to be delivered by mail or common carrier to a licensed practitioner is required to contain the following:
(i) The name, address, professional title, and signature of the practitioner making the request;
(ii) The practitioner’s State license or authorization number or, where a scheduled drug product is requested, the practitioner’s Drug Enforcement Administration number.
(iii) The proprietary or established name and the strength of the drug sample requested;
(iv) The quantity requested;
(v) The name of the manufacturer and the authorized distributor of record, if the drug sample is requested from an authorized distributor of record; and
(vi) The date of the request.
(2) A written request for a drug sample to be delivered by mail or common carrier to the pharmacy of a hospital or other health care entity is required to contain, in addition to all of the information in paragraph (b)(l) of this section, the name and address of the pharmacy of the hospital or other health care entity to which the drug sample is to be delivered.

(c) Contents of the receipt to be completed upon delivery of a drug sample.
The receipt is to be on a form designated by the manufacturer or distributor, and is required to contain the following:
(1) If the drug sample is delivered to the licensed practitioner who requested it, the receipt is required to contain the name, address, professional title, and signature of the practitioner or the practitioner’s designee who acknowledges delivery of the drug sample; the proprietary or established name and strength of the drug sample and the quantity of the drug sample delivered; and the date of the delivery.
(2) If the drug sample is delivered to the pharmacy of a hospital or other health care entity at the request of a licensed practitioner, the receipt is required to contain the name and address of the requesting licensed practitioner; the name and address of the hospital or health care entity pharmacy designated to receive the drug sample; the name, address, professional title, and signature of the person acknowledging delivery of the drug sample.
sample; the proprietary or established name and strength of the drug sample; the quantity of the drug sample delivered; and the date of the delivery.

§ 203.31 Sample distribution by means other than mail or common carrier (direct delivery by a representative or detailer).

(a) Requirements for drug sample distribution by means other than mail or common carrier. A manufacturer or authorized distributor of record may distribute by means other than mail or common carrier, by a representative or detailer, a drug sample to a practitioner licensed to prescribe the drug to be sampled or, at the written request of such a licensed practitioner, to the pharmacy of a hospital or other health care entity, provided that:

(1) The manufacturer or authorized distributor of record receives from the licensed practitioner a written request signed by the licensed practitioner before the delivery of the drug sample;

(2) The manufacturer or authorized distributor of record verifies with the appropriate State authority that the practitioner requesting the drug sample is licensed or authorized under State law to prescribe the drug product;

(3) A receipt is signed by the recipient, as set forth in paragraph (c) of this section, when the drug sample is delivered;

(4) The receipt is returned to the manufacturer or distributor; and

(5) The requirements of paragraphs (d) through (e) of this section are met.

(b) Contents of the written request forms for delivery of samples by a representative. (1) A written request for delivery of a drug sample by a representative to a licensed practitioner is required to contain the following:

(i) The name, address, professional title, and signature of the practitioner requesting the sample;

(ii) The practitioner’s State license or authorization number, or, where a scheduled drug product is requested, the practitioner’s Drug Enforcement Administration number;

(iii) The proprietary or established name and the strength of the drug sample requested;

(iv) The quantity requested;

(v) The name of the manufacturer and the authorized distributor of record, if the drug sample is requested from an authorized distributor of record; and

(vi) The date of the request.

(2) A written request for delivery of a drug sample by a representative to the pharmacy of a hospital or other health care entity is required to contain, in addition to the information in paragraph (b) of this section, the name and address of the pharmacy of the hospital or other health care entity to which the drug sample is to be delivered.

(c) Contents of the receipt to be completed upon delivery of a drug sample. The receipt is to be on a form designated by the manufacturer or distributor, and is required to contain the following:

(1) If the drug sample is received at the address of the licensed practitioner who requested it, the receipt is required to contain the name, address, professional title, and signature of the practitioner or the practitioner’s designee who acknowledges delivery of the drug sample; the proprietary or established name and strength of the drug sample; the quantity of the drug sample delivered; and the date of the delivery.

(2) If the drug sample is received by the pharmacy of a hospital or other health care entity at the request of a licensed practitioner, the receipt is required to contain the name and address of the requesting licensed practitioner; the name and address of the hospital or health care entity pharmacy designated to receive the drug sample; the name, address, professional title, and signature of the person acknowledging delivery of the drug sample; the proprietary or established name and strength of the drug sample; the quantity of the drug sample delivered; and the date of the delivery.

(d) Inventory and reconciliation of drug samples of manufacturers’ and distributors’ representatives. Each drug manufacturer or authorized distributor of record that distributes drug samples by means of representatives shall conduct, at least annually, a complete and accurate physical inventory of all drug samples. All drug samples in the possession or control of each manufacturer’s and distributor’s representatives are required to be inventoried and the results of the inventory are required to be recorded in an inventory record, as specified in paragraph (d)(1) of this section. In addition, manufacturers and distributors shall reconcile the results of the physical inventory with the most recently completed prior physical inventory and create a report documenting the reconciliation process, as specified in paragraph (d)(2) of this section.

(1) The inventory record is required to identify all drug samples in a representative’s stock by the proprietary or established name, dosage strength, and number of units.

(2) The reconciliation report is required to include:

(i) The inventory record for the most recently completed prior inventory;

(ii) A record of each drug sample shipment received since the most recently completed prior inventory, including the sender and date of the shipment, and the proprietary or established name, dosage strength, and number of sample units received;

(iii) A record of drug sample distributions since the most recently completed inventory showing the name and address of each recipient of each sample unit shipped, the date of the shipment, and the proprietary or established name, dosage strength, and number of sample units shipped. For the purposes of this paragraph and paragraph (d)(2)(v) of this section, “distributions” includes distributions to health care practitioners or designated hospital or health care entity pharmacies, transfers or exchanges with other firm representatives, returns to the manufacturer or authorized distributor, destruction of drug samples by a sales representative, and other types of drug sample dispositions. The specific type of distribution must be specified in the record;

(iv) A record of drug sample thefts or significant losses reported by the representative since the most recently completed prior inventory, including the approximate date of the occurrence and the proprietary or established name, dosage strength, and number of sample units stolen or lost; and

(v) A record summarizing the information required by paragraphs (d)(2)(ii) through (d)(2)(iv) of this section. The record must show, for each type of sample unit (i.e., sample units having the same established or proprietary name and dosage strength), the total number of sample units received, distributed, lost, or stolen since the most recently completed prior inventory. For example, a typical entry in this record may read “50 units risperidone (1 mg) returned to manufacturer.”

(3) Each drug manufacturer or authorized distributor of record shall take appropriate internal control measures to guard against error and possible fraud in the conduct of the physical inventory and reconciliation, and in the preparation of the inventory record and reconciliation report.

(4) A manufacturer or authorized distributor of record shall carefully evaluate any apparent discrepancy or significant loss revealed through the inventory and reconciliation process and shall fully investigate any such discrepancy or significant loss that cannot be justified.
The natural text is as follows:

(e) Lists of manufacturers’ and distributors’ representatives. Each drug manufacturer or authorized distributor of record who distributes drug samples by means of representatives shall maintain a list of the names and addresses of its representatives who distribute drug samples and of the sites where drug samples are stored.

§ 203.32 Drug sample storage and handling requirements.

(a) Storage and handling conditions. Manufacturers, authorized distributors of record, and their representatives shall store and handle all drug samples under conditions that will maintain their stability, integrity, and effectiveness and ensure that the drug samples are free of contamination, deterioration, and adulteration.

(b) Compliance with compendial and labeling requirements. Manufacturers, authorized distributors of record, and their representatives can generally comply with this section by following the compendial and labeling requirements for storage and handling of a particular prescription drug in handling samples of that drug.

§ 203.33 Drug sample forms.

A sample request or receipt form may be delivered by mail, common carrier, or private courier or may be transmitted photographically or electronically (i.e., by telephoto, radiophoto, facsimile transmission (FAX), xerography, or electronic data transfer) or by any other system, provided that the method or transmission meets the security requirements set forth in §203.60(c).

§ 203.34 Policies and procedures; administrative systems.

Each manufacturer or authorized distributor of record that distributes drug samples shall establish, maintain, and adhere to written policies and procedures describing its administrative systems for the following:

(a) Distributing drug samples by mail or common carrier, including methodology for reconciliation of requests and receipts;

(b) Distributing drug samples by means other than mail or common carrier including the methodology for:

(1) Reconciling requests and receipts, identifying patterns of nonresponse, and the manufacturer’s or distributor’s response when such patterns are found;

(2) Conducting the annual physical inventory and preparation of the reconciliation report;

(c) Implementing a sample distribution security and audit system, including conducting random and for-cause audits of sales representatives by personnel independent of the sales force; and

(d) Identifying any significant loss of drug samples and notifying FDA of the loss; and

(e) Storage of drug samples by representatives.

§ 203.35 Standing requests.

Manufacturers or authorized distributors of record shall not distribute drug samples on the basis of open-ended or standing requests, but shall require separate written requests for each drug sample or group of samples. An arrangement by which a licensed practitioner requests in writing that a specified number of drug samples be delivered over a period of not more than 6 months, with the actual delivery dates for parts of the order to be set by subsequent oral communication or electronic transmission, is not considered to be a standing request.

§ 203.36 Fulfillment houses, shipping and mailing services, comarketing agreements, and third-party recordkeeping.

(a) Responsibility for creating and maintaining forms, reports, and records. Any manufacturer or authorized distributor of record that uses a fulfillment house, shipping or mailing service, or other third party, or engages in a comarketing agreement with another manufacturer or distributor to distribute drug samples or to meet any of the requirements of PDMA, PDA, or this part, remains responsible for creating and maintaining all requests, receipts, forms, reports, and records required under PDMA, PDA, and this part.

(b) Responsibility for producing requested forms, reports, or records. A manufacturer or authorized distributor of record that contracts with a third party to maintain some or all of its records shall produce requested forms, reports, records, or other required documents within 2 business days of a request by an authorized representative of FDA or another Federal, State, or local regulatory or law enforcement official.

§ 203.37 Investigation and notification requirements.

(a) Investigation of falsification of drug sample records. A manufacturer or authorized distributor of record that has reason to believe that any person has falsified drug sample requests, receipts, or records, or is diverting drug samples, shall:

(1) Notify FDA, by telephone or in writing, within 5 working days;

(2) Immediately initiate an investigation; and

(3) Provide FDA with a complete written report, including the reason for and the results of the investigation, not later than 30 days after the date of the initial notification.

(b) Significant loss or known theft of drug samples. A manufacturer or authorized distributor of record that distributes drug samples or a charitable institution that receives donated drug samples from a licensed practitioner shall:

(1) Notify FDA, by telephone or in writing, within 5 working days of becoming aware of a significant loss or known theft;

(2) Immediately initiate an investigation into the significant loss or known theft; and

(3) Provide FDA with a complete written report, including the reason for and the results of the investigation, not later than 30 days after the date of the initial notification in paragraph (b)(1) of this section.

(c) Conviction of a representative.

(1) A manufacturer or authorized distributor of record that distributes drug samples shall notify FDA, by telephone or in writing, within 30 days of becoming aware of the conviction of one or more of its representatives for a violation of section 503(c)(1) of the act or any State law involving the sale, purchase, or trade of a drug sample or the offer to sell, purchase, or trade a drug sample.

(2) A manufacturer or authorized distributor of record shall provide FDA with a complete written report not later than 30 days after the date of the initial notification.

(d) Selection of individual responsible for drug sample information. A manufacturer or authorized distributor of record that distributes drug samples shall inform FDA in writing within 30 days of selecting the individual responsible for responding to a request for information about drug samples of that individual’s name, business address, and telephone number.

(e) Whom to notify at FDA.

Notifications and reports concerning prescription human drugs shall be made to the Division of Prescription Drug Compliance and Surveillance (HFD–330), Office of Compliance, Center for Drug Evaluation and Research, Food and Drug Administration, 7520 Standish Pl., Rockville, MD 20855. Notifications and reports concerning prescription human biological products shall be made to the Division of Inspections and Surveillance (HFM–650), Office of Compliance, Center for Biologics.
§ 203.38 Sample lot or control numbers; labeling of sample units.

(a) Lot or control number required on drug sample labeling and sample unit label. The manufacturer or authorized distributor of record of a drug sample shall include on the label of the sample unit and on the outside container or packaging of the sample unit, if any, an identifying lot or control number that will permit the tracking of the distribution of each drug sample unit.

(b) Records containing lot or control numbers required for all drug samples distributed. A manufacturer or authorized distributor of record shall maintain for all samples distributed records of drug sample distribution containing lot or control numbers that are sufficient to permit the tracking of sample units to the point of the licensed practitioner.

(c) Labels of sample units. Each sample unit shall bear a label that clearly denotes its status as a drug sample, e.g., “sample,” “not for sale,” “professional courtesy package.”

(1) A drug that is labeled as a drug sample is deemed to be a drug sample within the meaning of the act.

(2) A drug product dosage unit that bears an imprint identifying the dosage form as a drug sample is deemed to be a drug sample.

(3) Notwithstanding paragraphs (c)(1) and (c)(2) of this section, any article that is a drug sample as defined in section 503(c)(1) of the act and § 203.3(i) that fails to bear the label required in this paragraph (c) is a drug sample.

§ 203.39 Donation of drug samples to charitable institutions.

A charitable institution may receive a drug sample donated by a licensed practitioner or another charitable institution for dispensing to a patient of the charitable institution, or donate a drug sample to another charitable institution for dispensing to its patients, provided that the following requirements are met:

(a) A drug sample donated by a licensed practitioner or donating charitable institution shall be received by a charitable institution in its original, unopened packaging with its labeling intact.

(b) Delivery of a donated drug sample to a recipient charitable institution shall be completed by mail or common carrier. A collection by an authorized agent or employee of the recipient charitable institution, or personal delivery by a licensed practitioner or an agent or employee of the donating charitable institution. Donated drug samples shall be placed by the donor in a sealed carton for delivery to or collection by the recipient charitable institution.

(c) A donated drug sample shall not be dispensed to a patient or be distributed to another charitable institution until it has been examined by a licensed practitioner or registered pharmacist at the recipient charitable institution to confirm that the donation record accurately describes the drug sample delivered and that no drug sample is adulterated or misbranded for any reason, including, but not limited to, the following:

(1) The drug sample is out of date;

(2) The labeling has become mutilated, obscured, or detached from the drug sample packaging;

(3) The drug sample shows evidence of having been stored or shipped under conditions that might adversely affect its stability, integrity, or effectiveness;

(4) The drug sample is for a prescription drug product that has been recalled or is no longer marketed; or

(5) The drug sample is otherwise possibly contaminated, deteriorated, or adulterated.

(d) The recipient charitable institution shall dispose of any drug sample found to be unsuitable by destroying it or by returning it to the manufacturer. The charitable institution shall maintain complete records of the disposition of all destroyed or returned drug samples.

(e) The recipient charitable institution shall prepare at the time of collection or delivery of a drug sample a complete and accurate donation record, a copy of which shall be retained by the recipient charitable institution for at least 3 years, containing the following information:

(1) The name, address, and telephone number of the licensed practitioner (or donating charitable institution);

(2) The manufacturer, brand name, quantity, and lot or control number of the drug sample donated; and

(3) The date of the donation.

(f) Each recipient charitable institution shall maintain complete and accurate records of donation, receipt, inspection, inventory, dispensing, redistribution, destruction, and returns sufficient for complete accountability and auditing of drug sample stocks.

(g) Each recipient charitable institution shall conduct, at least annually, an inventory of prescription drug sample stocks and shall prepare a report reconciling the results of each inventory with the most recent prior inventory. Drug sample inventory discrepancies and reconciliation problems shall be investigated by the charitable institution and reported to FDA.

(b) A recipient charitable institution shall store drug samples under conditions that will maintain the sample’s stability, integrity, and effectiveness, and will ensure that the drug samples will be free of contamination, deterioration, and adulteration.

(i) A charitable institution shall notify FDA within 5 working days of becoming aware of a significant loss or known theft of prescription drug samples.

Subpart E—Wholesale Distribution

§ 203.50 Requirements for wholesale distribution of prescription drugs.

(a) Identifying statement for sales by unauthorized distributors. Before the completion of any wholesale distribution by a wholesale distributor of a prescription drug for which the seller is not an authorized distributor of record to another wholesale distributor or retail pharmacy, the seller shall provide to the purchaser a statement identifying each prior sale, purchase, or trade of such drug. This identifying statement shall include:

(1) The proprietary and established name of the drug;

(2) Dosage;

(3) Container size;

(4) Number of containers;

(5) The drug’s lot or control number(s);

(6) The business name and address of all parties to each prior transaction involving the drug, starting with the manufacturer; and

(7) The date of each previous transaction.

(b) The drug origin statement is subject to the record retention requirements of § 203.60 and must be retained by all wholesale distributors involved in the distribution of the drug product, whether authorized or unauthorized, for 3 years.

(c) Identifying statement not required when additional manufacturing processes are completed. A manufacturer that subjects a drug to any additional manufacturing processes to produce a different drug is not required to provide a purchaser a statement identifying the previous sales of the component drug or drugs.

(d) List of authorized distributors of record. Each manufacturer shall maintain at the corporate offices a current written list of all authorized distributors of record.

(1) Each manufacturer’s list of authorized distributors of record shall specify whether each distributor listed...
Section 203.60 Request and receipt forms, reports, and records

(a) Use of electronic records, electronic signatures, and handwritten signatures executed to electronic records.

(1) Provided the requirements of part 11 of this chapter are met, electronic records, electronic signatures, and handwritten signatures executed to electronic records may be used as an alternative to paper records and handwritten signatures executed on paper to meet any of the record and signature requirements of PDMA, PDA, or this part.

(2) Combinations of paper records and electronic records, electronic records and handwritten signatures executed on paper, or paper records and electronic signatures or handwritten signatures executed to electronic records, may be used to meet any of the record and signature requirements of PDMA, PDA, or this part, provided that:

(i) The requirements of part 11 of this chapter are met for the electronic records, electronic signatures, or handwritten signatures executed to electronic records; and

(ii) A reasonably secure link between the paper-based and electronic components exists such that the combined records and signatures are trustworthy and reliable, and to ensure that the signer cannot readily repudiate the signed records as not genuine.

(3) For the purposes of this paragraph (a), the phrase “record and signature requirements of PDMA, PDA, or this part” includes drug sample request and receipt forms, reports, records, and other documents, and their associated signatures required by PDMA, PDA, and this part.

(b) Maintenance of request and receipt forms, reports, records, and other documents created on paper. Request and receipt forms, reports, records, and other documents created on paper may be maintained on paper or by photographic imaging (i.e., photocopies or microfiche), provided that the security and authentication requirements described in paragraph (c) of this section are followed. Where a required document is created on paper and electronically scanned into a computer, the resulting record is an electronic record that must meet the requirements of part 11 of this chapter.

(c) Security and authentication requirements for request and receipt forms, reports, records, and other documents created on paper. A request or receipt form, report, record, or other document, and any signature appearing thereon, that is created on paper and that is maintained by photographic imaging, or transmitted electronically (i.e., by facsimile) shall be maintained or transmitted in a form that provides reasonable assurance of being:

(1) Resistant to tampering, revision, modification, fraud, unauthorized use, or alteration;

(2) Preserved in accessible and retrievable fashion; and

(3) Available to permit copying for purposes of review, analysis, verification, authentication, and reproduction by the person who executed the form or created the record, by the manufacturer or distributor, and by authorized personnel of FDA and other regulatory and law enforcement agencies.

(d) Retention of request and receipt forms, reports, lists, records, and other documents. Any person required to create or maintain reports, lists, or other records under PDMA, PDA, or this part, including records relating to the distribution of drug samples, shall retain them for at least 3 years after the date of their creation.

(e) Availability of request and receipt forms, reports, lists, and records. Any person required to create or maintain request and receipt forms, reports, lists, or other records under PDMA, PDA, or this part shall make them available, upon request, in a form that permits copying or other means of duplication, to FDA or other Federal, State, or local regulatory and law enforcement officials for review and reproduction. The records shall be made available within 2 business days of a request.

Part 205—Rewards

§ 205.70 Application for a reward.

(a) Reward for providing information leading to the institution of a criminal proceeding against, and conviction of, a person for the sale, purchase, or trade of a drug sample. A person who provides information leading to the institution of a criminal proceeding against, and conviction of, a person for the sale, purchase, or trade of a drug sample, or the offer to sell, purchase, or trade a drug sample, in violation of section 503(c)(1) of the act, is entitled to one-half the criminal fine imposed and collected for such violation, but not more than $125,000.

(b) Procedure for making application for a reward for providing information leading to the institution of a criminal proceeding against, and conviction of, a person for the sale, purchase, or trade of a drug sample. A person who provides information leading to the institution of a criminal proceeding against, and conviction of, a person for the sale, purchase, or trade of a drug sample, or the offer to sell, purchase, or trade a drug sample, in violation of section 503(c)(1) of the act, may apply for a reward by making written application to:

(1) Director, Office of Compliance (HFD–300), Center for Drug Evaluation and Research, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855; or

(2) Director, Office of Compliance and Biologics Quality (HFM–600), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, as appropriate.

PART 205—GUIDELINES FOR STATE LICENSING OF WHOLESALE PRESCRIPTION DRUG DISTRIBUTORS

2. The authority citation for 21 CFR part 205 continues to read as follows:


3. Section 205.3 is amended by adding paragraphs (f)(9), (f)(10), and (h) to read as follows:

§ 205.3 Definitions.

* * * * *

(f) * * *

(9) Drug returns, when conducted by a hospital, health care entity, or charitable institution in accordance with § 203.23 of this chapter; or

(10) The sale of minimal quantities of drugs by retail pharmacies to licensed practitioners for office use.

* * * * *

(h) Health care entity means any person that provides diagnostic, medical, surgical, or dental treatment, or chronic or rehabilitative care, but does not include any retail pharmacy or any wholesale distributor. A person cannot simultaneously be a “health care entity” and a retail pharmacy or wholesale distributor.

4. Section 205.50 is amended by revising paragraph (f)(2) to read as follows:

§ 205.50 Application for a license.

(f) Application for a license.

(2) Application fee. Any person who applies for a license shall pay an application fee of $500. The fee is nonrefundable. Application fees may be adjusted from time to time by the Secretary, on the basis of the cost of administering the Act and this chapter.

* * * * *
§ 205.50 Minimum requirements for the storage and handling of prescription drugs and for the establishment and maintenance of prescription drug distribution records.

(f) * * * * *

(2) Inventories and records shall be made available for inspection and photocopying by authorized Federal, State, or local law enforcement agency officials for a period of 3 years after the date of their creation.


Margaret M.Dotzel,
Acting Associate Commissioner for Policy.

[FR Doc. 99–30954 Filed 11–30–99; 12:38 pm]

BILLING CODE 4160–01–F

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

Determination of Tax Liability

CFR Correction

In Title 26 of the Code of Federal Regulations, part 1 (§§ 1.641 to 1.850), revised as of April 1, 1999, page 293, in §1.704–1(b)(0), in the table in the first column, under “Section” the first, second, fourth and fifth lines respectively should read, 1.704–1(b)(0), 1.704–1(b)(1), 1.704–1(b)(1)(ii) and 1.704–1(b)(1)(iii).


[FR Doc. 99–55540 Filed 12–2–99; 8:45 am]

BILLING CODE 1505–01–D

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 20

[TO 8846]

RIN 1545–AV45

Deductions for Transfers for Public, Charitable, and Religious Uses; In General Marital Deduction; Valuation of Interest Passing to Surviving Spouse

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final regulations.

SUMMARY: This document contains final regulations relating to the effect of certain administration expenses on the valuation of property that qualifies for either the estate tax marital deduction under section 2056 of the Internal Revenue Code or the estate tax charitable deduction under section 2055. The regulations distinguish between estate transmission expenses, which reduce the value of property for marital and charitable deduction purposes, and estate management expenses, which generally do not reduce the value of property for these purposes.

EFFECTIVE DATES: These regulations are effective on December 3, 1999.

FOR FURTHER INFORMATION CONTACT: Deborah Ryan, (202) 622–3090 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

On December 16, 1998, the Treasury Department and the IRS published in the Federal Register (63 FR 69248) a notice of proposed rulemaking (REG–114663–97) relating to the effect of certain administration expenses on the valuation of property which qualifies for the estate tax marital or charitable deduction. The proposed regulations were issued in response to the decision of the Supreme Court of the United States in Commissioner v. Estate of Hubert, 520 U.S. 93 (1997) (1997–2 C.B. 231). Written comments responding to the notice of proposed rulemaking were received, and a public hearing was held on April 21, 1999, at which time oral testimony was presented. This Treasury decision adopts final regulations with respect to the notice of proposed rulemaking. A summary of the principal comments received and revisions made in response to those comments is provided below.

The proposed regulations set forth the substantive provisions as applied to the estate tax marital deduction in §20.2056(b)–4(a). For the estate tax charitable deduction, the proposed regulations (under §20.2055–1(d)(6)) merely cross-reference the rules for the marital deduction.

Several commentators suggested that the regulations under section 2055 should contain specific rules relating to the charitable deduction, rather than just a cross-reference. The Treasury and the IRS agree with this suggestion. The final regulations contain rules under §20.2055–3 specifically addressing the effect of administration expenses on the valuation of property when all or a portion of the interests in property qualify for the estate tax charitable deduction.

Several commentators stated that the distinction between estate transmission expenses and estate management expenses was not clearly made in the proposed regulations and requested more concrete definitions of each type of expense. In response to these comments, the final regulations characterize estate transmission expenses as those expenses that would not have been incurred except for the decedent’s death. Although the amount of these expenses cannot be calculated with any degree of certainty on the date of the decedent’s death, they are expenses that are incurred because of the decedent’s death. Estate management expenses, on the other hand, are characterized in the final regulations as expenses that would be incurred with respect to the property even if the decedent had not died; that is, expenses incurred in investing, maintaining, and preserving the property. These expenses are those expenses that typically would have been incurred with respect to the property by the decedent before death or by the beneficiaries had they received the property on the date of death without any intervening period of administration. In order to be certain that all expenses are classified as either transmission expenses or management expenses, transmission expenses are defined to include all expenses that are not management expenses.

Three commentators stated that the different treatment accorded to estate transmission expenses and estate management expenses under the proposed regulations creates a new federal standard for allocating expenses that may be contrary to the manner in which the expenses must be charged under state law. However, the Treasury and the IRS believe that the allocation of administration expenses based on the distinction between transmission and management expenses provides the most accurate measure of the value of the property which passes to the surviving spouse or to the charity at the moment of the decedent’s death for federal estate tax marital and charitable deduction purposes. Transmission expenses that are charged to the property passing to the surviving spouse or to the charity reduce the amount of that property as of the date of the decedent’s death because the expenses, as well as the transfer to the surviving spouse or to charity, are a consequence of, and arise as a result of, the decedent’s death. In contrast, management expenses do not generally...
reduce the amount of the property passing from the decedent as of the date of the decedent’s death because these expenses are incurred in producing income and preserving and maintaining the property between the date of the decedent’s death and the date of distribution. These expenses are the ongoing, year-to-year expenses incurred in the investment, preservation, and maintenance of property by property owners.

In response to other comments, the final regulations illustrate the application of these rules to pecuniary bequests to the surviving spouse. If, under the terms of the governing instrument or applicable local law, the recipient of a pecuniary bequest is not entitled to income earned until distribution, the income is not included in the definition of the marital or charitable share. Thus, the amount of the property passing to the surviving spouse or charity for which a marital or charitable deduction is allowable will not be reduced even if estate transmission or estate management expenses are paid out of the income earned by assets that will be used to satisfy the pecuniary bequest.

Two commentators requested guidance in applying the regulations to estates that are intended to be nontaxable. Accordingly, the final regulations add two examples, one involving a formula designed to produce zero estate taxes and the other involving a pecuniary bequest designed to utilize the applicable exclusion amount under section 2010.

Many of the comments concerned the special rule of § 20.2056(b)(4)(ii) of the proposed regulations. Under the special rule, the value of the deductible property interest is not increased as a result of the decrease in the federal estate tax liability that is attributable to the deduction of estate management expenses as expenses of administration under section 2053 on the federal estate tax return. A similar rule would have applied for purposes of the estate tax charitable deduction.

Several of these commentators argued that the special rule is inconsistent with sections 2056(a) and 2056(c), because the value of the property passing to the surviving spouse or charity should be reduced only by the estate taxes actually paid. Thus, an estate should be permitted the full benefit of deducting management expenses on the federal estate tax return, including an increase to the marital or charitable deduction based on the resultant decrease in tax payable from the marital or charitable share.

Conversely, other commentators asserted that the special rule does not conform with section 2056(b)(9). Section 2056(b)(9) provides that nothing in section 2056 or any other estate tax provision shall allow the value of any interest in property to be deducted for federal estate tax purposes more than once with respect to the same decedent. These commentators pointed out that if estate management expenses paid from the marital or charitable share are deducted on the federal estate tax return, and no reduction is made to the allowable amount of the marital or charitable deduction, then the same property interest is deducted twice in violation of section 2056(b)(9).

After considering these comments, the Treasury and the IRS have eliminated the special rule of the proposed regulations. The final regulations provide that estate management expenses attributable to, and payable from, the property interest passing to the surviving spouse or charity do not reduce the value of the property interest. However, pursuant to section 2056(b)(9), the allowable amount of the marital or charitable deduction is reduced by the amount of these management expenses if they are deducted on the Federal estate tax return.

The Treasury and the IRS believe that the principles which apply for determining the value of the marital and charitable deductions should also apply for determining the value of property that passes from one decedent to another when calculating the amount of the credit for tax on prior transfers under section 2013. Therefore, the final regulations amend § 20.2013–4 by adding a cross reference to § 20.2056(b)–4(d).

Effective Dates

The regulations under sections 2055 and 2056 are applicable to estates of decedents dying on or after December 3, 1999. The regulations under section 2013 are applicable to transfers from estates of decedents dying on or after December 3, 1999.

Effect on Other Documents

The following publications are obsolete as of December 3, 1999.

<table>
<thead>
<tr>
<th>Publication</th>
<th>Date</th>
<th>C.B. Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rev. Rul. 73–98</td>
<td>1973–1</td>
<td>407</td>
</tr>
<tr>
<td>Rev. Rul. 80–159</td>
<td>1980–1</td>
<td>206</td>
</tr>
<tr>
<td>Rev. Rul. 93–48</td>
<td>1993–2</td>
<td>270</td>
</tr>
</tbody>
</table>

Special Analyses

This rule is not a significant regulatory action as defined in Executive Order 12866. Therefore, a regulatory assessment is not required. It also has been determined that section 553(b) of the Administrative Procedure Act (5 U.S.C. chapter 5) does not apply to these regulations, and, because the regulations do not impose a collection of information on small entities, the Regulatory Flexibility Act (5 U.S.C. chapter 6) does not apply. Pursuant to section 7805(f) of the Internal Revenue Code, these regulations were submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on their impact on small business.

Drafting information. The principal author of these regulations is Deborah Ryan, Office of the Assistant Chief Counsel (Passthroughs and Special Industries). However, other personnel from the IRS and Treasury Department participated in their development.

List of Subjects in 26 CFR Part 20

Estate taxes, Reporting and recordkeeping requirements.

Amendments to the Regulations

Accordingly, 26 CFR part 20 is amended as follows:

PART 20—ESTATE TAX; ESTATES OF DECEDENTS DYING AFTER AUGUST 16, 1954

Paragraph 1. The authority citation for part 20 continues to read in part as follows:

Authority: 26 U.S.C. 7805 * * *

Par. 2. Section 20.2013–4 is amended by:

1. Removing “and” at the end of paragraph (b)(2).

2. Redesignating paragraph (b)(3) as paragraph (b)(4).

3. Adding a new paragraph (b)(3).

The addition reads as follows:


(b) * * *

(3)(i) By the amount of administration expenses in accordance with the principles of § 20.2056(b)–4(d).

(ii) This paragraph (b)(3) applies to transfers from estates of decedents dying on or after December 3, 1999; and

* * *

Par. 3. Section 20.2055–3 is amended by:

1. Revising the section heading.

2. Adding a paragraph heading for paragraph (a).

3. Redesignating the text of paragraph (a) following the heading and paragraphs (b) and (c) as paragraph (a)(1) and paragraphs (a)(2) and (a)(3), respectively.

4. Adding a new paragraph (b).
§ 20.2055-3 Effect of death taxes and administration expenses.

(a) Death taxes. * * *

(b) Administration expenses—(1) Definitions—(i) Management expenses. Estate management expenses are expenses that are incurred in connection with the investment of estate assets or with their preservation or maintenance during a reasonable period of administration. Examples of these expenses could include investment advisory fees, stock brokerage commissions, custodial fees, and interest.

(ii) Transmission expenses. Estate transmission expenses are expenses that would not have been incurred but for the decedent’s death and the consequent necessity of collecting the decedent’s assets, paying the decedent’s debts and death taxes, and distributing the decedent’s property to those who are entitled to receive it. Estate transmission expenses include any administration expense that is not a management expense. Examples of these expenses could include executor commissions and attorney fees (except to the extent of commissions or fees specifically related to investment, preservation, and maintenance of the assets), probate fees, expenses incurred in construction proceedings and defending against will contests, and appraisal fees.

(iii) Charitable share. The charitable share is the property or interest in property that passed from the decedent for which a deduction is allowable under section 2055(a) with respect to all or part of the property interest. The charitable share includes, for example, bequests to charitable organizations and bequests to a charitable lead unitrust or annuity trust, a charitable remainder unitrust or annuity trust, and a pooled income fund, described in section 2055(e)(2). The charitable share also includes the income produced by the property or interest in property during the period of administration if the income, under the terms of the governing instrument or applicable local law, is payable to the charitable organization or is to be added to the principal of the property interest passing in whole or in part to the charitable organization.

(2) Effect of transmission expenses. For purposes of determining the charitable deduction, the value of the charitable share shall be reduced by the amount of the estate management expenses attributable to and paid from the charitable share. Pursuant to section 2056(b)(9), however, the amount of the allowable charitable deduction shall be reduced by the amount of any such management expenses that are deducted under section 2053 on the decedent’s federal estate tax return.

4. Effect of management expenses not attributable to the charitable share. For purposes of determining the charitable deduction, the value of the charitable share shall be reduced by the amount of the estate management expenses paid from the charitable share but attributable to a property interest not included in the charitable share.

(5) Example. The following example illustrates the application of this paragraph (b):

Example. The decedent, who died in 2000, leaves his residuary estate, after the payment of debts, expenses, and estate taxes, to a charitable remainder unitrust that satisfies the requirements of section 664(d). During the period of administration, the estate incurs estate transmission expenses of $400,000. The residue of the estate (the charitable share) must be reduced by the $400,000 of transmission expenses and by the Federal and State estate taxes before the present value of the remainder interest passing to the charitable remainder trust is determined in accordance with the provisions of §1.664-4 of this chapter. Because the estate taxes are payable out of the residue, the computation of the estate taxes and the allowable charitable deduction are interrelated. See paragraph (a)(2) of this section.

(ii) Transmission expenses. Estate transmission expenses are expenses that would not have been incurred but for the decedent’s death and the consequent necessity of collecting the decedent’s assets, paying the decedent’s debts and death taxes, and distributing the decedent’s property to those who are entitled to receive it. Estate transmission expenses include any administration expense that is not a management expense. Examples of these expenses could include executor commissions and attorney fees (except to the extent of commissions or fees specifically related to investment, preservation, and maintenance of the assets), probate fees, expenses incurred in construction proceedings and defending against will contests, and appraisal fees.

(iii) Marital share. The marital share is the property or interest in property that passed from the decedent for which a deduction is allowable under section 2056(a). The marital share includes the income produced by the property or interest in property during the period of administration if the income, under the terms of the governing instrument or applicable local law, is payable to the surviving spouse or is to be added to the principal of the property interest passing to, or for the benefit of, the surviving spouse.

(2) Effect of transmission expenses. For purposes of determining the marital deduction, the value of the marital share shall be reduced by the amount of the estate transmission expenses paid from the marital share.

(3) Effect of management expenses attributable to the marital share. For purposes of determining the marital deduction, the value of the marital share shall not be reduced by the amount of the estate management expenses attributable to and paid from the marital share. Pursuant to section 2056(b)(9), however, the amount of the allowable marital deduction shall be reduced by the amount of any such management expenses that are deducted under section 2053 on the decedent’s Federal estate tax return.

Par. 4. Section 20.2056(b)–4 is amended by:

1. Removing the last two sentences of paragraph (a).

2. Redesignating paragraph (d) as paragraph (e).

3. Adding a new paragraph (d).

The addition reads as follows:

§ 20.2056(b)–4 Marital deduction; valuation of interest passing to surviving spouse.

(d) Effect of management expenses not attributable to the marital share. For purposes of determining the marital deduction, the value of the marital share shall be reduced by the amount of the estate management expenses paid from the marital share but attributable to a property interest not included in the marital share.
(5) **Examples.** The following examples illustrate the application of this paragraph (d):

**Example 1.** The decedent dies after 2006 having made no lifetime gifts. The decedent makes a bequest of ABC Corporation stock to the decedent’s child. The bequest provides that the child is to receive the income from the shares from the date of the decedent’s death. The value of the bequeathed shares on the decedent’s date of death is $3,000,000. The value of the residue of the estate is bequeathed to a trust for which the executor properly makes an election under section 2056(b)(7) to treat as qualified terminable interest property. The value of the residue on the decedent’s date of death, before the payment of administration expenses and Federal and State estate taxes, is $6,000,000. Under applicable local law, the executor has the discretion to pay all estate administration expenses from the income or principal of the residuary estate. All estate taxes are to be paid from the residue. The State estate tax equals the State death tax credit available under section 2056.

During the period of administration, the estate incurs estate transmission expenses of $400,000, which the executor charges to the residue. For purposes of determining the marital deduction, the value of the residue is reduced by the Federal and State estate taxes and by the management expenses. The management expenses reduce the value of the residue because they are charged to the property passing to the spouse even though they were incurred with respect to stock passing to the child. If the management expenses are deducted on the estate’s Federal income tax return, the marital deduction is $3,011,111 ($6,000,000 minus $400,000 management expenses and minus $2,588,889 Federal and State estate taxes). If the management expenses are deducted on the estate’s Federal estate tax return, rather than on the estate’s income tax return, the marital deduction is $3,500,000 ($6,000,000 minus $400,000 management expenses and minus $2,100,000 in Federal and State estate taxes). The marital deduction is $6,000,000 minus $400,000, which the executor charges to the residue.

**Example 2.** The facts are the same as in Example 1, except that the decedent’s will provides that the child’s trust is to be funded in accordance with section 2056(b)(7) to treat as qualified terminable interest property. The applicable credit amount against the tax was fully consumed by the decedent’s lifetime gifts. Applicable State law requires the child to pay any estate taxes attributable to the marital deduction. Pursuant to the decedent’s will, the rest of the decedent’s estate passes outright to the surviving spouse. During the period of administration, the estate incurs estate management expenses of $150,000 in connection with the property passing to the surviving spouse. The value of the property passing to the surviving spouse is $2,850,000 ($3,000,000 less $150,000). The applicable credit amount against the tax was fully consumed by the decedent’s lifetime gifts. Pursuant to the decedent’s will, the net value of the property passing to the surviving spouse is $1,657,874 ($1,800,000 minus $142,106 Federal and State estate taxes). A marital deduction is claimed for that amount, and the resulting taxable estate is $1,000,000. The applicable exclusion amount shields from Federal estate tax the entire $1,000,000 passing to the child’s trust so that the amount of Federal and State estate taxes remains zero.

**Example 3.** The decedent dies after 2006 having made no lifetime gifts. The decedent, who dies in 2006, makes a bequest of $3,000,000 to the decedent’s child. Under the terms of the decedent’s will, the rest of the decedent’s estate passes outright to the surviving spouse. During the period of administration, the estate incurs estate transmission expenses of $200,000. If the transmission expenses are deducted on the Federal estate tax return, then the formula divides the residue so that the value of the property passing to the child’s trust is $1,000,000 and the value of the property passing to the marital trust is $1,800,000. The allowable marital deduction is $1,800,000. The applicable exclusion amount shields from Federal estate tax the entire $1,000,000 passing to the child’s trust so that the amount of Federal and State estate taxes remains zero. Alternatively, if the transmission expenses are deducted on the estate’s Federal income tax return, the formula divides the residue so that the value of the property passing to the child’s trust is $800,000 and the value of the property passing to the marital trust is $2,000,000. The allowable marital deduction remains $1,800,000. The applicable exclusion amount shields from Federal estate tax the entire $800,000 passing to the child’s trust and $200,000 of the $2,000,000 passing to the marital trust so that the amount of Federal and State estate taxes remains zero.

**Example 4.** The decedent, who dies in 2000, has a gross estate of $3,000,000. Included in the gross estate are proceeds of $150,000 from a policy insuring the decedent’s life and payable to the decedent’s child as beneficiary. The applicable credit amount against the tax was fully consumed by the decedent’s lifetime gifts. Pursuant to the decedent’s will, the net value of the property passing to the surviving spouse is $2,850,000 ($3,000,000 less $150,000). The applicable credit amount against the tax was fully consumed by the decedent’s lifetime gifts. Pursuant to the decedent’s will, the net value of the property passing to the surviving spouse is $1,657,874 ($1,800,000 minus $142,106 Federal and State estate taxes).
earned by the property that will be distributed to the surviving spouse in satisfaction of the pecuniary bequest. The income earned on this property is not part of the marital share. Therefore, the allowable marital deduction is $3,000,000, unreduced by the amount of the estate transmission expenses.

(6) Effective date. The provisions of this paragraph (d) apply to estates of decedents dying on or after December 3, 1999.

Robert E. Wenzel,
Deputy Commissioner of Internal Revenue.

Approved: November 22, 1999.

Jonathan Talisman,
Acting Assistant Secretary of the Treasury.

[FR Doc. 99–31094 Filed 12–2–99; 8:45 am]

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Parts 20, 25, 301 and 602

[TD 8845]

RIN 1545–AW20

Adequate Disclosure of Gifts

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final regulations.

SUMMARY: This document contains final regulations relating to changes made to Internal Revenue Code sections 2001, 2504, and 6501 by the Taxpayer Relief Act of 1997 and the Internal Revenue Service Restructuring and Reform Act of 1998 regarding the valuation of prior gifts in determining estate and gift tax liability, and the period of limitations for assessing and collecting gift tax. These regulations are necessary because section 6501(c)(9) now requires that a gift must be adequately disclosed on a gift tax return in order to commence the running of the period of limitations on assessment with respect to the gift. Once the period of limitations expires, the amount of that gift as reported on the return may not be adjusted for purposes of determining future gift and estate tax liability. The regulations provide guidance on what constitutes adequate disclosure for purposes of the statute.

DATES: These regulations are effective December 3, 1999.

FOR FURTHER INFORMATION CONTACT: William L. Blodgett, (202) 622–3090 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Paperwork Reduction Act

The collection of information contained in these final regulations has been reviewed and approved by the Office of Management and Budget in accordance with the Paperwork Reduction Act (44 U.S.C. 3507) under control number 1545–1637. Responses to this collection of information are mandatory.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number.

The reporting burden contained in § 301.6501(c)–1(f) is reflected in the burden for Form 709, “U.S. Gift (and Generation-Skipping Transfer) Tax Return.”

Comments concerning the accuracy of this burden estimate and suggestions for reducing this burden should be sent to the Internal Revenue Service, Attn: IRS Reports Clearance Officer, OP:FS-FP, Washington, DC 20224, and to the Office of Management and Budget, Attn: Desk Officer for the Department of the Treasury, Office of Information and Regulatory Affairs, Washington, DC 20503.

Books or records relating to this collection of information must be retained as long as their contents may be material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Background

On December 22, 1998, the IRS published in the Federal Register (63 FR 70701) a notice of proposed rulemaking under sections 2001 and 2504 relating to the value of prior gifts for purposes of computing the estate and gift tax, and under section 6501 relating to the period for assessment and collection of gift tax. Written comments responding to the notice of proposed rulemaking were received and a hearing was held on April 28, 1999, at which time oral testimony was presented. This document adopts final regulations with respect to this notice of proposed rulemaking. A summary of the principal comments received and the revisions made in response to those comments is provided below.

1. Requirements for Adequate Disclosure

Under section 6501(c)(9), the period of limitations on the assessment of gift tax with respect to a gift will commence to run only if the gift is adequately disclosed on the gift tax return. The proposed regulations provide a list of information required to satisfy the adequate disclosure standard.

In general, the comments objected to the quantity, detail, and nature of the information required under the proposed regulations. In some cases, information required in the proposed regulations is not required in the final regulations. However, Treasury and the IRS continue to believe that the adequate disclosure rule was intended to afford the IRS a viable means to identify the returns that should be examined, with a minimum expenditure of resources. Further, the more complete and comprehensive the information filed with the return is, the more readily the IRS will be able to identify the returns that should not be examined, thus saving taxpayers needless expenditures of time and money.

Several commentators suggested that the language in § 301.6501–1(f)(2) of the proposed regulations imposed two requirements for adequate disclosure. That is, the taxpayer had to provide information adequate to apprise the IRS of the nature of the gift, etc. and in addition, the taxpayer had to provide the information listed in the regulation. In response to these comments, the final regulations clarify that the adequate disclosure requirement is satisfied if the information listed in the regulation is provided.

Some commentators argued that Congress intended that the new adequate disclosure requirements be the same as the existing disclosure requirements under prior section 6501(c)(9) for pre-August 5, 1997 gifts of property subject to the special valuation rules of sections 2701 and 2702. Therefore, the commentators suggested that the IRS adopt the disclosure requirements under § 301.6501(c)–1(e)(2) for transfers of those interests. This suggestion was not adopted. The IRS and Treasury believe it is necessary to expand on those disclosure requirements to address the broader range of transfers covered by the new legislation, as well as transactions and entities that may not have been prevalent when the prior regulations were promulgated.

Under the proposed regulations, if property is transferred in trust, taxpayers are required to provide a brief description of the terms of the trust. In response to comments, the final regulations provide that taxpayers may submit a complete copy of the trust document in lieu of a description of the trust terms.

The proposed regulations require the submission of a detailed description of the method used in determining the fair
market value of the property, including “any relevant financial data.”

Commentators contended that “any relevant financial data” is a subjective concept that lacks specificity. Rather, the regulations should specify exactly what financial data must be submitted, such as balance sheets, net earnings statements, etc. In response to these comments, the final regulations require that any financial data that was used in valuing the interest must be submitted. This ensures that the information requested is available and was deemed relevant by the person valuing the interest.

Several commentators expressed concern over the requirement in the proposed regulations that, if a less-than-100-percent interest in a nonactively-traded entity is transferred, the taxpayer must submit a statement regarding the fair market value of 100 percent of the entity determined without regard to any discounts. It was contended that a less-than-100-percent interest in an operating company may not be valued based on a pro rata portion of the value of 100 percent of the entity; rather the appraiser often will determine the value based on indicia other than the value of the entire entity, such as the price/earnings ratio of stock in comparable publicly-traded entities. Because the entire entity is not valued in these situations, valuing 100 percent of the entity would not be relevant. One commentator stated that this requirement would be reasonable in valuing an interest in nonactively-traded entities, such as entities holding securities or real estate, since in those cases the value of an interest in the entity would be determined based on a pro rata portion of the value of 100 percent of the entity. In response to these comments, the final regulations do not require a statement of the fair market value of 100 percent of the entity (without regard to any discounts), if the value of the interest in the entity is properly determined without using the net asset value of the entire entity. If 100 percent of the value of the entity is not disclosed, the taxpayer bears the burden of demonstrating that the fair market value of the entity is properly determined by a method other than a method based on the net value of the assets held by the entity.

The proposed regulations also require valuation information for each entity (and its assets) that is owned or controlled by the entity subject to the transfer. Comments indicated that this requirement would be difficult to satisfy, because in some cases the information would not be within the control of the taxpayer and the entity subject to the transfer would not normally be required to maintain the financial records with respect to lower-tiered entities. The comments suggested that information on the lower-tiered entities should be required only to the extent such information is essential to a reasonable appraisal of the interest transferred and is in the personal control of the taxpayer. Many commentators suggested that the regulations require the submission of only that information that a qualified and competent appraiser would use in valuing the interest. In response to these comments, the final regulations provide that the information on the lower-tiered entities must be submitted if the information is relevant and material in determining the value of the interest in the entity.

Finally, comments suggested that a properly completed appraisal would contain all the information that is material and relevant to the valuation of the transferred property and, therefore, should be sufficient to satisfy any disclosure requirement. Accordingly, under the final regulations, an appraisal satisfying specific requirements may be submitted in lieu of a detailed description of the method used to determine the fair market value and in lieu of information regarding tiered entities. The proposed regulations require a statement of relevant facts that would apprise the IRS of the nature of any potential gift tax controversy concerning the transfer, or instead of that statement, a concise description of the legal issue presented by the facts. This requirement is similar to the disclosure required to avoid the accuracy-related penalty under section 6662. It was intended to enable the IRS to easily identify issues presented so that the IRS could evaluate whether an examination is warranted during the initial review of the gift tax return. Commentators indicated that the requirement was too subjective and open-ended, since it would be difficult for a practitioner to identify or anticipate “any” potential controversy. In response to these comments, that requirement has been eliminated from the final regulations. The proposed regulations also require that the taxpayer submit a statement describing any position taken that is contrary to any temporary or final regulations or any revenue ruling. Commentators were concerned that this requirement could be interpreted as including both regulations and revenue rulings that are published after the gift tax return is filed that affect earlier IRS positions. In response to these comments, the final regulations limit the required statement to positions taken that are contrary to any proposed, temporary or final regulation, and any revenue ruling published at the time the transfer occurred.

Commentators also noted that, under the proposed regulations, if a taxpayer failed to provide, for example, one item of information, the adequate disclosure requirement would not be satisfied, regardless of the significance of the item. The comments suggested that “substantial compliance” with the requirements of the regulations or a good-faith effort to comply should be deemed actual compliance. This suggestion was not adopted in view of the difficulty in defining and illustrating what would constitute substantial compliance. However, it is not intended that the absence of any particular item or items would necessarily preclude satisfaction of the regulatory requirements, depending on the nature of the item omitted and the overall adequacy of the information provided.

In response to comments, a rule was added regarding the application of the adequate disclosure rules in the case of “split gifts” under section 2513. Under this rule, gifts attributed to the non-donor spouse are deemed to be adequately disclosed if the gifts are adequately disclosed on the return filed by the donor spouse.

2. Finality With Respect to Adequately Disclosed Gifts

Under the proposed regulations, if a transfer is adequately disclosed on the gift tax return, and the period for assessment of gift tax has expired, then the IRS is foreclosed from adjusting the value of the gift under section 2504(c) (for purposes of determining the current gift tax liability) and under section 2001(f) (for purposes of determining the estate tax liability). However, the IRS is not precluded from making adjustments involving legal issues, even if the gift was adequately disclosed. This position was based on longstanding regulations applying section 2504(c) and relevant case law.

Commentators suggested that this rule is contrary to Congressional intent in enacting section 2001(f) and amending section 2504(c) to provide a greater degree of finality with respect to the gift and estate tax statutory scheme. In response to these comments, the final regulations preclude adjustments with respect to all issues related to a gift once the gift tax statute of limitations expires with respect to that gift.

3. Non-Gift Transactions

Under the proposed regulations, a completed transfer that did not
constitute a gift would be considered adequately disclosed if the taxpayer submitted the information required for adequate disclosure and an explanation describing why the transfer was not subject to the gift tax. One commentator suggested that the adequate disclosure requirement should be waived if the taxpayer reasonably, in good faith, believes the transfer is not a gift (for example, a salary payment made to a child employed in a family business). Another commentator noted that the standard for adequate disclosure is higher for a “non-gift” than it is for a gift transaction since, in the non-gift situation, the donor must provide all the information required by the regulation and a statement why the transaction is not a gift. Another comment requested more guidance for reporting non-gift business transactions. In response to the comments, the final regulations limit the information required in a non-gift situation. In addition, the final regulations provide that completed transfers to members of the transferor’s family (as defined in section 2032(a)(2)) in the ordinary course of operating a business are deemed to be adequately disclosed, even if not reported on a gift tax return, if the item is properly reported by all parties for income tax purposes. For example, in the case of a salary payment made to a child of the donor employed in the donor’s business, the transaction will be treated as adequately disclosed if the salary payment is properly reported by the business and the child on their income tax returns. This exception only applies to transactions conducted in the ordinary course of operating a business. It does not apply, for example, in the case of a sale of property (including a business) by a parent to a child.

4. Effective Date Provisions

Several comments were received regarding clarification of the statutory effective date rules.

One comment requested clarification of the effective date of section 6501(c)(9), as amended. The Taxpayer Relief Act of 1997 provides that the amendments to section 6501(c)(9) (commencing the running of the period of limitations only if the gift is adequately disclosed) apply to gifts made in calendar years ending after August 5, 1997 (that is, all gifts made in calendar year 1997 and thereafter).

However, the underlying legislative history indicates that the amendment to section 6501(c)(9) applies “to gifts made in calendar years after the date of enactment [August 5, 1997]”. H.R. Conf. Rep. No. 220, 105th Cong., 1st Sess. 408 (1997). Notwithstanding this statement in the legislative history, the statutory language is clear that the section as amended applies to all gifts made during the 1997 calendar year, and thereafter. In the final regulations, the statutory effective date language is restated in a manner that makes it clear that section 6501(c)(9) as amended applies to all gifts made after December 31, 1996.

Another comment suggested clarification of the application of the adequate disclosure rules and the interaction between sections 2504(c) and 6501(c)(9) with respect to gifts made between January 1, 1997, and August 6, 1997, since section 2504(c) as amended applies only to gifts made after August 5, 1997, but section 6501(c)(9) as amended applies to all gifts made in 1997. In response to this comment, an example has been added under §25.2504–2(c) involving a situation where a gift is made prior to August 6, 1997, that is not adequately disclosed on the return filed for 1997. The example clarifies that the period for assessment with respect to the pre-August 6, 1997 gift does not commence to run because the gift is not adequately disclosed. Accordingly, a gift tax may be assessed with respect to the gift at any time, and notwithstanding the effective date for section 2504(c), that 1997 gift can be adjusted as a part of prior taxable gifts in determining subsequent gift tax liability. Further, the 1997 gift can be adjusted as part of taxable gifts under section 2001 in determining estate tax liability.

Finally, in response to another comment, an example has been added illustrating the application of the effective date rules in a similar fact pattern, where the gifts are made in a calendar year prior to 1997. The example illustrates that the IRS may not revalue the gifts, for purposes of determining prior taxable gifts for gift tax purposes, if a gift tax was paid and assessed with respect to the calendar year, and the period for assessment has expired. Since the gifts were made prior to 1997, the rules of section 2304(c) and section 6501 prior to amendment apply. However, the IRS may adjust the gifts for purposes of determining adjusted taxable gifts for estate tax purposes.

Special Analyses

It has been determined that this Treasury decision is not a significant regulatory action as defined in Executive Order 12866. Therefore, a regulatory assessment is not required. It also has been determined that section 553(b) of the Administrative Procedure Act (5 U.S.C. chapter 5) does not apply to these regulations, and because these regulations do not impose a collection of information on small entities, the Regulatory Flexibility Act (5 U.S.C. chapter 6) does not apply. Therefore, a Regulatory Flexibility Analysis is not required. Pursuant to section 7805(f) of the Internal Revenue Code, the notice of proposed rulemaking preceding these regulations was submitted to the Small Business Administration for comment on their impact on small business.

Drafting information: The principal author of these regulations is William L. Blodgett, Office of Assistant Chief Counsel (Passthroughs and Special Industries), IRS. However, other personnel from the IRS and Treasury Department participated in their development.

List of Subjects

26 CFR Part 20

Estate taxes, Reporting and recordkeeping requirements.

26 CFR Part 25

Gift taxes, Reporting and recordkeeping requirements.

26 CFR Part 301

Employment taxes, Estate taxes, Excise taxes, Gift taxes, Income taxes, Penalties, Reporting and recordkeeping requirements.

26 CFR Part 602

Reporting and recordkeeping requirements.

Adoption of Amendments to the Regulations

Accordingly, 26 CFR parts 20, 25, 301 and 602 are amended as follows:

PART 20—ESTATE TAX; ESTATES OF DECEDENTS DYING AFTER AUGUST 16, 1954

Paragraph 1. The authority citation for part 20 continues to read in part as follows:

Authority: 26 U.S.C. 7805 * * *

Par. 2. Section 20.2001–1 is revised to read as follows:

§20.2001–1 Valuation of adjusted taxable gifts and section 2701(d) taxable events.

(a) Adjusted taxable gifts made prior to August 6, 1997. For purposes of determining the value of adjusted taxable gifts as defined in section 2001(b), if the gift was made prior to August 6, 1997, the value of the gift may be adjusted at any time, even if the time within which a gift tax may be assessed has expired under section 6501. This paragraph (a) also applies to adjustments involving issues other than
valuation for gifts made prior to August 6, 1997.

(b) Adjusted taxable gifts and section 2701(d) taxable events occurring after August 5, 1997.  For purposes of determining the amount of adjusted taxable gifts as defined in section 2001(b), if, under section 6501, the time has expired within which a gift tax may be assessed under chapter 12 of the Internal Revenue Code (or under corresponding provisions of prior laws) with respect to a gift made after August 5, 1997, or with respect to an increase in taxable gifts required under section 2701(d) and §25.2701–4 of this chapter, then the amount of the taxable gift will be the amount as finally determined for gift tax purposes under chapter 12 of the Internal Revenue Code and the amount of the taxable gift may not thereafter be adjusted. The rule of this paragraph (b) applies to adjustments involving all issues relating to the gift, including valuation issues and legal issues involving the interpretation of the gift tax law.

(c) Finally determined. For purposes of paragraph (b) of this section, the amount of a taxable gift as finally determined for gift tax purposes is—

(1) The amount of the taxable gift as shown on a gift tax return, or on a statement attached to the return, if the Internal Revenue Service does not contest such amount before the time has expired under section 6501 within which gift taxes may be assessed;

(2) The amount as specified by the Internal Revenue Service before the time has expired under section 6501 within which gift taxes may be assessed on the gift, if such specified amount is not timely contested by the taxpayer;

(3) The amount as finally determined by a court of competent jurisdiction; or

(4) The amount as determined pursuant to a settlement agreement entered into between the taxpayer and the Internal Revenue Service.

(d) Definitions. For purposes of paragraph (b) of this section, the amount is finally determined by a court of competent jurisdiction when the court enters a final decision, judgment, decree or other order with respect to the amount of the taxable gift that is not subject to appeal. See, for example, section 7481 regarding the finality of a decision by the U.S. Tax Court. Also, for purposes of paragraph (b) of this section, a settlement agreement means any agreement entered into by the Internal Revenue Service and the taxpayer that is binding on both. The term includes a closing agreement under section 7121, a compromise under section 7122, and an agreement entered into in settlement of litigation involving the amount of the taxable gift.

(e) Expiration of period of assessment. For purposes of determining if the time has expired within which a tax may be assessed under chapter 12 of the Internal Revenue Code, see §301.6501(c)–1(e) and (f) of this chapter.

(f) Effective dates. Paragraph (a) of this section applies to transfers of property by gift made prior to August 6, 1997, if the estate tax return for the donor/decedent’s estate is filed after December 3, 1999. Paragraphs (b) through (e) of this section apply to transfers of property by gift made after August 5, 1997, if the gift tax return for the calendar period in which the gift is made is filed after December 3, 1999.

PART 25—GIFT TAX; GIFTS MADE AFTER DECEMBER 31, 1954

Par. 3. The authority citation for part 25 continues to read in part as follows:

Authority: 26 U.S.C. 7805. * * *

Par. 4. In §25.2504–1, a sentence is added at the end of paragraph (d) to read as follows:

§25.2504–1 Taxable gifts for preceding calendar periods.

* * * * * * * * * (d) * * * * However, see §25.2504–2(b) regarding certain gifts made after August 5, 1997.

Par. 5. Section 25.2504–2 is revised to read as follows:

§25.2504–2 Determination of gifts for preceding calendar periods.

(a) Gifts made before August 6, 1997. If the time has expired within which a tax may be assessed under chapter 12 of the Internal Revenue Code (or under corresponding provisions of prior laws) on the transfer of property by gift made during a preceding calendar period, as defined in §25.2502–1(c)(2), the gift was made prior to August 6, 1997, and a tax has been assessed or paid for such prior calendar period, the value of the gift, for purposes of arriving at the correct amount of the taxable gifts for the preceding calendar periods (as defined under §25.2504–1(a)), is the value used in computing the tax for the last preceding calendar period for which a tax was assessed or paid under chapter 12 of the Internal Revenue Code or the corresponding provisions of prior laws.

However, this rule does not apply where no tax was paid or assessed for the prior calendar period. Furthermore, this rule does not apply to adjustments involving issues other than valuation. See §25.2504–1(d).

(b) Gifts made or section 2701(d) taxable events occurring after August 5, 1997. If the time has expired under section 6501 within which a gift tax may be assessed under chapter 12 of the Internal Revenue Code (or under corresponding provisions of prior laws) on the transfer of property by gift made during a preceding calendar period, as defined in §25.2502–1(c)(2), or with respect to an increase in taxable gifts required under section 2701(d) and §25.2701–4, and the gift was made, or the section 2701(d) taxable event occurred, after August 5, 1997, the amount of the taxable gift or the amount of the increase in taxable gifts, for purposes of determining the correct amount of taxable gifts for the preceding calendar periods (as defined in §25.2504–1(a)), is the amount that is finally determined for gift tax purposes (within the meaning of §20.2001–1(c) of this chapter) and such amount may not be thereafter adjusted. The rule of this paragraph (b) applies to adjustments involving all issues relating to the gift, including valuation issues and legal issues involving the interpretation of the gift tax law. For purposes of determining if the time has expired within which a gift tax may be assessed, see §301.6501(c)–1(e) and (f) of this chapter.

(c) Examples. The following examples illustrate the rules of paragraphs (a) and (b) of this section:

Example 1. (i) Facts. In 1996, A transferred closely-held stock in trust for the benefit of B, A’s child. A timely filed a Federal gift tax return reporting the 1996 transfer to B. No gift tax was assessed or paid as a result of the gift tax annual exclusion and the application of A’s available unified credit. In 2001, A transferred additional closely-held stock to the trust. A’s Federal gift tax return reporting the 2001 transfer was timely filed and the transfer was adequately disclosed under §301.6501(c)–1(f)(2) of this chapter. In computing the amount of taxable gifts, A claimed annual exclusions with respect to the transfers in 1996 and 2001. In 2003, A transfers additional property to B and timely files a Federal gift tax return reporting the gift. (ii) Application of the rule limiting adjustments to prior gifts. Under section 2504(c), in determining A’s 2003 gift tax liability, the amount of A’s 1996 gift can be adjusted for purposes of computing prior taxable gifts, since that gift was made prior to August 6, 1997, and therefore, the provisions of paragraph (a) of this section apply. Adjustments can be made with respect to the valuation of the gift and legal issues presented (for example, the availability of the annual exclusion with respect to the gift). However, A’s 2001 transfer was adequately disclosed on a timely filed gift tax return and, thus, under paragraph (b) of this section, the amount of the 2001 taxable gift by A may not be adjusted (either with respect to the valuation of the gift or any legal issue) for
purposes of computing prior taxable gifts in determining A’s 2003 gift tax liability.

Example 2. (i) Facts. In 1996, A transferred closely-held stock to B, A’s child. A timely filed a Federal gift tax return reporting the 1996 transfer to B and paid gift tax on the value of the gift reported on the return. On August 1, 1997, A transferred additional closely-held stock to B in exchange for a promissory note signed by B. Also, on September 10, 1997, A transferred closely-held stock to C, A’s other child. On April 15, 1998, A timely filed a gift tax return reporting the September 10, 1997, transfer to C and, under §301.6501(c)–1(f)(2) of this chapter, adequately disclosed that transfer and paid gift tax with respect to the transfer. However, A believed that the transfer to B on August 1, 1997, was for full and adequate consideration and A did not report the transfer to B on the 1997 Federal gift tax return. In 2002, A transfers additional property to B and timely files a Federal gift tax return reporting the gift.

(ii) Application of the rule limiting adjustments to prior gifts. Under section 2504(c), in determining A’s 2002 gift tax liability, the value of A’s 1996 gift cannot be adjusted for purposes of computing the value of prior taxable gifts, since that gift was made prior to August 6, 1997, and a timely Federal gift tax return was filed on which a gift tax was assessed and paid. However, A’s prior taxable gifts can be adjusted to reflect the August 1, 1997, transfer because, although a gift tax return for 1997 was timely filed and gift tax was paid, under §301.6501(c)–1(f) of this chapter the period for assessing gift tax with respect to the August 1, 1997, transfer did not commence to run since that transfer was not adequately disclosed on the 1997 gift tax return.

Accordingly, a gift tax may be assessed with respect to the August 1, 1997, transfer and the amount of the gift would be reflected in prior taxable gifts for purposes of computing A’s gift tax liability for 2002. A’s September 10, 1997, transfer to C was adequately disclosed on the gift tax return and, thus, under paragraph (b) of this section, the amount of the September 10, 1997, taxable gift by A may not be adjusted for purposes of computing prior taxable gifts in determining A’s 2002 gift tax liability.

Example 3. In 1994, A transferred closely-held stock to B and C, A’s children. A timely filed a Federal gift tax return reporting the 1994 transfers to B and C and paid gift tax on the value of the gifts reported on the return. Also in 1994, A transferred closely-held stock to B in exchange for a bona fide promissory note signed by B. A believed that the transfer to B in exchange for the promissory note was for full and adequate consideration and A did not report that transfer to B on the 1994 Federal gift tax return. In 2002, A transfers additional property to B and timely files a Federal gift tax return reporting the gift.

(ii) Application of the rule limiting adjustments to prior gifts. Under section 2504(c), in determining A’s 2002 gift tax liability, the value of A’s 1994 gifts cannot be adjusted for purposes of computing prior taxable gifts because those gifts were made prior to August 6, 1997, and a timely filed Federal gift tax return was filed with respect to which a gift tax was assessed and paid, and the period of limitations on assessment has expired. The provisions of paragraph (a) of this section apply to the 1994 transfers. However, for purposes of determining A’s adjusted taxable gifts in computing A’s estate tax liability, the gifts may be adjusted. See §20.2001–1(a) of this chapter.

(d) Effective dates. Paragraph (a) of this section applies to transfers of property by gift made prior to August 6, 1997. Paragraphs (b) and (c) of this section apply to transfers of property by gift made after August 5, 1997, if the gift tax return for the calendar period in which the transfer is reported is filed after December 3, 1999.

Par. 6. In §25.2511–2, paragraph (j) is revised to read as follows:

§25.2511–2 Cessation of donor’s dominion and control. * * * * * (j) If the donor contends that a power is of such nature as to render the gift incomplete, and hence not subject to the tax as of the calendar period (as defined in §25.2502–1(c)(1)) of the initial transfer, see §301.6501(c)–1(f)(5) of this chapter.

PART 301—PROCEDURE AND ADMINISTRATION

Par. 7. The authority citation for part 301 continues to read in part as follows:

Authority: 26 U.S.C. 7805 * * *

Par. 8. Section 301.6501(c)–1 is amended by:

1. Revising the heading to paragraph (e).

2. Adding paragraph (f).

The revision and addition reads as follows:

§301.6501(c)–1 Exceptions to general period of limitations on assessment and collection. * * * * * (e) Gifts subject to chapter 14 of the Internal Revenue Code not adequately disclosed on the return. * * *

(f) Gifts made after December 31, 1996, not adequately disclosed on the return—(1) In general. If a transfer of property, other than a transfer described in paragraph (e) of this section, is not adequately disclosed on gift tax return (Form 709, “United States Gift (and Generation-Skipping Transfer) Tax Return”), or in a statement attached to the return, filed for the calendar period in which the transfer occurs, then any gift tax imposed by chapter 12 of subtitle B of the Internal Revenue Code on the transfer may be assessed, or a proceeding in court for the collection of the appropriate tax may be begun without assessment, at any time.

(2) Adequate disclosure of transfers of property reported as gifts. A transfer will be adequately disclosed on the return only if it is reported in a manner adequate to apprise the Internal Revenue Service of the nature of the gift and the basis for the value so reported. Transfers reported on the gift tax return as transfers of property by gift will be considered adequately disclosed under this paragraph (f)(2) if the return (or a statement attached to the return) provides the following information—

(i) A description of the transferred property and any consideration received by the transferee;

(ii) The identity of, and relationship between, the transferee and each transferee;

(iii) If the property is transferred in trust, the trust’s tax identification number and a brief description of the terms of the trust, or in lieu of a brief description of the trust terms, a copy of the trust instrument;

(iv) Except as provided in §301.6501–1(f)(3), a detailed description of the method used to determine the fair market value of property transferred, including any financial data (for example, balance sheets, etc. with explanations of any adjustments) that were utilized in determining the value of the interest, any restrictions on the transferred property that were considered in determining the fair market value of the property, and a description of any discounts, such as discounts for blockage, minority or fractional interests, lack of marketability, claimed in valuing the property. In the case of a transfer of an interest that is actively traded on an established exchange, such as the New York Stock Exchange, the American Stock Exchange, the NASDAQ National Market, or a regional exchange in which quotations are published on a daily basis, including recognized foreign exchanges, recitation of the exchange where the interest is listed, the CUSIP number of the security, and the mean between the highest and lowest quoted selling prices on the applicable valuation date will satisfy all of the requirements of this paragraph and (f)(2)(iv).

In the case of the transfer of an interest in an entity (for example, a corporation or partnership) that is not actively traded, a description must be provided of any discount claimed in valuing the interests in the entity or any assets owned by such entity. In addition, if the value of the entity or of the interests in the entity is properly determined based on the net value of the assets held by the entity, a statement must be provided regarding the fair market value of 100 percent of the entity (determined without regard to any discounts in valuing the entity or any assets owned...
by the entity), the pro rata portion of the entity subject to the transfer, and the fair market value of the transferred interest as reported on the return. If 100 percent of the value of the entity is not disclosed, the taxpayer bears the burden of demonstrating that the fair market value of the entity is properly determined by a method other than a method based on the net value of the assets held by the entity. If the entity that is the subject of the transfer owns an interest in another non-actively traded entity (either directly or through ownership of an entity), the information required in this paragraph (f)(2)(v) must be provided for each entity if the information is relevant and material in determining the value of the interest; and

(v) A statement describing any position taken that is contrary to any proposed, temporary or final Treasury regulations or revenue rulings published at the time of the transfer (see § 601.601(d)(2) of this chapter).

(3) Submission of appraisals in lieu of the information required under paragraph (f)(2)(iv) of this section. The requirements of paragraph (f)(2)(iv) of this section will be satisfied if the donor submits an appraisal of the transferred property that meets the following requirements—

(i) The appraisal is prepared by an appraiser who satisfies all of the following requirements:

(A) The appraiser is an individual who holds himself or herself out to the public as an appraiser or performs appraisals on a regular basis.

(B) Because of the appraiser's qualifications, as described in the appraisal that details the appraiser's background, experience, education, and membership, if any, in professional appraisal associations, the appraiser is qualified to make appraisals of the type of property being valued.

(C) The appraiser is not the donor or the donee of the property or a member of the family of the donor or donee, as defined in section 2032A(e)(2), or any person employed by the donor, the donee, or a member of the family of either; and

(ii) The appraisal contains all of the following:

(A) The date of the transfer, the date on which the transferred property was appraised, and the purpose of the appraisal.

(B) A description of the property.

(C) A description of the appraisal process employed.

(D) A description of the assumptions, hypothetical conditions, and any limiting conditions and restrictions on the transferred property that affect the analyses, opinions, and conclusions.

(E) The information considered in determining the appraised value, including in the case of an ownership interest in a business, all financial data that was used in determining the value of the interest that is sufficiently detailed so that another person can replicate the process and arrive at the appraised value.

(F) The appraisal procedures followed, and the reasoning that supports the analyses, opinions, and conclusions.

(G) The valuation method utilized, the rationale for the valuation method, and the procedure used in determining the fair market value of the asset transferred.

(H) The specific basis for the valuation, such as specific comparable sales or transactions, sales of similar interests, asset-based approaches, merger-acquisition transactions, etc.

(4) Adequate disclosure of non-gift completed transfers or transactions.

Completed transfers to members of the transferor's family, as defined in section 2032A(e)(2), that are made in the ordinary course of operating a business are deemed to be adequately disclosed under paragraph (f)(2) of this section, even if the transfer is not reported on a gift tax return, provided the transfer is properly reported by all parties for income tax purposes. For example, in the case of salary paid to a family member employed in a family owned business, the transfer will be treated as adequately disclosed for gift tax purposes if the item is properly reported by the business and the family member on their income tax returns. For purposes of this paragraph (f)(4), any other completed transfer that is reported, in its entirety, not constituting a transfer by gift will be considered adequately disclosed under paragraph (f)(2) of this section only if the following information is provided on, or attached to, the return—

(i) The information required for adequate disclosure under paragraphs (f)(2)(i), (ii), (iii) and (v) of this section; and

(ii) An explanation as to why the transfer is not a transfer by gift under chapter 12 of the Internal Revenue Code.

(5) Adequate disclosure of incomplete transfers. Adequate disclosure of a transfer that is reported as a completed gift on the gift tax return will commence the running of the period of limitations for assessment of gift tax on the transfer, even if the transfer is ultimately determined to be an incomplete gift for purposes of § 25.2511–2 of this chapter. For example, if an incomplete gift is reported as a completed gift on the gift tax return and is adequately disclosed, the period for assessment of the gift tax will begin to run when the return is filed, as determined under section 6501(b). Further, once the period of assessment for gift tax expires, the transfer will not be subject to inclusion in the donor’s gross estate for estate tax purposes. On the other hand, if the transfer is reported as an incomplete gift whether or not adequately disclosed, the period for assessing a gift tax with respect to the transfer will not commence to run even if the transfer is ultimately determined to be a completed gift. In that situation, the gift tax with respect to the transfer may be assessed at any time, up until three years after the donor files a return reporting the transfer as a completed gift with adequate disclosure.

(6) Treatment of split gifts. If a husband and wife elect under section 2513 to treat a gift made to a third party as made one-half by each spouse, the requirements of this paragraph (f) will be satisfied with respect to the gift deemed made by the consenting spouse if the return filed by the donor spouse (the spouse that transferred the property) satisfies the requirements of this paragraph (f) with respect to that gift.

(7) Examples. The following examples illustrate the rules of this paragraph (f):

Example 1. (i) Facts. In 2001, A transfers 100 shares of common stock of XYZ Corporation to A’s child. The common stock of XYZ Corporation is actively traded on a major stock exchange. For gift tax purposes, the fair market value of one share of XYZ common stock on the date of the transfer, determined in accordance with § 25.2512–2(b) of this chapter (based on the mean between the highest and lowest quoted selling prices), is $150.00. On A’s Federal gift tax return, Form 709, for the 2001 calendar year, A reports the gift to A’s child of 100 shares of common stock of XYZ Corporation with a value for gift tax purposes of $15,000. A specifies the date of the transfer, recites that the stock is publicly traded, identifies the stock exchange on which the stock is traded, lists the stock’s CUSIP number, and lists the mean between the highest and lowest quoted selling prices for the date of transfer.

(ii) Application of the adequate disclosure standard. A has adequately disclosed the transfer. Therefore, the period of assessment for the transfer under section 6501 will run from the time the return is filed (as determined under section 6501(b)).

Example 2. (i) Facts. On December 30, 2001, A transfers closely-held stock to B, A’s child. A determined that the value of the transferred stock, on December 30, 2001, was $9,000. A made no other transfers to B, or any other donee, during 2001. On A’s Federal gift tax return, Form 709, for the 2001...
calendar year. A provides the information required under paragraph (f)(2) of this section such that the transfer is adequately disclosed. A claims an annual exclusion under section 2503(b) for the transfer.

(ii) Application of the adequate disclosure standard. The transfer is adequately disclosed under paragraph (f)(2) of this section, the period of assessment for the transfer will expire as prescribed by section 6501(b), notwithstanding that if A’s valuation of the closely-held stock was correct, A was not required to file a gift tax return reporting the transfer under section 6019. After the period of assessment has expired on the transfer, the Internal Revenue Service is precluded from redetermining the amount of the gift for purposes of assessing gift tax or for purposes of determining the estate tax liability. Therefore, the amount of the gift as reported on A’s 2001 Federal gift tax return may not be redetermined for purposes of determining A’s prior taxable gifts (for gift tax purposes) or A’s adjusted taxable gifts (for estate tax purposes).

Example 3. (i) Facts. A owns 100 percent of the common stock of X, a closely-held corporation. X does not hold an interest in any other entity that is not actively traded. In 2001, A transfers 20 percent of the X stock to B and C, A’s children, in a transfer that is not subject to the special valuation rules of section 2701. The transfer is made outright with no restrictions on ownership rights, including voting rights and the right to transfer the stock. Based on generally applicable valuation principles, the value of X would be determined based on the market value of the assets owned by X. The reported value of the transferred stock incorporates the use of minority discounts and lack of marketability discounts. No other discounts were used in arriving at the fair market value of the transferred stock or any assets owned by X. On A’s Federal gift tax return, Form 709, for the 2001 calendar year, A provides the information required under paragraph (f)(2) of this section including a statement reporting the fair market value of 100 percent of X (before taking into account any discounts), the pro rata portion of X subject to the transfer, and the reported value of the transfer. A also attaches a statement regarding the determination of value that includes a discussion of the discounts claimed and how the discounts were determined.

(ii) Application of the adequate disclosure standard. A has provided sufficient information such that the transfer will be considered adequately disclosed and the period of assessment for the transfer under section 6501 will run from the time the return is filed (as determined under section 6501(b)).

Example 4. (i) Facts. A owns a 70 percent limited partnership interest in PS. PS owns 40 percent of the stock in X, a closely-held corporation. The assets of X include a 50 percent general partnership interest in PB. PB owns an interest in commercial real property. None of the entities (PS, X, or PB) is actively traded and, based on generally applicable valuation principles, the value of each entity would be determined based on the net value of the assets owned by each entity. In 2001, A transfers a 25 percent limited partnership interest in PS to B, A’s child. On the Federal gift tax return, Form 709, for the 2001 calendar year, A reports the transfer of the 25 percent limited partnership interest in PS and that the fair market value of 100 percent of PS is $y and that the value of 25 percent of PS is $z, reflecting marketability and minority discounts with respect to the 25 percent interest. However, A does not disclose that PS owns 40 percent of X, and that X owns 50 percent of PB and that, in arriving at the $y fair market value of 100 percent of PS, discounts were claimed in valuing PS’s interest in X, X’s interest in PB, and PB’s interest in the commercial real property.

(ii) Application of the adequate disclosure standard. The information on the lower tiered entities is relevant and material in determining the value of the transferred interest in PS. Accordingly, because A has failed to comply with requirements of paragraph (f)(2)(iv) of this section regarding PS’s interest in X, X’s interest in PB, and PB’s interest in the commercial real property, the transfer will not be considered adequately disclosed and the period of assessment for the transfer under section 6501 will remain open indefinitely.

Example 5. The facts are the same as in Example 4 except that A submits, with the Federal tax return, an appraisal of the 25 percent limited partnership interest in PS that satisfies the requirements of paragraph (f)(3) of this section in lieu of the information required in paragraph (f)(2)(iv) of this section. Assuming the other requirements of paragraph (f)(2) of this section are satisfied, the transfer is considered adequately disclosed and the period for assessment for the transfer under section 6501 will run from the time the return is filed (as determined under section 6501(b) of this chapter).

Example 6. A owns 100 percent of the stock of X Corporation, a company actively engaged in a manufacturing business. B, A’s child, is an employee of X and receives an annual salary paid in the ordinary course of operating X Corporation. B reports the annual salary as income on his income tax returns. In 2001, A transfers property to family members and files a Federal gift tax return reporting the transfers. However, A does not disclose the 2001 salary payments made to B. Because the salary payments were reported as income on B’s income tax return, the salary payments are deemed to be adequately disclosed. The transfer of property to family members, other than the salary payments to B, reported on the gift tax return must satisfy the adequate disclosure requirements under paragraph (f)(2) of this section in order for the period of assessment under section 6501 to commence to run with respect to those transfers.

(8) Effective date. This paragraph (f) is applicable to gifts made after December 31, 1996, for which the gift tax return for such calendar year is filed after December 3, 1999.
OH, 44199–2060 between 6:30 a.m. and 3 p.m., Monday through Friday, except Federal holidays. The telephone number is (216) 902–6084.

FOR FURTHER INFORMATION CONTACT: Mr. Scot Striffler, Project Manager, Ninth Coast Guard District Bridge Branch, at (216) 902–6084.

SUPPLEMENTARY INFORMATION:

Discussion of Temporary Rule

The owner of the bridge, Michigan Department of Transportation (M–DOT), requested the Coast Guard approval of full closure of the bridge to complete deck replacement work and maintenance to the operating machinery. The regulations governing the operation of the bridge require it to open with 24 hours advance notice from mariners between January 1 and March 15 each year. M–DOT requested that the bridge not be required to open at all during this time, as well as a continuation of this status until April 25, 2000. Bridge logs submitted by M–DOT indicated 12 openings in the month of April in 1999, all by non-commercial vessels, with most of them occurring after April 14, 1999. A National Park Service vessel that operates between Houghton and Isle Royale Park required 3 of the openings in April 1999. The Park Service was contacted to provide input on the requested closure time and expressed no objections.

The closure dates of January 1 until April 25, 2000, were determined by Commander Ninth Coast Guard District to be appropriate in keeping the planned maintenance from interrupting the operations of the bridge during the traditional boating season in the waterway. Requests for openings by recreational boaters do not normally begin until approximately June 1 each year.

This temporary rule is being promulgated without a notice of proposed rulemaking. Under 5 U.S.C. 553(b)(3)(B) the Coast Guard finds that good cause exists for not publishing an NPRM. The factors underlying this finding include the extensive input already received from affected mariners, limited vessel activity during the authorized closure period due to severe weather and ice, and the need to perform the work necessary to maintain the bridge in a safe and operable condition during regular operating times.

Regulatory Evaluation

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

The Coast Guard expects the economic impact of this proposed rule to be so minimal that a full Regulatory Evaluation under paragraph 10e of the regulatory policies and procedures of DOT is unnecessary. There have been no bridge openings for commercial vessels in previous years during the authorized closure period.

Small Entities

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

Marine activity in the waterway is virtually non-existent during the authorized closure period due to extreme weather and ice. Therefore, the Coast Guard certifies under 5 U.S.C. 605(b) that this temporary rule will not have a significant economic impact on a substantial number of small entities.

Collection of Information

This temporary rule does not provide for a collection-of-information requirement under the Paperwork Reduction Act (44 U.S.C. 3501 et seq.).

Federalism

The Coast Guard has analyzed this temporary rule under the principles and criteria contained in Executive Order 13132 and has determined that this temporary rule does not have federalism implications under that Order.

Environment

The Coast Guard considered the environmental impact of this temporary rule and concluded that, under figure 2–1, paragraph 32(e) of Commandant Instruction M16475.1C, this temporary rule is categorically excluded from further environmental documentation. A “Categorical Exclusion Determination” is available in the docket for inspection or copying where indicated under ADDRESSES.

List of Subjects in 33 CFR Part 117

Bridges.

For the reasons set out in the preamble, the Coast Guard temporarily amends Part 117 of Title 33, Code of Federal Regulations, as follows:

PART 117—DRAWBRIDGE OPERATION REGULATIONS

1. The authority citation for Part 117 continues to read as follows:

Authority: 33 U.S.C. 499; 49 CFR 1.46; 33 CFR 1.05–1(g); section 117.255 also issued under the authority of Pub. L. 102–587, 106 Stat. 5039.

2. Effective from 12:01 a.m., January 1, 2000, to 11:59 p.m., April 25, 2000, §117.635 is suspended and a new §117.T636 is added to read as follows:

§117.T636 Keweenaw Waterway.

The draw of the U.S. 41 bridge, mile 16.0 over the Keweenaw Waterway in Houghton, Michigan, need not open for the passage of vessels and may be maintained in the closed-to-navigation position.

Dated: November 9, 1999.

James D. Hull,
Rear Admiral, U.S. Coast Guard, Commander, Ninth Coast Guard District.

[FR Doc. 99–31439 Filed 12–2–99; 8:45 am]

BILLING CODE 4910–15–U

DEPARTMENT OF COMMERCE

Patent and Trademark Office

37 CFR Parts 1 and 2

[Docket No. 991105297–9297–01]

RIN 0651–AB01

Revision of Patent and Trademark Fees for Fiscal Year 2000

AGENCY: Patent and Trademark Office, Commerce.

ACTION: Final rule.

SUMMARY: The Patent and Trademark Office (PTO) is amending the rules of practice in patent and trademark cases to adjust certain patent fee amounts to conform to the fee amounts set by law in the American Inventors Protection Act of 1999 as part of the conference report (H. Rep. 106–479) on H.R. 3194, Consolidated Appropriations Act, Fiscal Year 2000. The text of the American Inventors Protection Act of 1999 is contained in title IV of S. 1948, the Intellectual Property and Communications Omnibus Reform Act of 1999, which is incorporated by reference in Division B of the conference report. The PTO is also
adjusting certain trademark fee amounts to recover the cost of all trademark activities as provided for in H.R. 3194 (S. 1948). In addition, the PTO is adjusting, by a corresponding amount, two patent fees that track the basic filing fee.

**EFFECTIVE DATES:** The amendments to 37 CFR 1.16, 1.20, and 1.492 are effective on December 29, 1999. The amendments to 37 CFR 1.17 and 2.6 are effective on January 10, 2000.

**FOR FURTHER INFORMATION CONTACT:** Matthew Lee by telephone at (703) 305–8051, by e-mail at matthew.lee@uspto.gov, by facsimile at (703) 305–8007, or by mail marked to his attention and addressed to the Commissioner of Patents and Trademarks, Office of Finance, Crystal Park 1, Suite 802, Washington, DC 20231.

**SUPPLEMENTARY INFORMATION:** This final rule adjusts certain patent fees in accordance with the Consolidated Appropriations Act, Fiscal Year 2000 (H.R. 3194), which incorporates the Intellectual Property and Communications Omnibus Reform Act of 1999 (S. 1948), and adjusts certain trademark fees to recover costs.

**Background**

Section 31(a) of the Trademark Act of 1946 (15 U.S.C. 1113(a)) authorizes the Commissioner of Patents and Trademarks to annually adjust the fees established for the filing and processing of trademark applications, for the registration of trademarks and other marks, and for all other services performed by the PTO related to trademarks and other marks, to reflect aggregate fluctuations in the Consumer Price Index (CPI) during the previous twelve months. Trademark processing fees have not been adjusted since 1993, when the application fee was adjusted. Other trademark fees have not been changed since 1982.

As a result of increases in filings, efforts to reduce the pendency of trademark applications before the PTO, and to reduce the backlog of unexamined cases, the PTO has hired additional trademark examining attorneys and instituted an electronic filing system for trademark applications. Current trademark fee rates are insufficient to recover these additional costs. In addition, the PTO has employed activity-based cost accounting principles and systems on an agency-wide basis to measure the full cost of patent and trademark activities, including indirect costs. To fully recover the cost of all trademark activities, including indirect trademark operation costs, the PTO needs to adjust trademark fees sufficiently to recover an estimated $30 million in fiscal years 2000 and 2001. H.R. 3194 (S. 1948) authorizes the Commissioner to make such an adjustment to trademark fees. Patent fees were adjusted in 1998 as a result of Public Law 105–358. Public Law 105–358 set:

1. The basic filing fee for an original utility patent application (35 U.S.C. 41(a)(1)(A)) or a reissue patent application (35 U.S.C. 41(a)(4)(A)) at $760 ($380 for a small entity); and
2. The basic national fee for an international application in which the PTO was the International Searching Authority (ISA) but not the International Preliminary Examining Authority (IPEA) (35 U.S.C. 41(a)(10)) at $760 ($380 for a small entity).

The Commissioner may also adjust fees set forth in 35 U.S.C. 41(a) and (b) to reflect any fluctuations in the Consumer Price Index (CPI) during the previous twelve months. See 35 U.S.C. 41(f). With the recent implementation of activity-based cost accounting principles and systems on an agency-wide basis, the PTO recognized that patent fee revenue has been partially offsetting the indirect trademark operation costs. Since H.R. 3194 (S. 1948) authorizes the Commissioner to adjust trademark fees to fully cover the costs of trademark operations, an adjustment to selective patent fees is necessary in fiscal year 2000 because those fees will no longer be needed to offset indirect trademark operation expenses. Thus, H.R. 3194 (S. 1948) reduces:

- The basic filing fee for an original utility patent application (35 U.S.C. 41(a)(1)(A)) or a reissue patent application (35 U.S.C. 41(a)(4)(A)) to $690 ($345 for a small entity);
- The basic national fee for an international application in which the PTO was the ISA but not the IPEA (35 U.S.C. 41(a)(10)) to $690 ($345 for a small entity); and
- The first patent maintenance fee (35 U.S.C. 41(b)(1)) at $940 ($470 for a small entity).

This final rule conforms the patent fees specified in H.R. 3194 (S. 1948) to correspond to the basic filing fee specified in 35 U.S.C. 41(a)(1)(A), as amended by H.R. 3194 (S. 1948).

Section 1.53(d), which relates to a continued prosecution application (CPA), is not being revised by this final rule. However, it should be noted that § 1.53(d)(3) requires payment of the basic filing fee as set forth in 37 CFR 1.16.

Section 41(g) of title 35, United States Code, provides that new fee amounts established by the Commissioner under section 41 may take effect 30 days after notice in the Federal Register and the Official Gazette of the Patent and Trademark Office.

In addition, this final rule adjusts trademark fees set forth in 37 CFR 2.6(a)(1), (a)(4), (a)(5), (a)(13), (a)(16), and (a)(17), to recover costs.

Section 31 of the Trademark Act of 1946 (15 U.S.C. 1113(a)), allows new trademark fee amounts to take effect 30 days after notice in the Federal Register and the Official Gazette of the Patent and Trademark Office.

A comparison of the current fee amounts and the new fee amounts for fiscal year 2000 is included as an Appendix to this final rule.

**Procedures for Determining the Correct Fee Amount Owed**

The following subsections detail the procedures for determining the fees owed during the transition to the new fee schedule. Fees owed may be affected by proper use of a Certificate of Mailing or Transmission under § 1.8(a)(1), or use of “Express Mail Post Office to Addresser” under § 1.10(a).

- Items for which a Certificate of Mailing or Transmission under § 1.8(a)(1) is not proper include, for example, national (including a continued prosecution application (CPA) under § 1.53(d)) and international patent applications, and trademark applications. See 37 CFR 1.8(a)(2).
- Under § 1.10(a), any correspondence delivered by the “Express Mail Post Office to Addresser” service of the United States Postal Service (USPS) is considered filed or received in the Office on the date of deposit with the USPS. The date of deposit with the USPS is shown by the “date-in” on the “Express Mail” mailing label or other official USPS notation.

**a. The Post Issuance Fee for Patents Under 35 U.S.C. 41(b)**

Section 41(b) of title 35, United States Code, provides for maintenance fees. Any maintenance fee amount that is
paid on or after the effective date of the final fee adjustment will be subject to the new fee. 

If a Certificate of Mailing or Transmission was used, and was proper under § 1.8(a)(1), the fee required is the lower of:

1. The fee in effect on the date the PTO receives the fee; or
2. The fee in effect on the date of mailing indicated on a proper Certificate of Mailing or Transmission under § 1.8(a)(1).

Under § 1.10(a), any correspondence delivered by the “Express Mail Post Office to Addressee” service of the USPS is considered filed or received in the Office on the date of deposit with the USPS. The date of deposit with the USPS is shown by the “date-in” on the “Express Mail” mailing label or other official USPS notation.


Section 111 of title 35, United States Code, provides for the filing of a patent application with the PTO. If the filing fee for an application filed under 35 U.S.C. 111 is received when the application is filed, the filing fee required is the filing fee in effect on the filing date assigned to the application. If the PTO receives the filing fee on a date later than the filing date assigned to the application, the filing fee required is the higher of:

1. The filing fee in effect on the filing date assigned to the application; or
2. The filing fee in effect on the date the PTO receives the filing fee.

The filing fee includes the basic fee, excess claims fees (if any), and the multiple dependent claim fee (if any), for claims present on filing (unless the excess or multiple dependent claims are canceled before the filing fee is paid). Of course, if the basic filing fee is received on a date later than the filing date assigned to the application filed under 35 U.S.C. 111, a surcharge as set forth in § 1.16(e) is also required.

A Certificate of Mailing or Transmission under § 1.8(a)(1) cannot be used for national (including a continued prosecution application (CPA) under § 1.53(d)) and international patent applications. See 37 CFR 1.8(a)(2).

Under § 1.10(a), any correspondence delivered by the “Express Mail Post Office to Addressee” service of the USPS is considered filed or received in the Office on the date of deposit with the USPS. The date of deposit with the USPS is shown by the “date-in” on the “Express Mail” mailing label or other official USPS notation.


Section 371 of title 35, United States Code, provides for the national stage filing of a patent application under the Patent Cooperation Treaty. The basic national fee for an international application entering the national stage is due not later than the expiration of 20 months from the priority date in the international application (or 30 months from the priority date if the United States was elected prior to the expiration of 19 months from the priority date). The amount of the basic national fee that is required to be paid is the basic national fee in effect on the date the full fee is received.

A Certificate of Mailing or Transmission under § 1.8(a)(1) cannot be used for international patent applications. See 37 CFR 1.8(a)(2).

Under § 1.10(a), any correspondence delivered by the “Express Mail Post Office to Addressee” service of the USPS is considered filed or received in the Office on the date of deposit with the USPS. The date of deposit with the USPS is shown by the “date-in” on the “Express Mail” mailing label or other official USPS notation.

d. For Filing Trademark Applications Under 15 U.S.C. 1051

Section 1051 of title 15, United States Code, provides for the filing of trademark applications. The initial filing fee required for a trademark application filed under 15 U.S.C. 1051 is the filing fee in effect on the filing date assigned to the application.

Under § 1.6, documents are considered filed as of the date of receipt at the PTO, unless the documents are filed under § 1.10, which provides for filing by Express Mail. Under § 1.10(a), any correspondence delivered by the “Express Mail Post Office to Addressee” service of the USPS is considered filed or received in the Office on the date of deposit with the USPS. The date of deposit with the USPS is shown by the “date-in” on the “Express Mail” mailing label or other official USPS notation.

A Certificate of Mailing or Transmission under § 1.8(a)(1) cannot be used for filing a trademark application. See 37 CFR 1.8(a)(2).

Under § 2.21(a)(5), a trademark applicant must submit the filing fee for at least one class of goods or services before the application can be given a filing date. If the trademark application is accompanied by the fee for at least a single class of goods or services, but does not include fees sufficient to cover all the classes in the application, the application will be given a filing date, and the applicant will be required to submit the fees for the additional class(es) during examination. If the applicant submits fee(s) for additional class(es) after the application filing date, the fee(s) in effect on the date the fee(s) for the additional class(es) is received at the PTO will apply. The applicant may use a Certificate of Mailing or Transmission under § 1.8(a)(1) to file the additional fee(s).

e. For All Other Trademark Process Fees Affected by this Notice

For trademark process fees other than the initial fee for filing a trademark application, the applicant may use a Certificate of Mailing or Transmission under § 1.8(a)(1). If a Certificate of Mailing or Transmission is used to mail or transmit the fee, and the Certificate meets the requirements of § 1.8(a)(1), the fee in effect on the date indicated on the Certificate of Mailing or Transmission will apply.


Other Considerations

This final rule contains no information collection within the meaning of the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 et seq. This final rule has been determined to be not significant for purposes of Executive Order 12866.

This final rule adjusts certain patent fees and trademark fees indicated in Parts 1 and 2 of title 37, Code of Federal Regulations, to the fee amounts set by law or provided for by law. Therefore, prior notice and an opportunity for public comment are not required pursuant to 5 U.S.C. 553(a)(2) or any other law. As prior notice and an opportunity for public comment are not required pursuant to 5 U.S.C. 553, or any other law, the analytical requirements of the Regulatory Flexibility Act, 5 U.S.C. 601 et seq., are inapplicable.

Lists of Subjects in 37 CFR Part 1

Administrative practice and procedure, Inventions and patents, Reporting and record keeping requirements, Small businesses.
PART 1—RULES OF PRACTICE IN PATENT CASES

1. The authority citation for 37 CFR Part 1 continues to read as follows:

Authority: 35 U.S.C. 6, unless otherwise noted.

2. Section 1.16 is amended by revising paragraphs (a) and (h), to read as follows:

§ 1.16 National application filing fees.

(a) Basic fee for filing each application for an original patent, except provisional, design or plant applications:

By a small entity (§ 1.9(f)) ........... $345.00
By other than a small entity ...... 690.00

(h) Basic fee for filing each reissue application:

By a small entity (§ 1.9(f)) ........... $350.00
By other than a small entity ...... 690.00

3. Section 1.17 is amended by revising paragraphs (r) and (s), to read as follows:

§ 1.17 Patent application processing fees.

(r) For entry of a submission after final rejection under § 1.129(a):

By a small entity (§ 1.9(f)) ........... $345.00
By other than a small entity ...... 690.00

(s) For each additional invention requested to be examined under § 1.129(b):

By a small entity (§ 1.9(f)) ........... $345.00
By other than a small entity ...... 690.00

4. Section 1.20 is amended by revising paragraph (e) to read as follows:

§ 1.20 Post issuance fees.

(e) For maintaining an original or reissue patent, except a design or plant patent, based on an application filed on or after December 12, 1980, in force beyond four years; the fee is due by three years and six months after the original grant:

By a small entity (§ 1.9(f)) .......... $415.00
By other than a small entity ...... 830.00

5. Section 1.492 is amended by revising paragraph (a)(2) to read as follows:

§ 1.492 National stage fees.

(a) For filing an application, per class:

Basic fee (§ 1.9(f)) .......... $345.00
Basic fee (Small Entity) .......... $415.00

(2) Where no international preliminary examination fee as set forth in § 1.482 has been paid to the United States Patent and Trademark Office, but an international search fee as set forth in § 1.445(a)(2) has been paid on the international application to the United States Patent and Trademark Office as an International Searching Authority:

By a small entity (§ 1.9(f)) .......... $345.00
By other than a small entity ...... 690.00

APPENDIX A—COMPARISON OF CURRENT AND NEW FEE AMOUNTS

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<th>Fee code</th>
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2. Section 2.6 is amended by revising paragraphs (a)(1), (a)(4), (a)(5), (a)(13), (a)(16), and (a)(17), to read as follows:

§ 2.6 Trademark fees.

(a) For filing a request under section 3(d)(2) of the Act for a six-month extension of time for filing a statement of use under section 1(d)(1) of the Act, per class:

Basic fee (§ 1.9(f)) .......... $325.00

For filing an affidavit under § 15 of the Act, per class:

(1) For filing an affidavit under § 15 of the Act, per class | $200.00 |

(16) For filing a petition to cancel, per class | $300.00 |

(17) For filing a notice of opposition, per class | 300.00 |

Dated: November 30, 1999.

Q. Todd Dickinson,
Assistant Secretary of Commerce and Commissioner of Patents and Trademarks.

Note: The following appendix is provided as a courtesy to the public, but is not a substitute for the rules. It will not appear in the Code of Federal Regulations.
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<td>(4)</td>
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<td>1.21(k)</td>
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<td>1.21(l)</td>
<td>Retaining abandoned application</td>
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<td>617</td>
<td>1.21(m)</td>
<td>Processing returned checks</td>
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<td>1.21(n)</td>
<td>Handling of incomplete or improper application</td>
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<td>1.21(o)</td>
<td>APS—Text terminal session time, per hour</td>
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<td>Transmittal fee</td>
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<td>1.445(a)(2)(ii)</td>
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<td>1.482(a)(2)</td>
<td>Additional invention—ISA not the U.S.</td>
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<td>1.492(a)(4)</td>
<td>Claims—PEA</td>
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<td>Claims—extra independent (over three) (Small Entity)</td>
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<td>Extension for filing Statement of Use, per class</td>
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<td>Additional fee for late renewal, per class</td>
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<td>Publication of mark under §12(c), per class</td>
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<td>2.6(a)(9)</td>
<td>Certificate of correction, registrant's error</td>
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<td>2.6(b)(5)</td>
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<td>Recording trademark property, per mark, per document</td>
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<td>482</td>
<td>2.6(b)(6)</td>
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<td>2.6(b)(11)</td>
<td>Unspecified other services, excluding labor</td>
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<td>650</td>
<td>2.7(a)</td>
<td>Recordal application fee</td>
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<td>2.7(b)</td>
<td>Renewal application fee</td>
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</tr>
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</table>

1 Fees effective on December 29, 1999.
2 Fees effective on January 10, 2000.
4 Fees remain at FY 1999 amount.
5 Actual cost.
Final Rule To Extend the Stay of Action on Section 126 Petitions for Purposes of Reducing Interstate Ozone Transport

Agency: Environmental Protection Agency (EPA).

Action: Final rule.

Summary: Today, EPA is taking final action to extend the temporary stay of the effective date of the May 25, 1999 final rule (64 FR 28250) regarding petitions filed under section 126 of the Clean Air Act (CAA) until November 30, 1999. This stay provides EPA time to finalize its work on these petitions and publish its decision in the Federal Register. On June 24, 1999 (64 FR 33956) EPA issued an interim final rule that temporarily stayed the effective date of the May 25 final rule regarding petitions filed under section 126 of the CAA until November 30, 1999. This final action to extend the temporary stay will prevent the findings under section 126 from being triggered automatically on November 30, 1999, under the mechanism EPA established in the May 25 final rule.

Effective Date: This final rule is effective November 30, 1999.

Address(es): Documents relevant to this action are available for inspection at the Air and Radiation Docket and Information Center (6102), Attention: Docket No. A–97–43, U.S. Environmental Protection Agency, 401 M Street SW., room M–1500, Washington, DC 20460, telephone (202) 260–7548 between 8:00 a.m. and 5:30 p.m., Monday through Friday, excluding legal holidays. A reasonable fee may be charged for copying.

For Further Information Contact: Questions concerning today’s action should be addressed to Carla Oldham, Office of Air Quality Planning and Standards, Air Quality Strategies and Standards Division, MD–15, Research Triangle Park, NC, 27711, telephone (919) 541–3347, e-mail at oldham.carla@epa.gov.

Supplementary Information:

Availability of Related Information

The official record for the May 25, 1999 section 126 rulemaking, as well as the public version of the record, has been established under docket number A–97–43 (including comments and data submitted electronically as described below). The public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as confidential business information, is available for inspection from 8:00 a.m. to 5:30 p.m., Monday through Friday, excluding legal holidays. The official rulemaking record is located at the address in Addresses at the beginning of this document. In addition, the Federal Register rulemakings and associated documents are located at http://www.epa.gov/tnn/rto/126.

I. Background

A. Interim Final Rule To Stay Affirmative Technical Determinations Under Section 126 Petitions To Reduce Interstate Ozone Transport

On May 25, 1999 (64 FR 28250), EPA made final determinations that portions of the petitions filed by eight Northeastern States under section 126 of the CAA were technically meritorious. The petitions sought to mitigate what the EPA described as significant transport of one of the main precursors of ground-level ozone, nitrogen oxides (NOX), across State boundaries. Each petition specifically requested that EPA make a finding that certain stationary sources emit NOX in violation of the CAA’s prohibition on emissions that significantly contribute to nonattainment problems in the petitioning State.

On June 24, 1999 (64 FR 33956), EPA issued an interim final rule to temporarily stay the effectiveness of the May 25 final rule regarding the section 126 petitions until November 30, 1999. The purpose of the interim final rule was to provide EPA time to conduct notice-and-comment rulemaking addressing issues raised by two recent rulings of the U.S. Court of Appeals for the District of Columbia Circuit (D.C. Circuit). In one ruling in American Trucking Assn., Inc., v. EPA, 175 F.3d 1027 (D.C. Cir. 1999), the court remanded the 8-hour national ambient air quality standard (NAAQS) for ozone, which formed part of the underlying technical basis for certain of EPA’s determinations under section 126. On October 29, 1999, the D.C. Circuit granted in part EPA’s Petition for Rehearing and Rehearing En Banc (filed on June 28, 1999) in American Trucking, and modified portions of its opinion addressing EPA’s ability to implement the eight-hour standard. See American Trucking, 1999 WL 979463 (Oct. 29, 1999). The court denied the remainder of EPA’s rehearing petition. Id. EPA continues to evaluate the effect of American Trucking, as modified by the D.C. Circuit’s October 29, 1999 opinion and order. EPA expects, however, that the status of the eight-hour standard will be uncertain for some time to come. In a separate action, the D.C. Circuit granted a motion to stay the State implementation plan (SIP) submission deadlines established in a related EPA action, the NOX SIP call (October 27, 1998 63 FR 57556). In the interim final rule, EPA explained why it would be contrary to the public interest for the May 25 rule to remain in effect while EPA conducted rulemaking to respond to issues raised by the court rulings. The reader should refer to the June 24, 1999 interim final rule (64 FR 33956) and May 25, 1999 final rule (64 FR 28250) for further details and background information.

B. Proposal To Amend the May 25, 1999 Final Rule

On June 24, 1999 (64 FR 33962), EPA proposed to amend two aspects of the May 25 final rule. The EPA proposed to stay indefinitely the affirmative technical determinations based on the 8-hour standard pending further developments in the NAAQS litigation. The EPA also proposed to remove the trigger mechanism for making section 126 findings that was based on the NOX SIP call deadlines and instead make the findings in a final rule to be issued in November 1999. In the June 24 proposal, EPA explained why it originally made sense to link the section 126 action to the NOX SIP call and why EPA believes it is no longer appropriate to do so in the absence of a compliance schedule for the NOX SIP call. At that time, the EPA indicated that it expected to promulgate the final rule based on the proposal by November 30, 1999, when the interim final rule would expire. To address the possibility that there could be a delay in amending the May 25 final rule, EPA requested comments in the June 24 proposal on extending the temporary stay beyond November 30 until EPA completed the final rule. The EPA noted that if additional time were needed, it would likely not be more than two or three months. Two commenters agreed that it would be appropriate for EPA to further extend the stay under such circumstances, while one commenter expressed concern that an extension of time would increase the likelihood of delay.
II. Today's Final Rule To Extend the Temporary Stay

Today’s final rule, which is effective November 30, 1999, temporarily extends the stay of the May 25 rule until January 10, 2000. Today’s action will prevent findings under section 126 from being automatically triggered on November 30, 1999 under the mechanism in the May 25 rule. The EPA plans to sign the final rule to modify the May 25, 1999 rule no later than early to mid December 1999. However, a stay needs to apply until the effective date of the final section 126 rule. As the final section 126 rule will not become effective until 30 days after publication in the Federal Register, EPA is extending the stay until January 10, 2000. If necessary, given the ultimate date of publication of the final section 126 rule, EPA will further extend the stay for a few additional weeks.

This extension of the stay does not affect the compliance date of May 1, 2003 for emission reductions under the section 126 rule. Also, the affected entities will have notice of the requirements under section 126 as of the date that EPA signs and releases the final section 126 rule to the public.

III. Rulemaking Procedures

As noted above, this rule will be effective on November 30, 1999. Providing for a delay of the effective date of this final rule (either 30 or 60 days after publication) would be unnecessary and contrary to the public interest. Because the final rule relieves a regulatory burden that would otherwise be imposed, there is no need to provide time for education and compliance with a new regulatory requirement. Moreover, allowing the stay to lapse before the final rule becomes effective would allow the section 126 findings to be automatically triggered upon November 30, 1999 for sources potentially subject to the section 126 findings in all States that had not submitted SIPs in compliance with the NOX SIP call and for which EPA had not proposed approval of such SIPs. As explained in the June 24 proposal (64 FR 33962), EPA believes it is no longer appropriate to link the section 126 findings with compliance with the NOX SIP call, in light of the judicial stay of the compliance dates under the NOX SIP call. Thus, allowing the findings to be triggered automatically would be contrary to the purposes of the ongoing section 126 rulemaking and contrary to the public interest. In addition, under the automatic trigger mechanism, findings would be made on November 30 based on both the 1-hour and 8-hour standards. The EPA believes it is appropriate in light of the court’s decision in American Trucking Ass’n v. EPA to stay the findings based on the 8-hour standard at this time. Given the lack of burden upon affected parties and the need to make this final rule effective on November 30, 1999, EPA finds good cause for expediting the effective date of this portion of today’s rule. EPA believes that this is consistent with 5 U.S.C. 553(d)(1) and (3).

V. Administrative Requirements

A. Executive Order 12866: Regulatory Planning and Review

Under Executive Order 12866 (58 FR 51735, October 4, 1993), the Agency must determine whether a regulatory action is “significant” and therefore subject to Office of Management and Budget (OMB) review and the requirements of the Executive Order. The Order defines “significant regulatory action” as one that is likely to result in a rule that may:

(1) have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities;

(2) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;

(3) materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or

(4) raise novel legal or policy issues arising out of legal mandates, the President’s priorities, or the principles set forth in the Executive Order.

The EPA believes that this final rule is not a “significant regulatory action” because it relieves, rather than imposes, regulatory requirements, and raises no novel legal or policy issues.

B. Regulatory Flexibility

EPA has determined that it is not necessary to prepare a regulatory flexibility analysis in connection with this final rule. EPA has also determined that this rule will not have a significant economic impact on a substantial number of small entities. Small entities include small businesses, small organizations, and small governmental jurisdictions. Today’s action does not create any new requirements. Thus, this rule will not have a significant economic impact on a substantial number of small entities.

C. Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), Public Law 104–4, establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, local, and tribal governments and the private sector. Under section 202 of the UMRA, 2 U.S.C. 1532, EPA generally must prepare a written statement, including a cost-benefit analysis, for any proposed or final 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 * * * in any one year.” A “Federal mandate” is defined to include a “Federal intergovernmental mandate” and a “Federal private sector mandate” (2 U.S.C. 658(6)). A “Federal intergovernmental mandate,” in turn, is defined to include a regulation that “would impose an enforceable duty upon State, local, or tribal governments (2 U.S.C. 658(5)(A)(i)), except for, among other things, a duty that is “a condition of Federal assistance (2 U.S.C. 658(5)(A)(ii)(I)).” A “Federal private sector mandate” includes a regulation that “would impose an enforceable duty upon the private sector,” with certain exceptions (2 U.S.C. 658(7)(A)).

The EPA has determined that this action does not include a Federal mandate that may result in estimated costs of $100 million or more to either State, local, or tribal governments in the aggregate, or to the private sector. This Federal action imposes no new requirements. Accordingly, no additional costs to State, local, or tribal governments, or to the private sector, result from this action.

D. Paperwork Reduction Act

This final rule does not impose any new information collection requirements. Therefore, an Information Collection Request document is not required.

E. Executive Order 13045—Protection of Children From Environmental Health Risks and Safety Risks

Executive Order 13045 applies to any rule that (1) is determined to be “economically significant” as defined under Executive Order 12866, and (2) concerns an environmental health or safety risk that EPA has reason to believe may have a disproportionate effect on children. If the regulatory action meets both criteria, the Agency must evaluate the environmental health or safety effects of the rule on children, and explain why the regulation is preferable to other potentially effective
provide to the Office of Management and Budget (OMB), in a separately identified section of the preamble to the rule, a federalism summary impact statement (FSIS). The FSIS must include a description of the extent of EPA’s prior consultation with State and local officials, a summary of the nature of their concerns and the agency’s position supporting the need to issue the regulation, and a statement of the extent to which the concerns of State and local officials have been met. Also, when EPA transmits a draft final rule with federalism implications to OMB for review pursuant to Executive Order 12866, EPA must include a certification from the agency’s Federalism Official stating that EPA has met the requirements of Executive Order 13132 in a meaningful and timely manner.

This final rule will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132. Today’s rule does not create a mandate on State, local or Tribal governments. The rule does not impose any enforceable duties on these entities. Thus, the requirements of section 6 of the Executive Order do not apply to this rule.

H. Executive Order 13084: Consultation and Coordination With Indian Tribal Governments

Under Executive Order 13084, EPA may not issue a regulation that is not required by statute, that significantly or uniquely affects the communities of Indian tribal governments, and that imposes substantial direct compliance costs on those communities, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by the tribal governments, or EPA consults with those governments. If EPA complies by consulting, Executive Order 13084 requires EPA to provide to the Office of Management and Budget, in a separately identified section of the preamble to the rule, a description of the extent of EPA’s prior consultation with representatives of affected tribal governments, a summary of the nature of their concerns, and a statement supporting the need to issue the regulation. In addition, Executive Order 13084 requires EPA to develop an effective process permitting elected officials and other representatives of Indian tribal governments “to provide meaningful and timely input in the development of regulatory policies on matters that significantly or uniquely affect their communities.”

Today’s rule does not significantly or uniquely affect the communities of Indian tribal governments. This action does not impose any requirements that affect Indian Tribes. Accordingly, the requirements of section 3(b) of E.O. 13084 do not apply to this rule.

I. National Technology Transfer and Advancement Act

Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Pub. L. No. 104–113, directs EPA to use voluntary consensus standards in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g., materials specifications, test methods, sampling procedures, and business practices) that are developed or adopted by voluntary consensus standards bodies. The NTTAA directs EPA to provide Congress, through OMB, explanations when the Agency decides not to use available and applicable voluntary consensus standards.

This final rule does not involve the promulgation of any new technical standards. Therefore, NTTAA requirements are not applicable to today’s rule.

J. Judicial Review

Section 307(b)(1) of the CAA indicates which Federal Courts of Appeal have venue for petitions of review of final actions by EPA. This Section provides, in part, that petitions for review must be filed in the Court of Appeals for the District of Columbia Circuit (i) when the agency action consists of “nationally applicable regulations promulgated, or final actions taken, by the Administrator,” or (ii) when such action is locally or regionally applicable, if “such action is based on a determination of nationwide scope or effect and if in taking such action the Administrator finds and publishes that such action is based on such a determination.”

For the reasons discussed in the May 25 NFR, the Administrator determined that final action regarding the section 126 petitions is of nationwide scope and effect for purposes of section 307(b)(1). Thus, any petitions for review of final actions regarding the section 126 rulemaking must be filed in the Court of Appeals for the District of Columbia Circuit within 60 days from the date final action is published in the Federal Register.
K. Congressional Review Act

The Congressional Review Act (CRA), 5 U.S.C. 801 et seq., as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. The EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to November 30, 1999. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Emissions trading, Nitrogen oxides, Ozone transport, Reporting and recordkeeping requirements.

Date: November 29, 1999.

Carol M. Browner, Administrator.

40 CFR part 52 is amended as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

1. The authority citation for part 52 continues to read as follows:
   Authority: 42 U.S.C. 7401 et seq.

Subpart A—General Provisions

2. Section 52.34 is amended by revising paragraph (l) to read as follows:

§ 52.34 Action on petitions submitted under section 126 relating to emissions of nitrogen oxides.

(l) Temporary stay of rules.

Notwithstanding any other provisions of this subpart, the effectiveness of this section is stayed from July 26, 1999 until January 10, 2000.

[FR Doc. 99–31355 Filed 12–3–99; 3:02 pm]
BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[084–1084; FRL–6483–4]

Approval and Promulgation of Implementation Plans and Approval Under Section 112(l); State of Iowa

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is taking final action to approve State Implementation Plan (SIP) revisions submitted by the state of Iowa. These revisions will strengthen the SIP with respect to attainment and maintenance of established air quality standards and with respect to hazardous air pollutants. The effect of this action is to ensure Federal enforceability of the state’s air program rule revisions.

EFFECTIVE DATE: This rule will be effective January 3, 2000.

ADDRESSES:Copies of the state submittal(s) are available at the following addresses for inspection during normal business hours:

Environmental Protection Agency, Air Planning and Development Branch, 901 North 5th Street, Kansas City, Kansas 66101; and the Environmental Protection Agency, Air and Radiation Docket and Information Center, Air Docket (6102), 401 M Street, SW, Washington, D.C. 20460.

FOR FURTHER INFORMATION CONTACT:
Wayne Kaiser, Air Planning and Development Branch, 901 North 5th Street, Kansas City, Kansas 66101 at (913) 551–7603.

SUPPLEMENTARY INFORMATION:
Throughout this document wherever “we, us, or our” is used, we mean EPA.

What Is the Background Information?

On May 13, 1999, we published proposed and direct final Federal Register notices (64 FR 25855 and 64 FR 25825) which took action to approve as a revision to the Iowa SIP a set of rule revisions submitted by the state of Iowa on December 11, 1998, and January 29, 1999. Because adverse comments were received during the public comment period, we published a withdrawal notice in the Federal Register on July 2, 1999 (64 FR 35941). Today’s document takes final action on the state’s submissions and addresses the public comments.

What Comments Were Received?

We received four comment letters. All commenters objected to our approving the revision in the SIP to Iowa rule Chapter 28, “Ambient Air Quality Standards,” Rule 28.1. In this rule, the state had adopted by reference the national ambient air quality standards (NAAQS) promulgated by us on July 18, 1997, which revised the particulate matter and ozone NAAQS.

The commenters stated that Rule 28.1 should not be approved by us in light of the recent decision of the United States Court of Appeals for the District of Columbia Circuit in the case of American Trucking Associations, Inc. v. United States Environmental Protection Agency. The commenters stated that since the Court vacated the revised PM10 standard and remanded other standards to EPA, it would be inappropriate for EPA to approve Iowa’s adoption of these standards. Some commenters also questioned Iowa’s authority to adopt the NAAQS rules in light of the Court’s decision.

What Action Did the State Take in Response to the Comments?

The Iowa Department of Natural Resources subsequently submitted a letter, dated July 15, 1999, which requested that Rule 28.1 be removed from its earlier request for approval as a SIP revision. Therefore, Rule 28.1 is no longer part of the submission by Iowa. We did not receive adverse comments on any of the other revisions discussed in the May 13 actions.

What Final Action Are We Taking Now?

We are taking final action today to approve the rules discussed in our May 13, 1999, Federal Register document, except for Rule 28.1. EPA is eliminating Rule 28.1 from its approval in light of the state’s withdrawal of that rule, which, in effect, means that Rule 28.1 is no longer before EPA to act upon. This action has no impact on the state’s ability (and obligation) to meet the relevant requirements specified in section 110 of the Clean Air Act (CAA) with respect to attainment and maintenance of NAAQS. EPA’s rationale for approval of the remainder of the rules is discussed in detail in the May 13 proposal.

Conclusion

Final action: EPA is taking final action to approve a revision to the Iowa SIP.

Administrative Requirements

A. Executive Order (E.O.) 12866

The Office of Management and Budget (OMB) has exempted this regulatory action from E.O. 12866, entitled “Regulatory Planning and Review.”

B. E.O. On Federalism

Under E.O. 12875, EPA may not issue a regulation that is not required by statute and that creates a mandate upon a state, local, or tribal government, unless the Federal Government provides the funds necessary to pay the direct compliance costs incurred by those governments. If the mandate is unfunded, EPA must provide to the Office of Management and Budget a description of the extent of EPA’s prior
consultation with representatives of affected state, local, and tribal governments, the nature of their concerns, copies of written communications from the governments, and a statement supporting the need to issue the regulation. In addition, E.O. 12875 requires EPA to develop an effective process permitting elected officials and other representatives of state, local, and tribal governments “to provide meaningful and timely input in the development of regulatory proposals containing significant unfunded mandates.” Today’s rule does not create a mandate on state, local or tribal governments. The rule does not impose any enforceable duties on these entities. Accordingly, the requirements of section 1(a) of E.O. 12875 do not apply to this rule.

On August 4, 1999, President Clinton issued a new E.O. on federalism, E.O. 13132 (64 FR 43255 (August 10, 1999)), which will take effect on November 2, 1999. In the interim, the current E.O. 12612 (52 FR 41685 (October 30, 1987)) on federalism still applies. This rule will not have a substantial direct effect on 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 E.O. 12612, because it merely codifies Federal approval of preexisting requirements. The rule affects only one state, and does not alter the relationship or the distribution of power and responsibilities established in the CAA.

C. E.O. 13045

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

This rule is not subject to E.O. 13045 because it is not an economically significant regulatory action as defined by E.O. 12866, and it does not establish a further health or risk-based standard because it codifies provisions which implement a previously promulgated health or safety-based standard.

D. E.O. 13084

Under E.O. 13084, Consultation and Coordination with Indian Tribal Governments, EPA may not issue a regulation that is not required by statute, that significantly or uniquely affects the communities of Indian tribal governments, and that imposes substantial direct compliance costs on those communities, unless the Federal Government provides the funds necessary to pay the direct compliance costs incurred by the tribal governments, or EPA consults with those governments. If EPA complies by consulting, E.O. 13084 requires EPA to provide to the OMB, in a separately identified section of the preamble to the rule, a description of the extent of EPA’s prior consultation with representatives of affected tribal governments, a summary of the nature of their concerns, and a statement supporting the need to issue the regulation. In addition, E.O. 13084 requires EPA to develop an effective process permitting elected officials and other representatives of Indian tribal governments “to provide meaningful and timely input in the development of regulatory policies on matters that significantly or uniquely affect their communities.”

Today’s rule does not significantly or uniquely affect the communities of Indian tribal governments. This action does not involve or impose any requirements that affect Indian tribes. Accordingly, the requirements of Section 3(b) of E.O. 13084 do not apply to this rule.

E. Regulatory Flexibility Act (RFA)

The RFA generally requires an agency to conduct a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements, unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Small entities include small businesses, small not-for-profit enterprises, and small governmental jurisdictions. This final rule will not have a significant impact on a substantial number of small entities because SIP approvals under section 110 and Subchapter I, Part D of the CAA do not create any new requirements, but simply approve requirements that the state is already imposing. In addition, this final rule merely codifies Federal approvals of state requirements which have already occurred. Therefore, I certify that this action will not have a significant economic impact on a substantial number of small entities. Moreover, due to the nature of the Federal-state relationship under the CAA, preparation of flexibility analysis would constitute Federal inquiry into the economic reasonableness of state action. The CAA forbids EPA to base its actions concerning SIPs on such grounds. Union Electric Co., v. U.S. EPA, 427 U.S. 246, 255-66 (1976); 42 U.S.C. 7410(a)(2).

F. Unfunded Mandates

Under section 202 of the Unfunded Mandates Reform Act of 1995 (“Unfunded Mandates Act”), signed into law on March 22, 1995, EPA must prepare a budgetary impact statement to accompany any proposed or final rule that includes a Federal mandate that may result in estimated annual costs to state, local, or tribal governments in the aggregate, or to the private sector, of $100 million or more. Under section 205, EPA must select the most cost-effective and least burdensome alternative that achieves the objectives of the rule and is consistent with statutory requirements. Section 203 requires EPA to establish a plan for informing and advising any small governments that may be significantly or uniquely impacted by the rule. EPA has determined that the approval action promulgated does not include a Federal mandate that may result in estimated annual costs of $100 million or more to either state, local, or tribal governments in the aggregate, or to the private sector. This Federal action codifies Federal approvals of preexisting requirements under state or local law, and imposes no new requirements. Accordingly, no additional costs to state, local, or tribal governments, or to the private sector, result from this action.

G. Submission to Congress and the Comptroller General

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

H. Petitions for Judicial Review

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

**List of Subjects 40 CFR Part 52**

Environmental protection, Air pollution control, Carbon monoxide, Hydrocarbons, Incorporation by reference, Intergovernmental relations, Lead, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements, Sulfur oxides, Volatile organic compounds.

**PART 52—[AMENDED]**

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

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

**Subpart Q—Iowa**

2. In § 52.820 the following entries for paragraph (c), EPA-approved regulations, are revised to read as follows:

   **§ 52.820 Identification of plan.**

   * * * * *

   (c) EPA-approved regulations.

**EPA-APPROVED IOWA REGULATIONS**

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[FR Doc. 99–31290 Filed 12–2–99; 8:45 am]
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Agency (EPA).


Sulfur dioxide (SO\textsubscript{2}).

The intended effect of approving these rules is to regulate emissions of SO\textsubscript{2} in accordance with the requirements of the Clean Air Act, as amended in 1990 (CAA or the Act).

The修订s rules control the sulfur content of fuels. Thus, EPA is finalizing the approval of these revisions into the California SIP under provisions of the CAA regarding EPA action on SIP submittals and SIPs for national primary and secondary ambient air quality standards.

This action is effective on January 3, 2000.

Copies of the submitted rule revisions and EPA’s evaluation report for each rule are available for public inspection at EPA’s Region IX office during normal business hours. Copies of the submitted rule revisions are available for inspection at the following locations:

Rulemaking Office (AIR–4), Air Division, U.S. Environmental Protection Agency, Region IX, 75 Hawthorne Street, San Francisco, CA 94105.

Environmental Protection Agency, Air Docket (6102), 401 “M” Street, S.W., Washington, D.C. 20460.

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

South Coast Air Quality Management District, 21865 E. Copley Dr., Diamond Bar, CA 91765–4182.

Ventura County APCD, 669 County Square Dr., 2nd Fl., Ventura, CA 93003–5417.

FOR FURTHER INFORMATION CONTACT:

SUMMARY:
EPA is finalizing the approval of revisions to the California State Implementation Plan (SIP) proposed in the Federal Register on September 22, 1999. The revisions concern rules from the following districts: South Coast Air Quality Management District (SCAQMD) and the Ventura County Air Pollution Control District (VCAPCD). This approval action will incorporate these rules into the federally approved SIP. The intended effect of approving these rules is to regulate emissions of sulfur dioxide (SO\textsubscript{2}) in accordance with the requirements of the Clean Air Act, as amended in 1990 (CAA or the Act).

The revised rules control the sulfur content of fuels. Thus, EPA is finalizing the approval of these revisions into the California SIP under provisions of the CAA regarding EPA action on SIP submittals and SIPs for national primary and secondary ambient air quality standards.

This action is effective on January 3, 2000.

II. Background

On September 22, 1999 in 64 FR 51278, EPA proposed to approve the following rules into the California SIP: SCAQMD’s Rule 431.1, Sulfur Content of Gaseous Fuels and VCAPCD’s Rule 64, Sulfur Content of Fuels. Rule 431.1 was adopted by the SCAQMD on June 12, 1998. On September 29, 1998, this rule was submitted by the CARB to EPA. Rule 64 was adopted by the VCAPCD on April 13, 1999. On June 3, 1999, this rule was submitted by the CARB to EPA. VCAPCD Rule 64 was submitted in response to a limited approval/limited disapproval EPA published on January 15, 1999 in 64 FR 2375 for an earlier version of the rule. Both SCAQMD and VCAPCD are in attainment for the National Ambient Air Quality Standards for SO\textsubscript{2}. A detailed discussion of the background for each of the above rules is provided in the Notice of Proposed Rulemaking (NPRM) cited above.

EPA has evaluated both of the above rules for consistency with the requirements of the CAA and EPA regulations and EPA interpretation of these requirements as expressed in the various EPA policy guidance documents referenced in the NPRM cited above.

EPA has found that the rules meet the applicable EPA requirements. A detailed discussion of the rule provisions and evaluations has been provided in 64 FR 51278 and in the technical support document (TSD) available at EPA’s Region IX office (TSD dated 8/23/99).

III. Response to Public Comments

A 30-day public comment period was provided in 64 FR 51278, EPA received no comments on these rules.

IV. EPA Action

EPA is finalizing action to approve the above rules for inclusion into the California SIP. EPA is approving the submittal under section 110(k)(3) as meeting the requirements of section 110(a) of the CAA. This approval action will incorporate these rules into the federally approved SIP. The intended effect of approving these rules is to regulate emissions of SO\textsubscript{2} in accordance with the requirements of the CAA.

V. Administrative Requirements

A. Executive Order 12866

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

B. Executive Order 13132

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

This final rule will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132. Thus, the requirements of section 6 of the
Executive Order do not apply to this rule.

C. Executive Order 13045

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

This rule is not subject to Executive Order 13045 because it does not involve decisions intended to mitigate environmental health or safety risks.

D. Executive Order 13084

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

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

E. Regulatory Flexibility Act

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

This final rule will not have a significant impact on a substantial number of small entities because the amendments to EPA’s prior consultation requirements. Section 203 requires EPA to consider and use voluntary consensus standards (VCS) if available and applicable when developing programs and policies unless doing so would be inconsistent with applicable law or otherwise impractical.

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

I. Petitions for Judicial Review

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

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Hydrocarbons, Incorporation by reference,
Intergovernmental relations, Ozone, Reporting and recordkeeping requirements, Sulfur Oxides.

Dated: November 9, 1999.

Felicia Marcus,
Regional Administrator, Region IX.

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

PART 52—[AMENDED]
1. The authority citation for part 52 continues to read as follows:
Authority: 42 U.S.C. 7401 et seq.

Subpart F—California
2. Section 52.220 is amended by adding paragraphs (c),(264) and (266)(i)(A)(2).

§ 52.220 Identification of Plan.
(c) * * * * *
(264) * * *
(i) * * *
(C) Ventura County Air Pollution Control District.
(1) Rule 64, adopted on April 13, 1999.
* * * * *
(266) * * *
(i) * * *
(A) * * *
* * * * *

[FR Doc. 99–31212 Filed 12–2–99; 8:45 am]
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ENVIROMENTAL PROTECTION AGENCY

40 CFR Part 63
[AD–FRL–6500–2]
RIN 2060–A137

National Emission Standards for Hazardous Air Pollutants for Ethylene Oxide Commercial Sterilization and Fumigation Operations

AGENCY: Environmental Protection Agency (EPA).

ACTION: Interim final rule.

SUMMARY: Today’s action suspends the National Emission Standards for Hazardous Air Pollutants for Ethylene Oxide Commercial Sterilization and Fumigation Operations (EO NESHAP) requirements for chamber exhaust and aeration room vents. The suspension allows affected sources subject to the EO NESHAP to defer compliance with the NESHAP requirements for chamber exhaust until December 6, 2001 and aeration room vents until December 6, 2000. This suspension does not affect the requirement for sources subject to the EO NESHAP to comply with provisions for sterilizer vents. This action does not change the level of the standards or the intent of the NESHAP promulgated in 1994.

DATES: This action is effective December 3, 1999. Comments may be submitted until January 3, 2000.

ADDRESSES: Docket No. A–88–03, category VIII Amendments, contains supporting information used in developing the standards. The docket is located at the U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460 in room M–1500, Waterside Mall (ground floor), and may be inspected from 8:30 a.m. to 5:30 p.m., Monday through Friday, excluding legal holidays. This docket also contains information considered by the EPA in proposing and promulgating the original EO NESHAP.

FOR FURTHER INFORMATION CONTACT: For information concerning the analysis performed in developing this interim rule, contact David W. Markwordt at the Emission Standards Division (MD–13), U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711; telephone number (919) 541–0837, facsimile (919) 541–0942, e-mail address markwordt.david@epa.gov.

SUPPLEMENTARY INFORMATION:

Docket
The docket is an organized file of information considered by the EPA in the development of this rulemaking. The docket is a dynamic file because information considered by the EPA in developing the standards. The docket is an organized file of information considered by the EPA in the development of this rulemaking. The docket is a dynamic file because information material is added throughout the rulemaking process. The docketing system is intended to allow members of the public and industries involved to readily identify and locate documents so that they can effectively participate in the rulemaking process. Along with the proposed and promulgated standards and their preambles, the contents of the docket will serve as the record in the case of judicial review. (See section 307(d)(2)(A) of the Clean Air Act (Act).) The regulatory text and other materials related to this rulemaking are available for review in the docket or copies may be mailed on request from the Air Docket by calling (202) 260–7548. A reasonable fee may be charged for copying docket materials.

Judicial Review
Under section 307(b)(1) of the Clean Air Act (Act), judicial review of this final action is available only by filing a petition for review in the U.S. Court of Appeals for the District of Columbia Circuit within 60 days of today’s publication of this interim final rule. Under section 307(b)(2) of the Act, the actions taken in today’s notice may not be challenged later in civil or criminal proceedings brought by the EPA to enforce these requirements.

Technology Transfer Network
In addition to being available in the docket, an electronic copy of today’s interim final rule is also available through the Technology Transfer Network (TTN). Following signature, a copy of the rule will be posted on the TTN’s policy and guidance page for newly proposed or promulgated rules http://www.epa.gov/ttn/oarpg. The TTN provides information and technology exchange in various areas of air pollution control. If more information regarding the TTN is needed, call the TTN HELP line at (919) 541–5384.

Regulated Entities
Regulated categories and entities include:

<table>
<thead>
<tr>
<th>TABLE 1.—REGULATED CATEGORIES AND ENTITIES</th>
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<tbody>
<tr>
<td>Entity category</td>
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</tr>
<tr>
<td>Federal Government</td>
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<tr>
<td>State/Local/Tribal Gov</td>
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<tr>
<td>Not Affected.</td>
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<tr>
<td>Not Affected.</td>
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This table is not intended to be exhaustive, but rather provides a guide for readers regarding entities regulated by the NESHAP addressed in this interim final rule. If you have questions regarding the applicability of the NESHAP addressed in this interim final rule to a particular entity, consult the person listed in the preceding FOR FURTHER INFORMATION section.

I. What Is the Background for This Suspension?

On December 6, 1994, we promulgated the EO NESHAP which regulates emissions of ethylene oxide from new and existing commercial sterilization and fumigation operations using 1 ton or more of EO per year (59 FR 62585). The regulated category and entities affected by today’s action are the sources described in 40 CFR 63.360. That provision includes commercial operations using ethylene oxide as a
sterilant and fumigant in the production of medical equipment and supplies, and in miscellaneous sterilization and fumigation operations at both major and area sources. Note that this description is not intended to be exhaustive but, rather, to provide a guide for readers interested in this suspension. To determine whether your facility is affected by today’s action, you should carefully examine the applicability criteria in 40 CFR 63.360 and the explanation provided in this interim final rule. If you have questions about the applicability of today’s action to a particular entity, consult the appropriate person listed in the preceding *FOR FURTHER INFORMATION CONTACT* section.

In July 1997, we learned of reports of explosions at ethylene oxide sterilization and fumigation facilities. We subsequently suspended the EO NESHAP for 1 year until December 6, 1998 to provide time to determine the appropriate action necessary to mitigate the cause of the explosions (62 FR 64736).

After becoming aware of the explosions, the industry worked through the Ethylene Oxide Sterilization Association (EOSA) to begin investigations. The EOSA established a Safety Committee in September 1997 which has been meeting on a bimonthly basis since then. Sterilization industry leaders, abatement device vendors, and Federal, State and local agencies have been participating in the Safety Committee meetings.

In a June 2, 1998 letter to EPA, the EOSA recommended, “additional time to consider safe and economical control, installation, operation and maintenance alternatives applicable to aeration and chamber exhaust (backvent) emissions * * *” (see Docket No. A–88–03). The Health Industries Manufacturers Association (HIMA) reviewed the recommendation. The EOSA and HIMA membership represent most of the ethylene oxide sterilization and fumigation industry. The EOSA concluded that the oxidizer systems had not been properly integrated with traditional ethylene oxide sterilization process operations, that is, installation, operation and maintenance issues had not been sufficiently addressed by sterilizer operators.” The EOSA also concluded that “improperly overheating the oxidizer system from the chamber backvent was the primary safety concern.”

We also conducted an independent investigation of the accidents and reviewed reports by EPA Regional Offices and by EOSA member sterilization companies and, based on that investigation and review, concurred with the industry conclusion and recommendation (see Docket No. A–88–03). We further suspended the EO NESHAP for both aeration room vents and chamber backvents for 1 year until December 6, 1999 to provide time to determine the appropriate action necessary to mitigate the cause of the explosions (63 FR 66990). Aeration room vents were included in the suspension because control systems typically integrate both vents to the same control device.

II. What Is the Rationale for Today’s Suspension of Chamber Exhaust and Aeration Room Vent Requirements?

As noted above, in July 1997, the Agency learned of reports of explosions at ethylene oxide facilities. Several of these explosions occurred at facilities subject to the EO NESHAP. The Agency immediately began conducting a preliminary investigation to determine if the emission control equipment mandated by 40 CFR part 63, subpart O, was in any way associated with the cause of the problems at these facilities. The Agency, on December 9, 1997, wishing to adopt a cautious approach in order to assure public and worker safety, published in the *Federal Register* an interim final rule suspending 40 CFR part 63, subpart O (62 FR 64736). Since publication of the December 9, 1997 rule, both EPA and industry have continued to investigate the cause of the accidents.

In 1998, the Agency agreed with industry that, in the cases where explosions occurred, the catalytic oxidizer units were overfed with ethylene oxide in concentrations above the safe operations limit due to abnormal activation of the chamber exhaust (backvent). The Agency concluded that main vent emissions routed through the vacuum pump played no role in the explosions. The Agency also concluded that any emissions control technology necessary to comply with the EO NESHAP needs to be properly integrated into the sterilization system and operations and must reflect the full range of normal and abnormal conditions that may occur.

The suspension, in December 1998, for chamber exhaust vents was based on the assumption that sterilization chamber operators would be able to evaluate and integrate the emission control technology with sterilizer operation to ensure prevention of future explosions by December 6, 1999. To date, solutions to the safety problems have not been developed. Consequently, the EOSA and individual plant operators have requested EPA to eliminate the requirement for backdraft vents (see Docket No. A–88–03).

It is beyond the Agency’s legal mandate and technical expertise to certify equipment for safe use. The Clean Air Act generally requires the Agency to assess existing emission control technology for application to non-controlled emission sources. The use of existing technology by some sources in the relevant category preserves the ability to operate that technology in a proven safe manner. At the time of promulgation (December 1994), state-of-the-art control technology for chamber exhaust emissions apparently involved safety hazards not known at that time. Therefore, the Agency will reconsider its original MACT determination for chamber exhaust vents and propose a course of action in the near future.

Today’s 2-year suspension of control requirements for chamber exhaust emissions is based on the anticipated time required to propose and promulgate changes to the Federal *Register*. It’s our intent to resolve this matter as quickly as possible, and we hope to finalize a revised rule in less than 2 years.

Today’s 1-year suspension of control requirements for aeration room vents is based on the fact that many facilities are routing chamber exhaust emissions to the emission control device for aeration room vents. Facilities that control both aeration and chamber exhaust emissions via one abatement device will need to disconnect the chamber exhaust vent from the aeration room control device. Therefore, the Agency is providing time to separate chamber exhaust emissions from integrated control systems, if needed.

In this matter, we wish to err, if at all, on the side of safety. Accordingly, we are, today, further suspending the EO NESHAP emission limitation requirements in 40 CFR part 63, subpart O, for chamber exhaust and aeration room vents, as those emission points are defined at 40 CFR 63.361, until December 6, 2001 and December 6, 2000, respectively, pursuant to our general rulemaking authority under section 301(a) of the Act, 42 U.S.C. 7601(a). Sources must continue to comply with the EO NESHAP emission limitation requirements in 40 CFR part 63, subpart O, for sterilization chamber vents, as those emission points are defined at 40 CFR 63.361, because we have determined that their controls do not pose a safety concern.

Section 301(a) of the Act grants the Administrator of the EPA the authority “to prescribe such regulations as are necessary to carry out his functions
under this Act.” Given the unique circumstances and uncertainty surrounding the EO NESHAP, as described in this interim final rule, EPA believes that it is necessary to further suspend this rule’s requirements for chamber exhaust and aeration room vents for the safety of the public and workers in and around EO facilities. The control requirements of the EO NESHAP for chamber exhaust and aeration room vents continue to pose potential safety problems for which viable solutions are not currently available. This action is consistent with the objectives of the Act as stated in section 101(b), 42 U.S.C. 7401(b), “(T)he purposes of this subchapter are * * * to promote the public health and welfare and the productive capacity of its population * * *.”

The original EO NESHAP and today’s interim final rule are promulgated pursuant to section 307(d) of the Act, 42 U.S.C. 7607(d), which requires that any rule subject to that section be issued only after the public has received notice of, and an opportunity to comment on, the rule. However, section 307(d)(1) exempts from those requirements any rule for which the Agency finds under the Administrative Procedure Act, 5 U.S.C. 553(b), that providing prior notice-and-comment would be impracticable, unnecessary or contrary to the public interest.

We believe the circumstances presented here provide good cause to take this action without prior notice-and-comment. We find providing prior notice-and-comment would be impracticable and contrary to the public interest based on the potential ongoing danger to public and worker safety posed by the recent incidents at ethylene oxide facilities. There is simply not enough time to provide notice-and-comment procedures before the current compliance date of December 6, 1999, and until the compliance date is extended, sources are faced with having to install control equipment in time to meet the current compliance date. Only by omitting notice-and-comment from this action can we provide sources affected by the EO NESHAP with timely legal relief from the current compliance date while we further investigate the situation. Consequently, this action is being promulgated without prior notice-and-comment as provided for in section 307(b)(1) of the Act and is immediately effective as provided for in section 112(d)(10) of the Act.

Nonetheless, we are providing 30 days for submission of public comments. We will consider all written comments submitted in the allotted time period to determine if any change to this action is necessary.

In suspending the EO NESHAP requirements for chamber exhaust and aeration room vents, the Administrator wishes to remind the public and the regulated community that the role of the EPA has been and continues to be protection of public health and the environment in a way that is consistent with safety concerns.

III. Administrative Requirements
A. Paperwork Reduction Act

The information collection requirements of the EO NESHAP were submitted to and approved by the Office of Management and Budget (OMB). A copy of this Information Collection Request (ICR) document (OMB control number 2060–0283) may be obtained from Ms. Sandy Farmer, Information Policy Branch (2136), U.S. EPA, 401 M Street, SW, Washington, DC 20460, or by calling (202) 260–2740.

Today’s action has no impact on the information collection burden estimates made previously. Today’s action merely suspends the EO NESHAP requirements for chamber exhaust and aeration room vents for 1 year. This change does not impose new requirements. Consequently, the ICR has not been revised.

B. Executive Order 12866

Under Executive Order 12866 (58 FR 51735, October 4, 1993), EPA must determine whether the regulatory action is “significant” and therefore subject to review by OMB on the basis of the requirements of the Executive Order in addition to its normal review requirements. The Executive Order defines “significant regulatory action” as one that is likely to result in a rule that may:

1. Have an annual effect on the economy of $100 million or more or adversely affect a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or Tribal governments or communities;
2. Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;
3. Materiaely alter the budgetary impact of entitlements, grants, user fees, or loan programs, or the rights and obligations of recipients thereof; or
4. Raise novel legal or policy issues arising out of legal mandates, the President’s priorities, or the principles set forth in the Executive Order.

Today’s action does not fall within any of the four categories described above. Instead, it reduces the burden on certain sources by temporarily suspending the EO NESHAP requirements for chamber exhaust and aeration vents. Consequently, under Executive Order 12866, this action is not a “significant regulatory action” and is therefore not subject to review by OMB.

C. Executive Order 13132

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

If EPA complies by consulting, Executive Order 13132 requires EPA to provide to OMB, in a separately identified section of the preamble to the rule, a federalism summary impact statement (FSIS). The FSIS must include a description of the extent of EPA’s prior consultation with State and local officials, a summary of the nature of their concerns and the Agency’s position supporting the need to issue the regulation, and a statement of the extent to which the concerns of State and local officials have been met. Also, when EPA transmits a draft final rule with federalism implications to OMB for review pursuant to Executive Order 12866, EPA must include a certification from the agency’s Federalism official stating that EPA has met the requirements of Executive Order 13132 in a meaningful and timely manner. This final rule will not have substantial direct effects on the States,
on the relationship between the national
government and the States, or on the
distribution of power and
responsibilities among the various
levels of government, as specified in
Executive Order 13132. Today’s action
suspends existing requirements which
were promulgated in December 1994.
There are minimal, if any, impacts
associated with this action, thus, the
requirements of section 6 of the
Executive Order do not apply to this
rule.
D. Regulatory Flexibility/Small Business
Regulatory Enforcement Fairness Act of
1996
Under the Regulatory Flexibility Act,
Pub. L. 96–354, whenever an Agency
publishes any proposed or final rule in
the Federal Register, it must, except
under certain circumstances, prepare a
Regulatory Flexibility Analysis (RFA)
that describes the impact of the rule on
small entities (i.e., small businesses,
organizations, and governmental
jurisdictions). That analysis is not
necessary if the Agency determines that
the rule will not have a significant
economic impact on a substantial
number of small entities.
The EPA believes that there will be
little or no adverse impact on any small
entities as a result of the promulgation
of this rule because, rather than
imposing additional requirements, this
rule provides additional time to comply
with parts of the EO NESHAP. Because
the impacts are anticipated to be
insignificant or beneficial, EPA has
concluded that this rule will not have a
significant economic impact on a
substantial number of small entities.
Consequently, an RFA is not required.
E. Unfunded Mandates Reform Act
Title II of the Unfunded Mandates
Reform Act of 1995 (UMRA), Public
Law 104–4, establishes requirements for
Federal agencies to assess the effects of
their regulatory actions on State, local,
and tribal governments and the private
sector. Under section 202 of the UMRA,
EPA generally must prepare a written
statement, including a cost-benefit
analysis, for proposed and final rules
with “Federal mandates” that may
result in expenditures to State, local,
and tribal governments, in the aggregate,
or to the private sector of $100 million
or more in any 1 year. Before
promulgating an EPA rule for which a
written statement is needed, section 205
of the UMRA generally requires EPA to
identify and consider a reasonable
number of regulatory alternatives and
adopt the least costly, most cost-
effective or least burdensome alternative
that achieves the objects of the rule. The
provisions of section 205 do not apply
when they are inconsistent with
applicable law. Moreover, section 205
allows EPA to adopt an alternative other
than the least costly, most cost-effective
or least burdensome alternative if the
Administrator publishes with the final
rule an explanation of why that
alternative was not adopted. Before EPA
establishes any regulatory requirements
that may significantly or uniquely affect
small governments, including tribal
governments, it must have developed
under section 203 of the UMRA a small
government-agency plan. The plan must
provide for notifying potentially
affected small governments, enabling
officials of affected small governments
to have meaningful and timely input in
the development of EPA regulatory
proposals with significant Federal
tergovernmental mandates, and
informing, educating, and advising
small governments on compliance with
the regulatory requirements.
Today’s rule contains no Federal
mandates (under the regulatory
provisions of Title II of the UMRA) for
State, local, or tribal governments or the
private sector. Instead, this rule
provides additional time to comply with
some requirements of the EO NESHAP.
Because the rule is not expected to
result in the expenditure by State, local,
and tribal governments or the private
sector of $100 million or more in any 1
year, the Agency has not prepared a
budgetary impact statement or
specifically addressed the selection of
the least costly, most effective, or least
burdensome alternative. Because small
governments will not be significantly or
uniquely affected by this rule, the
Agency is not required to develop a plan
with regard to small governments. For
the reasons stated above, the
requirements of the UMRA do not apply
to this section.
F. National Technology Transfer and
Advancement Act
Section 12 of the National Technology
Transfer and Advancement Act of 1995
(NTTAA) requires Federal agencies to
evaluate existing technical standards
when developing new regulations. To
comply with the NTTAA, EPA must
consider and use “voluntary consensus
standards” (VCS) if available and
applicable when developing programs
and policies unless doing so would be
inconsistent with applicable law or
otherwise impractical.
The EPA believes that the use of VCS
in this interim final rule is impractical.
The suspension of the EO NESHAP
requirements on exhaust and
aeration room vents is merely a
procedural action that does not require
sources to take substantive steps that
lend themselves to VCS.
G. Executive Order 13045
Executive Order 13045, entitled
Protection of Children from
Environmental Health Risks and Safety
Risks (62 FR 19885, April 23, 1997),
applies to any rule that (1) OMB
determines is “economically
significant” as defined under Executive
Order 12866, and (2) EPA determines
the environmental health or safety risk
addressed by the rule has a
disproportionate effect on children. If
the regulatory action meets both
criteria, the Agency must evaluate the
environmental health or safety aspects
of the planned rule on children, and
explain why the planned regulation is
preferable to other potentially effective
and reasonably feasible alternatives
considered by the Agency.
This interim final rule is not subject
to the Executive Order because it is not
economically significant as defined in
E.O. 12866, and because the Agency
does not have reason to believe the
environmental health or safety risks
addressed by this action present a
disproportionate risk to children.
H. Executive Order 13084
Under Executive Order 13084, EPA
may not issue a regulation that is not
required by statute, that significantly or
uniquely affects the communities of
Indian tribal governments, and that
imposes substantial direct compliance
costs on those communities, unless the
Federal government provides the funds
necessary to pay the direct compliance
costs incurred by the tribal
governments, or EPA consults with	hose governments. If EPA complies by
consulting, Executive Order 13084
requires EPA to provide to the Office of
Management and Budget, in a separately
identified section of the preamble to the
rule, a description of the extent of EPA’s
prior consultation with representatives
of affected tribal governments, a
summary of the nature of their concerns,
and a statement supporting the need to
issue the regulation. In addition,
Executive Order 13084 requires EPA to
develop an effective process permitting
consulting officials and other
representatives of Indian tribal
governments “to provide meaningful
and timely input in the development of
regulatory policies on matters that
significantly or uniquely affect their
communities.”
Today’s rule does not significantly or
uniquely affect the communities of
Indian tribal governments. This interim
final rule imposes no enforceable duties
on these entities. Rather, the interim
final rule temporarily suspends certain regulatory requirements. Accordingly, the requirements of section 3(b) of Executive Order 13084 do not apply to this rule.

I. Congressional Review Act

Under the Small Business Regulatory Enforcement Fairness Act of 1996, we submitted a report containing these final amendments and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the General Accounting Office prior to publication of these final amendments in the Federal Register. This is not a "major rule" as defined by the Small Business Regulatory Enforcement Fairness Act.

List of Subjects in 40 CFR Part 63

Environmental protection, Air pollution control, Ethylene oxide sterilization, Hazardous substances, Reporting and recordkeeping requirements.


Carol M. Browner, Administrator.

For the reasons set out in the preamble, title 40, chapter I, of the Code of Federal Regulations is amended as follows:

PART 63—[AMENDED]

1. The authority citation for part 63 continues to read as follows:

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

Subpart O—[Amended]

2. Section 63.360 is amended by revising paragraphs (g)(4), (g)(5), and (g)(6) and adding paragraphs (g)(7), (g)(8), (g)(9), and (g)(10) to read as follows:

§ 63.360 Applicability.

(g) * * * *

(4) All aeration room vents subject to the emissions standards in § 63.362 with an initial startup date before December 2, 1994, immediately upon becoming subject to the emissions standards.

(5) All aeration room vents subject to the emissions standards in § 63.362 with an initial startup date on or after December 6, 2000, immediately upon initial startup of the source.

(6) All aeration room vents at sources using less than 10 tons that increase their ethylene oxide usage after December 6, 2000, such that the aeration room vents become subject to the emissions standards in § 63.362, immediately upon becoming subject to the emission standards.

(7) All chamber exhaust vents subject to the emissions standards in § 63.362 with an initial startup date before December 2, 1994, immediately upon becoming subject to the emissions standards.

(8) All chamber exhaust vents subject to the emissions standards in § 63.362 with an initial startup date on or after December 6, 2001, immediately upon initial startup of the source.

(9) All chamber exhaust vents at sources using less than 10 tons that increase their ethylene oxide usage after December 6, 2001, such that the chamber exhaust vents become subject to the emissions standards in § 63.362, immediately upon becoming subject to the emission standards.

(10) All chamber exhaust vents at sources using less than 10 tons that increase their ethylene oxide usage after December 6, 2001, such that the chamber exhaust vents become subject to the emissions standards in § 63.362(e)(1), immediately upon becoming subject to the emission standards.

* * * * *

[FR Doc. 99–31354 Filed 12–2–99; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 63

[AD–FRL–6500–1]

National Emission Standards for Hazardous Air Pollutants: Halogenated Solvent Cleaning

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule; amendments.

SUMMARY: This action promulgates amendments to the “National Emission Standards for Hazardous Air Pollutants: Halogenated Solvent Cleaning” originally promulgated on December 2, 1994. These amendments to the rule were proposed on August 19, 1999. Today’s action finalizes compliance options for continuous web cleaning machines, as well as amendments to the national emission standards for hazardous air pollutants (NESHAP) that apply to steam-heated vapor cleaning machines and to cleaning machines used to clean transformers. The EPA is finalizing these amendments to ensure that all owners or operators of solvent cleaning machines have appropriate and attainable requirements for their cleaning machines.

EFFECTIVE DATE: December 3, 1999.

ADDRESSES: Interested parties may review items used to support these final rule amendments at: Air and Radiation Docket and Information Center (6102), Attention Docket Number A–92–39, Room M–1500, U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460.

FOR FURTHER INFORMATION CONTACT: For information concerning the standards, contact Mr. Paul Almodovar, Coatings and Consumer Products Group, Emission Standards Division (MD–13), U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711, telephone number (919) 541–0283. For information regarding the applicability of this action to a particular entity, contact Ms. Acquanetta Delaney, Manufacturing Branch, Office of Compliance (2223A), U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460; telephone (202) 564–7061.

SUPPLEMENTARY INFORMATION:

Docket

The docket number for this rulemaking is A–92–39. The docket is an organized file of information compiled by the EPA in the development of this rulemaking. The docket is a dynamic file because material is added throughout the rulemaking development. The docketing system is intended to allow members of the public and industries involved to readily identify and locate documents so that they can effectively participate in the rulemaking process. Along with the proposed and promulgated standards and their preambles, the docket contains the record in the case of judicial review. (See section 307(d)(7)(A) of the Clean Air Act.)

Regulated Entities

The following entities are potentially regulated by this final rule.

<table>
<thead>
<tr>
<th>Category</th>
<th>SIC Codes</th>
<th>Examples of potentially regulated entities</th>
</tr>
</thead>
<tbody>
<tr>
<td>Industry</td>
<td>33, 34, 36, and 37</td>
<td>Facilities engaging in cleaning operations using halogenated solvent cleaning machines.</td>
</tr>
</tbody>
</table>
This list is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. This list includes the types of entities that the EPA is now aware could potentially be regulated by this action. Other types of entities not listed could also be affected. To determine whether your facility or company is regulated by this final rule, you should carefully examine the applicability criteria in §63.460 of the promulgated rule. If you have any questions regarding the applicability of this final rule to a particular entity, consult the person listed in the preceding FOR FURTHER INFORMATION CONTACT section.

The information presented in this preamble is organized as follows:

I. Background
A. Why is EPA amending the NESHAP for halogenated solvent cleaning?
B. What is the purpose of these final rule amendments?
C. What changes have been made since the August 10, 1999 proposed amendments?
D. Do the changes in today’s final rule amendments apply to my machines?

II. Review of Requirements for Continuous Web Cleaning Machines
A. How do I know if my machine is a continuous web cleaning machine?
B. How will these changes impact my continuous web cleaning machines?
C. How do I know if my machine is a “new” or an “existing” continuous web cleaning machine?
D. When must I comply with these new requirements?

III. Other Changes
A. What changes is EPA making that apply to my transformer cleaning operations?
B. What changes impact my steam-heated vapor cleaning machines?

IV. Impacts
V. Administrative Requirements
A. Executive Order 12866: Regulatory Planning and Review
B. Executive Order 13132: Federalism
C. Executive Order 13084: Consultation and Coordination with Indian Tribal Governments
D. Unfunded Mandates Reform Act
E. Regulatory Flexibility/Small Business Regulatory Enforcement Fairness Act
F. Paperwork Reduction Act
G. Executive Order 13045: Protection of Children from Environmental Health Risks and Safety Risks
H. Congressional Review Act
I. National Technology Transfer and Advancement Act

I. Background
A. Why is EPA amending the NESHAP for halogenated solvent cleaning?

The EPA promulgated the halogenated solvent cleaning (HSC) NESHAP on December 2, 1994, as subpart T of 40 CFR part 63 (59 FR 61801). That rule included requirements for batch and in-line cleaning machines and both control device and work practice requirements. A batch cleaning machine is defined in the HSC NESHAP as “a solvent cleaning machine in which individual parts or sets of parts move through the entire cleaning cycle before new parts are introduced.” Inherent in some of the requirements is the understanding that the part or set of parts stops at one or various points in the machine for cleaning and for removal of cleaned parts. In contrast, an in-line cleaning machine (or continuous cleaning machine) is defined in the HSC NESHAP as “a solvent cleaning machine that uses an automated parts handling system, typically a conveyor, to automatically provide a continuous supply of parts to be cleaned.”

After promulgation, several industry groups raised concerns about how some cleaning machines would be classified under the rule. These commenters stated that some machines did not clearly and completely fit into any of the categories of cleaning machines included in the HSC NESHAP. The machines in question included movie film cleaning machines and machines used to clean strips, rods, and wire.

After some review, the EPA concluded that these issues warranted additional consideration. On May 5, 1998 (63 FR 24768), the EPA issued an immediate stay of compliance for the continuous web cleaning machines until August 3, 1998. In that same action, the EPA proposed to extend the compliance date for these units for an additional year, to August 3, 1999, to allow for an equivalency determination. The EPA received comments on the proposed extension. One commenter expressed concern that the 1-year extension may not be sufficient time to review the data, complete the technical analysis, propose and promulgate an equivalency determination, and allow sufficient time for facilities to comply with the new requirements. The EPA recognized these concerns and on December 11, 1998 (63 FR 68397) extended the compliance date for continuous web cleaning machines to December 2, 1999.

On August 19, 1999, EPA published a direct final rule (64 FR 45187) and parallel proposal (64 FR 45221) to amend the “National Emission Standards for Hazardous Air Pollutants: Halogenated Solvent Cleaning.” The proposed amendments would have provided additional compliance options for continuous web cleaning machines, as well as clarifications that apply to steam-heated vapor cleaning machines and to cleaning machines used to clean transformers.

The EPA stated in the direct final rule that if relevant, adverse comments were received by September 20, 1999, the EPA would publish a notice withdrawing the direct final rule before its effective date of October 18, 1999. The EPA received adverse comments on the direct final rule from two commenters on September 20, 1999 and, therefore, withdrew the direct final rule on October 18, 1999 (64 FR 56173).

Today’s final rule amendments are based on the public comments received on the proposed amendments.

B. What is the purpose of these final rule amendments?

This final rule does two things. First, it promulgates alternative compliance requirements for continuous web cleaning machines consistent with the August 19, 1999 proposal (64 FR 45221). A continuous web cleaning machine is a cleaning machine that cleans a continuous web part at speeds typically in excess of 11 feet per minute. Changes to the rule impacting continuous web cleaning machines are discussed in section II.A of this final rule. Second, this final rule promulgates two minor changes, discussed in section III.B, that impact cleaning machines other than continuous web cleaning machines.

C. What changes have been made since the August 19, 1999 proposed amendments?

The EPA has made several changes and clarifications to the amendments proposed on August 19, 1999 (64 FR 45221) in response to the public comments that were received. A full discussion of the comments and the EPA responses is included in the docket for this rulemaking. Following is a summary of the major changes that have been made to the proposed amendments.

1. Clarification of Requirements for Remote Reservoir Continuous Web Cleaning Machines

The EPA has clarified that the owner or operator of a remote reservoir continuous web cleaning machine is not required to comply with freeboard refrigerated device requirements or freeboard ratio requirements. The EPA concluded that these requirements are redundant to the emission reductions obtained from the remote reservoir design. Upon further review, the EPA concluded that a separate section devoted to remote reservoir continuous web cleaning machines was warranted to ensure the requirements applicable to these machines were clear; these requirements were added as §63.463(h).
2. Equivalent Requirements for Complying With Downtime and Idling Mode Covers

The EPA has added equivalent requirements for covers during idling and downtime. These equivalent requirements include the ability to consider the continuous web part itself as a port cover if it fills the entry and exit port, thereby achieving the same control as a port cover. Also, a machine kept under negative pressure and vented to an appropriately maintained and operated carbon adsorption system is equivalent to maximum achievable control technology (MACT) and is now allowed under this rule.

3. Addition of an Alternative Standard for Continuous Web Cleaning Machines

The EPA has added an alternative standard for continuous web cleaning machines based on the calculation of an overall cleaning system control efficiency. This approach was recommended by a commenter and reviewed and accepted by the EPA.

4. Addition of Combined Squeegee and Air Knife System

Under the proposed amendments to the NESHAP, EPA allowed for the use of either a squeegee system or an air knife system. The EPA has clarified that a system that combines squeegees and air knives is allowed as long as the components are within a single enclosure. The visible emission test is not required until after the web part exits the combined system.

In addition to these changes, EPA wishes to clarify that there are four different compliance options that refer to carbon adsorber requirements for continuous web cleaning machines:

a. Under § 63.463(g)(1), a carbon adsorber system is allowed in the control device combinations for existing and new machines. The owners or operators of these machines must demonstrate that the exhaust concentration limit of 100 parts per million is maintained using the provisions of § 63.463(e)(2)(vii). The owners or operators must still demonstrate compliance with the work practice requirements and the basic design requirements contained in the rule.

b. Under § 63.463(g)(2), a carbon adsorption system with an overall control efficiency of 70 percent is allowed in lieu of complying with one of the control combinations cited above. The owners or operators of these machines are not required to demonstrate the 100 parts per million limit; the owners or operators must work with their regulating authority to define the appropriate monitoring parameters to demonstrate the 70 percent control. In addition, the owners or operators must demonstrate compliance with the work practice requirements and the basic design requirements contained in the rule.

c. Under §§ 63.463(g)(3)(vii) or 63.463(h)(2)(v), any facility with a lip or other exhaust within a machine must ensure that the exhaust is vented to a carbon adsorber system. The carbon adsorber system can be shown to meet either the 100 parts per million exhaust limit of § 63.463(e)(2)(vii) or the 70 percent carbon adsorber system efficiency of § 63.463(g)(2).

d. Under the new alternative standard of § 63.464(d), an owner or operator may elect to use a carbon adsorber system (or any other emission control system) to demonstrate compliance with the overall solvent cleaning machine reduction efficiency of 70 percent. A facility complying with this option is not subject to the work practice or basic design requirements, which includes the squeegee and air knife requirements.

The EPA would also like to clarify that under the HSC NESHAP, emissions from multiple solvent cleaning machines are allowed to be controlled using a single carbon adsorber. In this situation, the affected source would need to develop and get approval from the regulatory authority of a procedure to apportion the solvent recovered by the carbon adsorber to each machine venting through it. A likely procedure would apportion the solvent recovered from the carbon adsorber based on the percentage of total fresh solvent added to each solvent cleaning machine.

D. Do the Changes in Today’s Final Rule Amendments Apply to My Machines?

Today’s final rule amendments only apply to you if your machines meet any of the following criteria:

1. Halogenated solvent cleaning machines that are classified as continuous web cleaning machines. (Changes impacting these machines are discussed in section II.B.)

2. Halogenated solvent cleaning machines that are used to clean polychlorinated biphenyl (PCB) laden transformers. (A change impacting these machines is discussed in section III.A.)

3. Halogenated solvent cleaning machines that are steam-heated vapor cleaning machines. (The definition of continuous web cleaning machines and a change impacting these machines is discussed in section II.B.)

II. Review of Requirements for Continuous Web Cleaning Machines

This section discusses changes made to the HSC NESHAP proposed amendments published on August 19, 1999 (64 FR 45221).

A. How Do I Know if My Machine Is a Continuous Web Cleaning Machine?

A continuous web cleaning machine is a solvent cleaning machine in which parts such as film, coils, wire, and metal strips are cleaned at speeds typically in excess of 11 feet per minute. Parts are generally uncoiled, cleaned such that the same part is simultaneously entering and exiting the solvent application area of the solvent cleaning machine, and then recoiled or cut. For the purposes of subpart T to 40 CFR part 63, all continuous web cleaning machines are considered to be a subset of in-line solvent cleaning machines. These units tend to be used in two distinct areas: movie film cleaning and continuous strip, wire, or rod cleaning.

Movie Film Cleaning

The movie film cleaning industry typically uses a continuous web cleaning machine to clean the surfaces on large reels of film. Typically, a reel is loaded onto the machine and the film threaded through a series of rollers. The film is then either fed into a vat or past a series of spray nozzles that apply the chlorinated solvent onto the film. The film is then dried using air jets, cloth pads, or a combination of both.

Strip, Rod, or Wire Cleaning

This group of continuous web cleaning machines cleans a more diverse product group, including large flat pieces of metal, metal rods, and thin wires. The machines can be dip tanks, spray applications, or a combination. While the EPA has currently only identified continuous web cleaning machines used to clean metal products, these machines may clean nonmetal products which would also be covered by the HSC NESHAP. The EPA considered both of the above types of continuous web cleaning machines when developing the changes discussed today.

B. How Will These Changes Impact My Continuous Web Cleaning Machines?

The changes will enable you to comply with all of the requirements of the HSC NESHAP. The options are similar to the options for other in-line cleaning machines. The final rule amendments provide for emission controls equivalent to existing requirements codified at 40 CFR part 63, subpart T, and include new equivalent...
controls for certain cleaning machines and clarifications of the EPA’s interpretation of existing requirements germane to continuous web cleaning machines. The changes account for the inherent differences between the solvent cleaning machines that were the basis for the HSC NESHAP promulgated in 1994 and continuous web cleaning machines. The changes to the rule that apply only to continuous web cleaning machines are:

1. An alternative to the requirement for a maximum parts speed of 11 feet per minute and the requirement for a dwell time in some options. You are not required to meet the speed and dwell time requirements if your continuous web cleaning machine meets other specific requirements. These requirements include a properly designed, operated, and maintained system to eliminate visible carry out of solvent on your continuous web product. In addition, you must comply with the monitoring, recordkeeping, and reporting requirements for the controls that replace the hoist speed and dwell requirements.

2. A change in the alternative for continuous web cleaning machines venting to a carbon adsorber. A properly designed and operated continuous web cleaning machine can comply with the new or existing source requirements by venting the exhaust from the enclosed cleaning chamber through a properly operated and maintained carbon adsorption system instead of one of the equipment combinations listed in the HSC NESHAP. However, the system used must be demonstrated to the Administrator’s satisfaction to achieve an overall solvent control efficiency of 70 percent.

3. A clarification that there is no freeboard ratio requirement and freeboard refrigeration device requirement if your continuous web cleaning machine does not have an exposed sump. That is, if your continuous web cleaning machine has a remote reservoir, no freeboard ratio and freeboard refrigeration device requirements apply. Requirements for remote reservoir continuous web cleaning machines have been included in a new paragraph that has been added to § 63.463 of the rule.

4. A clarification that the ban on the cleaning of absorbent materials does not apply to cloth rollers used in the cleaning process inside your machine. However, you do have requirements that apply when you remove these rollers from the machine.

5. A clarification on the interpretation of superheated vapor technology for continuous web cleaning machines. The new interpretation allows for any technology that raises the continuous web part above the boiling point of the solvent. A new term, superheated part technology, has been added to the rule to more clearly address this situation. Therefore, as with the HSC NESHAP promulgated in 1994, your specific compliance options in the amended HSC NESHAP depend on whether your cleaning machines are considered to be new or existing.

C. How Do I Know if My Machine Is a “New” or an “Existing” Continuous Web Cleaning Machine?

Machines are classified as either new or existing based on the date of construction. Continuous web cleaning machines on which construction started before November 29, 1993, the date the HSC NESHAP was proposed, are existing affected sources. Machines upon which construction started on November 29, 1993 or later are new affected sources.

D. When Must I Comply With These New Requirements?

You must comply with these requirements by December 2, 1999 for both your new and existing affected sources. This date was established in a Federal Register final rule published on December 11, 1998 (63 FR 68397).

III. Other Changes

A. What Change Is EPA Making That Applies to My Transformer Cleaning Operations?

The EPA has recently become aware of a potential conflict between the HSC NESHAP and some specific Toxic Substances Control Act (TSCA) permits. Some facilities clean transformers contaminated with PCBs using batch cold halogenated solvent cleaning machines. The cleaning of these PCB-laden transformers is covered under TSCA permits, which include requirements to ensure proper draining and proper disposal of all materials. These transformers often include absorbent materials (i.e., cardboard). The HSC NESHAP requirements for cold cleaning machines state that “Sponges, fabric, wood, and paper shall not be cleaned.” (§ 63.462(c)(8)).

It is not EPA’s intent to prohibit the proper decontamination operation for PCB-laden transformers. The intent of this requirement in the HSC NESHAP is to reduce the amount of solvent loss due to improper cleaning of absorbent materials, such as rags and cloths. The EPA has reviewed the requirements in an example permit of a facility conducting decontamination of these transformers and concluded that TSCA permits should adequately ensure that the intent of the HSC NESHAP is met for these operations. For example, these permits have sufficient requirements for proper draining and disposal of the transformers. Therefore, EPA is adding an exclusion for cleaning absorbent materials in PCB-laden transformers, in compliance with a permit issued under TSCA, in the final rule.

B. What Changes Impact My Steam-Heated Vapor Cleaning Machines?

Steam-heated vapor cleaning machines will no longer be required to have a device that shuts off the sump heat if the liquid level drops to the sump heater coils (§ 63.463(a)(4)). This requirement was included in the HSC NESHAP for all machines. However, since the promulgation of the HSC NESHAP, EPA has determined that this device is not necessary for steam-heated machines because these machines are not able to heat the solvent to a temperature above the decomposition temperatures of any of the regulated halogenated solvents.

IV. Impacts

The changes contained in these final rule amendments are corrections, clarifications, and equivalent compliance alternatives and do not change the intended coverage of the HSC NESHAP (subpart T). These changes will not affect the estimated emission reductions or the control costs for these rules. These clarifications and corrections should make it easier for owners and operators of affected sources, and for local and State authorities, to understand and implement the requirements in subpart T. The equivalent compliance alternatives will make it possible for owners and operators of continuous web cleaning machines to comply with all requirements of subpart T.

V. Administrative Requirements

A. Executive Order 12866: Regulatory Planning and Review

Under Executive Order 12866 (58 FR 51735, October 4, 1993), the EPA must submit significant regulatory actions to the Office of Management and Budget (OMB) for review. The Executive Order defines “significant regulatory action” as one that OMB determines is likely to result in a rule that may:

(1) Have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or
with federalism implications to OMB for review pursuant to Executive Order 12866, EPA must include a certification from the Agency’s Federalism Official stating that EPA has met the requirements of Executive Order 13132 in a meaningful and timely manner.

This final rule will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as required in Executive Order 13132. This final rule only provides amendments to ensure that all owners or operators of solvent cleaning machines have appropriate and attainable requirements for their cleaning machines. Thus, the requirements of section 6 of the Executive Order do not apply to this rule.

C. Executive Order 13084: Consultation and Coordination With Indian Tribal Governments

Under Executive Order 13084, the EPA may not issue a regulation that is not required by statute, that significantly or uniquely affects the communities of Indian tribal governments, and that imposes substantial direct compliance costs on those communities unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by the tribal governments. If the EPA complies by consulting, Executive Order 13084 requires the EPA to provide to OMB, in a separately identified section of the preamble to the rule, a description of the extent of the EPA’s prior consultation with representatives of affected tribal governments, a summary of the nature of their concerns, and a statement supporting the need to issue the regulation. In addition, Executive Order 13084 requires the EPA to develop an effective process permitting elected officials and other representatives of Indian tribal governments “to provide meaningful and timely input in the development of regulatory policies on matters that significantly or uniquely affect their communities.”

These final rule amendments do not impose any duties or compliance costs on Indian tribal governments. Further, the final rule amendments provided herein do not significantly alter the control standards imposed by the HSC NESHAP for any source, including any that may affect Indian tribal governments. Hence, today’s final rule amendments do not significantly or uniquely affect the communities of Indian tribal governments. Accordingly, the requirements of section 3(b) of Executive Order 13084 do not apply.

D. Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act (UMRA) of 1995, Pub. L. No. 104–4, establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, local, and tribal governments and the private sector. Under section 202 of the UMRA, the EPA generally must prepare a written statement, including a cost-benefit analysis, for proposed and final rules with “Federal mandates” that may result in expenditures to State, local, and tribal governments, in the aggregate, or to the private sector, of $100 million or more in any 1 year. Before promulgating an EPA rule for which a written statement is needed, section 205 of the UMRA generally requires the EPA to identify and consider a reasonable number of regulatory alternatives and adopt the least costly, most cost-effective, or least burdensome alternative that achieves the objectives of the rule. The provisions of section 205 do not apply when they are inconsistent with applicable law. Moreover, section 205 allows the EPA to adopt an alternative other than the least costly, most cost-effective, or least burdensome alternative if the Administrator publishes with the final rule an explanation why that alternative was not adopted. Before the EPA establishes any regulatory requirements that may significantly or uniquely affect small governments, including tribal governments, it must have developed under section 203 of the UMRA a small government agency plan. The plan must provide for notifying potentially affected small governments, enabling officials of affected small governments to have meaningful and timely input in the development of the EPA regulatory proposals with significant Federal intergovernmental mandates, and informing, educating, and advising small governments on compliance with the regulatory requirements.

The EPA has determined that these final rule amendments do not include a Federal mandate that may result in estimated costs of $100 million or more to either State, local, or tribal governments in the aggregate or to the private sector in any 1 year, and that these final rule amendments do not significantly or uniquely impact small governments, because they contain no regulatory requirements that alter Federal programs or impose obligations upon them. The EPA has not prepared
a budgetary impact statement or specifically addressed the selection of the least costly, most cost-effective, or least burdensome alternative. In addition, because small governments will not be significantly or uniquely affected by these final rule amendments, the EPA is not required to develop a plan with regard to small governments. Therefore, the requirements of the UMRA do not apply.

E. Regulatory Flexibility/Small Business Regulatory Enforcement Fairness Act

The Regulatory Flexibility Act of 1980 (5 U.S.C. 601, et seq.), as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA) of 1996, requires the EPA to give special consideration to the effect of Federal regulations on small entities and to consider regulatory options that might mitigate any such impacts. The EPA must prepare a regulatory flexibility analysis unless the EPA certifies that the rule will not have a “significant impact on a substantial number of small entities.” Small entities include small businesses, small not-for-profit enterprises, and small government jurisdictions.

These final rule amendments would not have a significant impact on a substantial number of small entities because they clarify and make corrections to the promulgated HSC NESHAP, but impose no additional regulatory requirements on owners or operators of affected sources.

F. Paperwork Reduction Act

The information collection request (ICR) was submitted to the OMB under the Paperwork Reduction Act (44 U.S.C. 3501, et seq.) at the time this rule was originally promulgated. These final rule amendments to the HSC NESHAP will have no impact on the information collection burden estimates made previously. Therefore, the ICR has not been revised.

G. Executive Order 13045: Protection of Children from Environmental Health Risks and Safety Risks

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

The EPA interprets Executive Order 13045 as applying only to those regulatory actions that are based on health or safety risks, so that the analysis required under section 5–501 of the Executive Order has the potential to influence the regulation. These final rule amendments are not subject to Executive Order 13045 because they are not an “economically significant” regulatory action as defined by Executive Order 12866 and are based on technology performance rather than health or risks that may disproportionately affect children.

H. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801, et seq., as added by the SBREFA of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. The EPA will submit a report containing this direct final rule and other required information to the United States Senate, the United States House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the Federal Register.

A major rule cannot take effect until 60 days after it is published in the Federal Register. These final amendments are not a “major rule” as defined by 5 U.S.C. 804(2).

I. National Technology Transfer and Advancement Act

Section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) of 1995, Public Law 104–113, Section 12(d) (15 U.S.C. 272 note), directs the EPA to use voluntary consensus standards in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g., materials specifications, test methods, sampling procedures, business practices, etc.) that are developed or adopted by one or more voluntary consensus standards bodies. The NTTAA requires the EPA to provide Congress, through OMB, with explanations when the EPA decides not to use available and applicable voluntary consensus standards. This action does not involve the proposal of any new technical standards.

As part of a larger effort, the EPA is undertaking a project to cross-reference existing voluntary consensus standards on testing, sampling, and analysis with current and future EPA test methods. When completed, this project will assist the EPA in identifying potentially applicable voluntary consensus standards which can then be evaluated for equivalency and applicability in determining compliance with future regulations.

List of Subjects in 40 CFR Part 63

Environmental protection, Administrative practice and procedure, Air pollution control, Hazardous substances, Intergovernmental relations, Reporting and recordkeeping requirements.


Carol M. Browner, Administrator.

For the reasons set out in the preamble, part 63, title 40, chapter I of the Code of Federal Regulations is amended as follows.

PART 63—[AMENDED]

1. The authority for part 63 continues to read as follows:

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

Subpart T—National Emission Standards for Halogenated Solvent Cleaning

2. Section 63.461 is amended by adding, in alphabetical order, definitions for “Air knife system,” “Combined squeegee and air knife system,” “Remote reservoir continuous web cleaning machine,” “Squeegee system,” and “Superheated part technology,” and by revising the definition of “Continuous web cleaning machine” to read as follows:

§ 63.461 Definitions.

* * * * * 

Air knife system means a device that directs forced air at high pressure, high volume, or a combination of high pressure and high volume, through a small opening directly at the surface of a continuous web part. The purpose of this system is to remove the solvent film from the surfaces of the continuous web part.

* * * * * 

Combined squeegee and air-knife system means a system consisting of a combination of a squeegee system and an air-knife system within a single enclosure.

* * * * * 

Continuous web cleaning machine means a solvent cleaning machine in
which parts such as film, coils, wire, and metal strips are cleaned at speeds typically in excess of 11 feet per minute. Parts are generally uncoiled, cleaned such that the same part is simultaneously entering and exiting the solvent application area of the solvent cleaning machine, and then recoiled or cut. For the purposes of this subpart, all continuous web cleaning machines are considered to be a subset of in-line solvent cleaning machines.

Remote reservoir continuous web cleaning machine means a continuous web cleaning machine in which there is no exposed solvent sump. In these units, the solvent is pumped from an enclosed chamber and is typically applied to the continuous web part through a nozzle or series of nozzles. The solvent then drains from the part and is collected and recycled through the machine, allowing no solvent to pool in the work or cleaning area.

Squeegee system means a system that uses a series of pliable surfaces to remove the solvent film from the surfaces of the continuous web part. These pliable surfaces, called squeegees, are typically made of rubber or plastic media, and need to be periodically replaced to ensure continued proper function.

Superheated part technology means a system that is part of the continuous web process that heats the continuous web part either directly or indirectly to a temperature above the boiling point of the cleaning solvent. This could include a process step, such as a tooling die that heats the part as it is processed, as long as the part remains superheated through the cleaning machine.

3. Section 63.462 is amended by revising paragraph (c) introductory text, paragraph (c)(8), and adding paragraph (c)(9) to read as follows:

§ 63.462 Batch cold cleaning machine standards.

(c) Each owner or operator of a batch cold solvent cleaning machine complying with paragraph (a)(2) or (b) of this section shall comply with the work and operational practice requirements specified in paragraphs (c)(1) through (c)(9) of this section as applicable.

(b) Except as provided in paragraph (c)(9) of this section, sponges, fabric, wood, and paper products shall not be cleaned.

4. Section 63.463 is amended by:

(a) Except as provided in § 63.464 for all cleaning machines, each owner or operator of a solvent cleaning machine subject to the provisions of this subpart shall ensure that each existing or new batch vapor or in-line solvent cleaning machine subject to the provisions of this subpart conforms to the design requirements specified in paragraphs (a)(1) through (7) of this section. The owner or operator of a continuous web cleaning machine shall comply with the requirements of paragraph (g) or (h) of this section, as appropriate, in lieu of complying with this paragraph.

§ 63.463 Batch vapor and in-line cleaning machine standards.

(e) Each owner or operator of a solvent cleaning machine complying with paragraph (b), (c), or (g) of this section shall comply with the requirements specified in paragraphs (e)(1) through (4) of this section.

(ii) If a superheated part system is used to comply with the standards for continuous web cleaning machines in paragraph (g) of this section, the owner or operator shall ensure that the temperature of the continuous web part is at least 10 degrees Fahrenheit above the solvent boiling point while the part is traveling through the cleaning machine.

(iv) If a squeegee system is used to comply with the continuous web cleaning requirements of paragraph (g)(3)(ii) of this section, the owner or operator shall comply with the following requirements.

(A) Conduct the weekly monitoring required by § 63.466(a)(3). Record both the results of the visual inspection and the length of continuous web produced since the squeegees were replaced and compare to the maximum product throughput for the squeegees.

(B) If an air knife system is used to comply with the continuous web cleaning requirements of paragraph (g)(3)(iii) of this section, the owner or operator shall comply with the following requirements.

(A) The prohibition in paragraph (c)(8) of this section does not apply to the cleaning of porous materials that are part of polychlorinated biphenyl (PCB) laden transformers if those transformers are handled throughout the cleaning process and disposed of in compliance with an approved PCB disposal permit issued in accordance with the Toxic Substances Control Act.

(B) Determine during each monitoring period whether each control device used to comply with these standards meets the requirements specified in paragraphs (e)(2)(i) through (xi) of this section.

(c) Except as provided in § 63.464 for all cleaning machines, each owner or operator of an in-line cleaning machine shall comply with paragraph (c)(1) or (2) of this section as appropriate. The owner or operator of a continuous web cleaning machine shall comply with the requirements of paragraph (g) or (h) of this section, as appropriate, in lieu of complying with this paragraph.

(d) Except as provided in § 63.464 for all cleaning machines, each owner or operator of an existing or new batch vapor or in-line solvent cleaning machine shall meet all of the following required work and operational practices specified in paragraphs (d)(1) through (12) of this section as applicable. The owner or operator of a continuous web cleaning machine shall comply with the requirements of paragraph (g) or (h) of this section, as appropriate, in lieu of complying with this paragraph.

(iv) If a superheated part system is used to comply with the standards for continuous web cleaning machines in paragraph (g) of this section, the owner or operator shall ensure that the temperature of the continuous web part is at least 10 degrees Fahrenheit above the solvent boiling point while the part is traveling through the cleaning machine.
(B) Maintain the selected air knife parameter value at the level determined in paragraph (a) of this section.

(C) Conduct the weekly monitoring required by § 63.466(a)(3).

(D) Redetermine the proper air knife parameter value if any solvent film is visible on the continuous web part immediately after it exits the cleaning machine.

(xi) If a combination squeegee and air knife system is used to comply with the continuous web cleaning requirements of paragraph (g)(3)(iii) of this section, the owner or operator shall comply with the following requirements:

(A) Determine the system parameter and value that demonstrate to the Administrator’s satisfaction that the system is properly operating.

(B) Maintain the selected parameter value at the level determined in paragraph (a) of this section.

(C) Conduct the weekly monitoring required by § 63.466(a)(3).

(D) Redetermine the proper parameter value if any solvent film is visible on the continuous web part immediately after it exits the cleaning machine.

* * * * *

(g) Except as provided in § 63.464 and in paragraph (h) of this section for remote reservoir continuous web cleaning machines, each owner or operator of a continuous web cleaning machine shall comply with paragraphs (g)(1) through (4) of this section for each continuous web cleaning machine.

(1) Except as provided in paragraph (g)(2) of this section, install, maintain, and operate one of the following control combinations on each continuous web cleaning machine:

(i) Each existing continuous web cleaning machine, the following control combinations are allowed:

(A) Superheated vapor or superheated part technology, and a freeboard ratio of 1.0 or greater.

(B) Freeboard refrigeration device and a freeboard ratio of 1.0 or greater.

(C) Carbon adsorption system meeting the requirements of paragraph (e)(2)(vii) of this section.

(ii) For each new continuous web cleaning machine, the following control combinations are allowed:

(A) Superheated vapor or superheated part technology, and a freeboard refrigeration device.

(B) A freeboard refrigeration device and a carbon adsorber meeting the requirements of paragraph (e)(2)(vii) of this section.

(C) Superheated vapor or superheated part technology, and a carbon adsorber meeting the requirements of paragraph (e)(2)(vii) of this section.

(2) If a carbon adsorber system can be demonstrated to the Administrator’s satisfaction to have an overall solvent control efficiency (i.e., capture efficiency removal efficiency) of 70 percent or greater, this system is equivalent to the options in paragraph (g) of this section.

(3) In lieu of complying with the provisions of paragraph (a) of this section, the owner or operator of a continuous web cleaning machine shall comply with the following provisions:

(i) Each cleaning machine shall meet one of the following control equipment or technique requirements:

(A) An idling and downtime mode cover, as described in paragraph (d)(1)(i) of this section, that may be readily opened or closed; that completely covers the cleaning machine openings when in place; and is free of cracks, holes, and other defects. A continuous web part that completely occupies an entry or exit port when the machine is idle is considered to meet this requirement.

(B) A reduced room draft as described in paragraph (e)(2)(ii) of this section.

(C) Gasketed or leakproof doors that separate both the continuous web part feed reel and take-up reel from the room atmosphere if the doors are checked according to the requirements of paragraph (e)(2)(iii) of this section.

(D) A cleaning machine that is demonstrated to the Administrator’s satisfaction to be under negative pressure during idling and downtime and is vented to a carbon adsorption system that meets the requirements of either paragraph (e)(2)(vi) of this section or paragraph (g)(2) of this section.

(ii) Each continuous web cleaning machine shall have a freeboard ratio of 0.75 or greater unless that cleaning machine is a remote reservoir continuous web cleaning machine.

(iii) Each cleaning machine shall have an automated part-handling system capable of moving parts or parts baskets at a speed of 3.4 meters per minute (11 feet per minute) or less from the initial loading of parts through removal of cleaned parts, unless the cleaning machine is a continuous web cleaning machine that has a squeegee system or air knife system installed, maintained, and operated on the continuous web cleaning machine meeting the requirements of paragraph (g) of this section.

(iv) Each vapor cleaning machine shall be equipped with a device that shuts off the sump heat if the sump liquid solvent level drops to the sump heater coils.

(v) Each vapor cleaning machine shall be equipped with a vapor level control device that shuts off sump heat if the vapor level in the vapor cleaning machine rises above the height of the primary condenser.

(vi) Each vapor cleaning machine shall have a primary condenser.

(vii) Each cleaning machine that uses an exhaust shall be designed and operated to route all collected solvent vapors through a properly operated and maintained carbon adsorber that meets the requirements of paragraph (e)(2)(ii) of this section.

(4) In lieu of complying with the provisions of paragraph (d) of this section, the owner or operator of a continuous web cleaning machine shall comply with the following provisions:

(i) Control air disturbances across the cleaning machine openings by incorporating one of the following control equipment or techniques:

(A) Cover(s) to each solvent cleaning machine shall be in place during the idling mode and during the downtime mode unless either the solvent has been removed from the machine or maintenance or monitoring is being performed that requires the cover(s) in place. A continuous web part that completely occupies an entry or exit port when the machine is idle is considered to meet this requirement.

(B) A reduced room draft as described in paragraph (e)(2)(iii) of this section.

(C) Gasketed or leakproof doors or covers that separate both the continuous web part feed reel and take-up reel from the room atmosphere if the doors are checked according to the requirements of paragraph (e)(2)(iii) of this section.

(D) A cleaning machine that is demonstrated to the Administrator’s satisfaction to be under negative pressure during idling and downtime and is vented to a carbon adsorption system that meets either the requirements of paragraph (e)(2)(viii) or the requirements of paragraph (g)(2) of this section.

(ii) Any spraying operations shall be conducted in a section of the solvent cleaning machine that is not directly exposed to the ambient air (i.e., a baffled or enclosed area of the solvent cleaning machine) or within a machine having a door or cover that meets the requirements of paragraph (g)(4)(ii)(C) of this section.

(iii) During startup of each vapor cleaning machine, the primary condenser shall be turned on before the sump heater.

(iv) During shutdown of each vapor cleaning machine, the sump heater shall be turned off and the solvent vapor layer
allowed to collapse before the primary condenser is turned off.

(v) When solvent is added or drained from any solvent cleaning machine, the solvent shall be transferred using threaded or other leakproof couplings, and the end of the pipe in the solvent sump shall be located beneath the liquid solvent surface.

(vi) Each solvent cleaning machine and associated controls shall be maintained as recommended by the manufacturer of the equipment or using alternative maintenance practices that have been demonstrated to the Administrator’s satisfaction to achieve the same or better results as those recommended by the manufacturer.

(vii) Waste solvent, still bottoms, sump bottoms, and waste absorbent materials used in the cleaning process for continuous web cleaning machines shall be collected and stored in waste containers. The closed containers may contain a device that would allow pressure relief, but would not allow liquid solvent to drain from the container.

(viii) Except as provided in paragraph (g)(4)(ix) of this section, sponges, fabric, wood, and paper products shall not be cleaned.

(ix) The prohibition in paragraph (g)(4)(viii) of this section does not apply to absorbent materials that are used as part of the cleaning process of continuous web cleaning machines, including rollers and roller covers.

(h) Except as provided in § 63.464, each owner or operator of a remote reservoir continuous web cleaning machine shall comply with paragraphs (h)(1) through (4) of this section.

(1) Except as provided in paragraph (h)(2) of this section, install, maintain, and operate one of the following controls on each new remote reservoir continuous web cleaning machine:

(i) Superheated vapor or superheated part technology.

(ii) A carbon adsorber meeting the requirements of paragraph (e)(2)(vii) of this section.

(iii) If a carbon adsorber system can be demonstrated to the Administrator’s satisfaction to have an overall solvent control efficiency (i.e., capture efficiency removal efficiency) of 70 percent or greater, this system is equivalent to the options in paragraphs (h)(1)(i) and (h)(1)(ii) of this section.

(ii) In lieu of complying with the provisions of paragraph (a) of this section, the owner or operator of a remote reservoir continuous web cleaning machine shall comply with the following provisions:

(i) Each cleaning machine shall have an automated parts handling system capable of moving parts or parts baskets at a speed of 3.4 meters per minute (11 feet per minute) or less from the initial loading of parts through removal of cleaned parts, unless the cleaning machine is a continuous web cleaning machine that has a squeegee system or air knife system installed, maintained, and operated on the continuous web cleaning machine meeting the requirements of paragraph (e) of this section.

(ii) Each vapor cleaning machine shall be equipped with a device that shuts off the sump heat if the sump liquid solvent level drops to the sump heater coils.

(iii) Each vapor cleaning machine shall be equipped with a vapor level control device that shuts off sump heat if the vapor level in the vapor cleaning machine rises above the height of the primary condenser.

(iv) Each vapor cleaning machine shall have a primary condenser.

(v) Each cleaning machine that uses an exhaust shall be designed and operated to route all collected solvent vapors through a properly operated and maintained carbon adsorber that meets the requirements of either paragraph (e)(2)(vii) of this section or paragraph (g)(2) of this section.

(3) In lieu of complying with the provisions of paragraph (d) of this section, the owner or operator of a remote reservoir continuous web cleaning machine shall comply with the following provisions:

(i) Any spraying operations shall be conducted in a section of the solvent cleaning machine that is not directly exposed to the ambient air (i.e., a baffled or enclosed area of the solvent cleaning machine) or within a machine having a door or cover that meets the requirements of paragraph (g)(4)(i)(C) of this section.

(ii) During startup of each vapor cleaning machine, the primary condenser shall be turned on before the sump heater.

(iii) During shutdown of each vapor cleaning machine, the sump heater shall be turned off and the solvent vapor layer allowed to collapse before the primary condenser is turned off.

(iv) When solvent is added or drained from any solvent cleaning machine, the solvent shall be transferred using threaded or other leakproof couplings, and the end of the pipe in the solvent sump shall be located beneath the liquid solvent surface.

(v) Each solvent cleaning machine and associated controls shall be maintained as recommended by the manufacturers of the equipment or using alternative maintenance practices that have been demonstrated to the Administrator’s satisfaction to achieve the same or better results as those recommended by the manufacturer.

(vi) Waste solvent, still bottoms, sump bottoms, and waste absorbent materials used in the cleaning process for continuous web cleaning machines shall be collected and stored in waste containers. The closed containers may contain a device that would allow pressure relief, but would not allow liquid solvent to drain from the container.

(vii) Except as provided in paragraph (h)(3)(viii) of this section, sponges, fabrics, wood, and paper products shall not be cleaned.

(viii) The prohibition in paragraph (h)(3)(vii) of this section does not apply to absorbent materials that are used as part of the cleaning process of continuous web cleaning machines, including rollers and roller covers.

5. Section 63.464 is amended by adding paragraph (d) to read as follows:

§ 63.464 Alternative Standards.

* * * * *

(d) As an alternative to meeting the requirements in § 63.463, each owner or operator of a continuous web cleaning machine can demonstrate an overall cleaning system control efficiency of 70 percent using the procedures in § 63.465(g).

6. Section 63.465 is amended by:

a. Revising paragraph (a);

b. Revising paragraph (b);

c. Revising paragraph (c) introductory text; and

d. Adding paragraphs (f), (g), and (h).

The revisions and additions read as follows:

§ 63.465 Test methods.

* * * * *

(a) Except as provided in paragraphs (f) and (g) of this section for continuous web cleaning machines, each owner or operator of a batch vapor or in-line solvent cleaning machine complying with an idling emission limit standard in § 63.463(b)(1)(ii), (b)(2)(ii), (c)(1)(ii), or (c)(2)(ii) shall determine the idling emission rate of the solvent cleaning machine using Reference Method 307 in appendix A of this part.

(b) Except as provided in paragraphs (f) and (g) of this section for continuous web cleaning machines, each owner or operator of a batch vapor or in-line solvent cleaning machine complying with § 63.464 shall, on the first operating day of every month, ensure that the solvent cleaning machine system contains only clean liquid solvent. This includes, but is not limited to, fresh unused solvent, recycled solvent and used solvent that has been
cleaned of soils. A fill-line must be indicated during the first month the measurements are made. The solvent level within the machine must be returned to the same fill-line each month, immediately prior to calculating monthly emissions as specified in paragraph (c) of this section. The solvent cleaning machine does not have to be emptied and filled with fresh unused solvent prior to the calculations.

(c) Except as provided in paragraphs (f) and (g) of this section for continuous web cleaning machines, each owner or operator of a batch vapor or in-line solvent cleaning machine complying with §63.464 shall, on the first operating day of the month, comply with the requirements specified in paragraphs (c)(1) through (3) of this section.

(3) If a squeegee system, air knife system, or combination squeegee and air knife system is used to comply with the requirements of §63.463(g) or (h), the owner or operator shall visually inspect the continuous web part exiting the solvent cleaning machine to ensure that no solvent film is visible on the part.

(4) Except as provided in paragraph (a)(5) of this section, if a superheated part system is used to comply with the requirements of §63.463(g) or (h), the owner or operator shall use a thermometer, thermocouple, or other temperature measurement device to measure the temperature of the continuous web part while it is in the solvent cleaning machine. This measurement can also be taken at the exit of the solvent cleaning machine.

(5) As an alternative to complying with paragraph (a)(4) of this section, the owner or operator can provide data, sufficient to satisfy the Administrator, that demonstrate that the part temperature remains above the boiling point of the solvent at all times that the part is within the continuous web solvent cleaning machine. This data could include design and operating conditions such as information supporting any exothermic reaction inherent in the processing.

8. Section 63.467 is amended by revising paragraph (a) introductory text, paragraph (c) introductory text and by adding paragraph (a)(6), paragraph (a)(7) and paragraph (e) to read as follows:

§63.467 Recordkeeping requirements.

(a) Each owner or operator of a batch vapor or in-line solvent cleaning machine complying with the provisions of §63.463 shall maintain records in written or electronic form specified in paragraphs (a)(1) through (7) of this section for the lifetime of the machine.

(6) If a squeegee system is used to comply with these standards, records of the test required by §63.466(f) to determine the maximum product throughput for the squeegees.

(7) If an air knife system or a combination squeegee and air knife system is used to comply with these standards, records of the determination of the proper operating parameter and parameter value for the air knife system.

(c) Except as provided in paragraph (e) of this section for continuous web cleaning machines, each owner or operator of a batch vapor or in-line steam cleaning machine demonstrating compliance with the alternative standard of §63.464(d) shall, on the first day of every month, ensure that the solvent cleaning machine contains only clean liquid solvent. This includes, but is not limited to, fresh unused solvent, recycled solvent, and used solvent that has been cleaned of soils. A fill-line must be indicated during the first month the measurements are made. The solvent level with the machine must be returned to the same fill-line each month, immediately prior to calculating overall cleaning system control efficiency emissions as specified in paragraph (h) in this section. The solvent cleaning machine does not need to be emptied and filled with fresh unused solvent prior to the calculation.

(h) Each owner or operator of a continuous web cleaning machine complying with §63.464(d) shall, on the first operating day of the month, comply with the following requirements.

(1) Using the records of all solvent additions, solvent deletions, and solvent recovered for the previous monthly reporting period required under §63.467(e), determine overall cleaning system control efficiency (Eo) using Equation 8 as follows:

\[
E_o = R / \left( R_i + (S_a_i - SSR_i) \right) \quad \text{(Eq. 8)}
\]

Where:

- \( R \) = overall cleaning system control efficiency
- \( R_i \) = the total amount of halogenated HAP liquid solvent recycled to the solvent cleaning machine during the most recent monthly reporting period i, (kilograms of solvent per month).
- \( S_a_i \) = the total amount of halogenated HAP liquid solvent added to the solvent cleaning machine during the most recent monthly reporting period i, (kilograms of solvent per month).
- \( SSR_i \) = the total amount of halogenated HAP solvent removed from the solvent cleaning machine in solid waste, obtained as described in paragraph (c)(2) of this section, during the most recent monthly reporting period i, (kilograms of solvent per month).

7. Section 63.466 is amended by revising paragraph (a) introductory text and adding paragraphs (a)(3) through (5) to read as follows:

§63.466 Monitoring procedures.

(a) Except as provided in paragraph (g) of this section, each owner or operator of a batch vapor or in-line solvent cleaning machine complying with the equipment standards in §63.463(b)(1)(i), (b)(2)(i), (c)(1)(i), (c)(2)(i), (g)(1), or (g)(2) shall conduct monitoring and record the results on a weekly basis for the control devices, as appropriate, specified in paragraphs (a)(1) through (5) of this section.

* * * * *
solvent cleaning machine complying with the provisions of § 63.464 shall maintain records specified in paragraphs (c)(1) through (3) of this section either in electronic or written form for a period of 5 years.

(e) Each owner or operator of a continuous web cleaning machine complying with the provisions of § 63.464(d) shall maintain the following records in either electronic or written form for a period of 5 years.

1. The dates and amounts of solvent that are added to the solvent cleaning machine.
2. The dates and amounts of solvent that are recovered from the desorption of the carbon adsorber system.
3. The solvent composition of wastes removed from each cleaning machine as determined using the procedures in § 63.465(c)(2).
4. Calculation sheets showing the calculation and results of determining the overall cleaning system control efficiency, as required by § 63.465.
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 TRANSPORTATION

Federal Aviation Administration

14 CFR Part 25

[Docket No. NM165, Notice No. 25–99–09–SG]

Special Conditions: McDonnell Douglas DC–9–30 Series Airplanes;
High Intensity Radiated Fields (HIRF)

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed special conditions.

SUMMARY: This notice proposes special conditions for the McDonnell Douglas DC–9–30 series airplanes modified by Lockheed Martin Aircraft Center. These airplanes will have novel and unusual design features when compared to the state of technology envisioned in the airworthiness standards for transport category airplanes. The applicable type certification regulations do not contain adequate or appropriate safety standards for the protection of this system from the effects of high-intensity radiated fields (HIRF). These proposed special conditions contain the additional safety standards that the Administrator considers necessary to establish a level of safety equivalent to that provided by the existing airworthiness standards.

DATES: Comments must be received on or before January 18, 2000.


SUPPLEMENTARY INFORMATION:

Comments Invited

Interested persons are invited to participate in the making of these proposed special conditions by submitting such written data, views, or arguments, as they may desire. Communications should identify the regulatory docket or notice number and be submitted in duplicate to the address specified above. All communications received on or before the closing date for comments will be considered by the Administrator before further rulemaking action on this proposal is taken. The proposals contained in this notice may be changed in light of the comments received. All comments received will be available by the Rules Docket for examination by interested persons, both before and after the closing date for comments. A report summarizing each substantive public contact with FAA personnel concerning this rulemaking will be filed in the docket. Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this notice must include a self-addressed, stamped postcard on which the following statement is made: "Comments to Docket No. NM165." The postcard will be date stamped and returned to the commenter.

Background

On April 20, 1998, Lockheed Martin Aircraft Center, Inc. (LMAC), 244 Terminal Road, Greenville, NC 29605, applied for a supplemental type certificate (STC) to modify McDonnell Douglas DC–9–30 series airplanes listed on Type Certificate A6WE. The modification incorporates the installation of an Innovative Solution & Support System, consisting of an electronic flight instrument system, including an electronic horizontal situation indicator, and a display controller for each pilot. This advanced system uses electronics to a far greater extent than the original pneumatic pitot-static instruments and may be more susceptible to electrical and magnetic interference. This disruption of signals could result in loss of air data display or present misleading attitude information to the pilot.

In addition, on August 18, 1998, LMAC applied for an additional STC to modify McDonnell Douglas DC–9–30 series airplanes listed on Type Certificate A6WE. The modification incorporates the installation of an Innovative Solution & Support electronic air data instrument system, which consists of an electronic airspeed display, an electronic altimeter, and a digital air data computer for each pilot. This advanced system uses electronics to a far greater extent than the original pneumatic pitot-static instruments and may be more susceptible to electrical and magnetic interference. This disruption of signals could result in loss of air data display or present misleading air data information to the pilot.

Type Certification Basis

Under the provisions of 14 CFR 21.101, LMAC must show that the McDonnell Douglas DC–9–30 series airplanes, as changed, continue to meet the applicable provisions of the regulations incorporated by reference in Type Certificate No. A6WE, or the applicable regulations in effect on the date of application for the change. The regulations incorporated by reference in the type certificate are commonly referred to as the "original type certification basis." The certification basis for the modified the McDonnell Douglas DC–9–30 series airplanes include CAR 4b, dated December 31, 1953, with Amendments 4b–1 through 4b–16, as amended by Type Certificate Data Sheet (TCDS) A6WE.

If the Administrator finds that the applicable airworthiness regulations (i.e., CAR 4b, as amended) do not contain adequate or appropriate safety standards for the McDonnell Douglas DC–9–30 series airplanes because of novel or unusual design features, special conditions are prescribed under the provisions of § 21.16.

In addition to the applicable airworthiness regulations and special conditions, the Model DC–9–30 must comply with the fuel vent and exhaust emission requirements of 14 CFR part 34 and the noise certification requirements of 14 CFR part 36.

Special conditions, as appropriate, are issued in accordance with 14 CFR 11.49, as required by §§ 11.28 and 11.29, and become part of the type certification basis in accordance with § 21.101(b)(2).
Special conditions are initially applicable to the model for which they are issued. Should LMAC apply at a later date for design change approval to modify any other model already included on the same type certificate to incorporate the same novel or unusual design feature, this special conditions would also apply to the other model under the provisions of § 21.101(a)(1).

**Novel or Unusual Design Features**

The modified McDonnell Douglas DC-9–30 series airplanes will incorporate an electronic attitude display system and an electronic air data system, which were not available at the time of certification of these airplanes, both of which perform critical functions. These systems may be vulnerable to HIRF external to the airplane.

**Discussion**

There is no specific regulation that addresses protection requirements for electrical and electronic systems from HIRF. Increased power levels from ground-based radio transmitters and the growing use of sensitive electrical and electronic systems to command and control airplanes have made it necessary to provide adequate protection.

To ensure that a level of safety is achieved equivalent to that intended by the regulations incorporated by reference, special conditions are needed for the McDonnell Douglas DC-9–30 series airplanes. These special conditions require that new electrical and electronic systems, such as the electronic attitude and air data display systems that perform critical functions, be designed and installed to preclude component damage and interruption of function due to both the direct and indirect effects of HIRF.

**High-Intensity Radiated Fields (HIRF)**

With the trend toward increased power levels from ground-based transmitters, plus the advent of space and satellite communications, coupled with electronic command and control of the airplane, the immunity of critical digital avionics systems to HIRF must be established.

It is not possible to precisely define the HIRF to which the airplane will be exposed in service. There is also uncertainty concerning the effectiveness of airframe shielding for HIRF. Furthermore, coupling of electromagnetic energy to cockpit-installed equipment through the cockpit window apertures is undefined. Based on surveys and analysis of existing HIRF emitters, an adequate level of protection exists when compliance with the HIRF protection special condition is shown with either paragraph 1, or 2 below:

1. A minimum threat of 100 volts rms per meter electric field strength from 10 KHz to 18 GHz.
   a. The threat must be applied to the system elements and their associated wiring harnesses without the benefit of airframe shielding.
   b. Demonstration of this level of protection is established through system tests and analysis.

2. A threat external to the airframe of the following field strengths for the frequency ranges indicated.

<table>
<thead>
<tr>
<th>Frequency</th>
<th>Peak</th>
<th>Average</th>
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<tbody>
<tr>
<td>10 kHz—100 kHz</td>
<td>50</td>
<td>50</td>
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<td>100 kHz—500 kHz</td>
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<tr>
<td>18 GHz—40 GHz</td>
<td>600</td>
<td>600</td>
</tr>
</tbody>
</table>

The field strengths are expressed in terms of peak root-mean-square (rms) values.

The threat levels identified above are the result of an FAA review of existing studies on the subject of HIRF in light of the ongoing work of the Electromagnetic Effects Harmonization Working Group of the Aviation Rulemaking Advisory Committee.

**Applicability**

As discussed above, these special conditions would be applicable initially to the McDonnell Douglas DC-9–30 series airplanes modified by LMAC. Should LMAC apply at a later date for a supplemental type certificate to modify any other model included on the same type certificate to incorporate the same novel or unusual design feature, these special conditions would apply to that model as well under the provisions of § 21.101(a)(1).

**Conclusion**

This action affects only certain novel or unusual design features on the McDonnell Douglas DC-9–30 series airplanes modified by LMAC. It is not a rule of general applicability and affects only the applicant who applied to the FAA for approval of these features on the airplane.

**List of Subjects in 14 CFR Part 25**

Aircraft, Aviation safety, Reporting and recordkeeping requirements.

The authority citation for these special conditions is as follows: Authority: 49 U.S.C. 106(g), 40113, 44701, 44702, 44704.

**The Proposed Special Conditions**

Accordingly, the Federal Aviation Administration proposes the following special conditions as part of the type certification basis for McDonnell Douglas DC-9–30 series airplanes modified by Lockheed Martin Aircraft Center.
1. Protection from Unwanted Effects of High-Intensity Radiated Fields (HIRF). Each electrical and electronic system that performs critical functions must be designed and installed to ensure that the operation and operational capability of these systems to perform critical functions are not adversely affected when the airplane is exposed to high intensity radiated fields.

2. For the purpose of these special conditions, the following definition applies:

Critical Functions. Functions whose failure would contribute to or cause a failure condition that would prevent the continued safe flight and landing of the airplane.

Issued in Renton, Washington, on November 17, 1999.

Donald L. Riggin,
Acting Manager, Transport Airplane Directorate, Aircraft Certification Service, ANM–100.

[FR Doc. 99–31397 Filed 12–2–99; 8:45 am]

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 98–ANE–33–AD]

RIN 2120–AA64

Airworthiness Directives; Rolls-Royce, plc RB211 Trent 875, 877, 884, 892, 892B Series Turboprop Engines

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This document proposes the supersede of an existing airworthiness directive (AD), applicable to certain Rolls-Royce, plc RB211 Trent 800 series turboprop engines, that currently requires initial and repetitive ultrasonic inspections of fan blade roots for cracks, and replacement, if necessary, with serviceable parts. This proposed action would reduce initial cyclic compliance threshold and repetitive inspection intervals. This proposal would also allow inspections to be accomplished within 100 cycles-in-service if the initial or repetitive thresholds are exceeded on the effective date of the AD. This proposal is prompted by an improved understanding of the crack propagation mechanism and the latest service operational data. The actions specified by the proposed AD are intended to prevent fan blade failure, which could result in multiple fan blade releases, uncontained engine failure, and possible damage to the airplane.

DATES: Comments must be received by February 1, 2000.

ADDRESSES: Submit comments to the Federal Aviation Administration (FAA), New England Region, Office of the Regional Counsel, Attention: Rules Docket No. 98–ANE–33–AD, 12 New England Executive Park, Burlington, MA 01803–5299. Comments may also be sent via the Internet using the following address: “9-ane-adcomment@faa.gov”. Comments sent via the Internet must contain the docket number in the subject line. Comments may be inspected at this location between 8:00 a.m. and 4:30 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Jason Yang, Aerospace Engineer, Engine Certification Office, FAA, Engine and Propeller Directorate, 12 New England Executive Park, Burlington, MA.

FOR FURTHER INFORMATION CONTACT: Jason Yang, Aerospace Engineer, Engine Certification Office, FAA, Engine and Propeller Directorate, 12 New England Executive Park, Burlington, MA.

SUPPORTING INFORMATION:

Comments Invited

Interested persons are invited to participate in the making of the proposed rule by submitting such written data, views, or arguments as they may desire. Communications should identify the Rules Docket number and be submitted to the address specified above. All communications received on or before the closing date for comments, specified above, will be considered before taking action on the proposed rule. The proposals contained in this notice may be changed in light of the comments received.

Comments are specifically invited on the overall regulatory, economic, environmental, and energy aspects of the proposed rule. All comments submitted will be available, both before and after the closing date for comments, in the Rules Docket for examination by interested persons. A report summarizing each FAA-public contact concerned with the substance of this proposal will be filed in the Rules Docket for comment.

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this notice must submit a self-addressed, stamped postcard on which the following statement is made: “Comments to Docket Number 98–ANE–33–AD.” The postcard will be date stamped and returned to the commenter.

Availability of NPRMs


Discussion

On September 11, 1998, the Federal Aviation Administration (FAA) issued airworthiness directive 98–19–21, Amendment 39–10762 (63 FR 50484, September 22, 1998, corrected by 63 FR 52961, October 2, 1998), applicable to Rolls-Royce, plc (R–R) RB211 Trent 800 series turboprop engines, to require initial and repetitive ultrasonic inspections of fan blade roots for cracks, and replacement, if necessary, with serviceable parts. That action was prompted by reports of multiple fan blade root cracks in several factory test engines. That condition, if not corrected, could result in fan blade failure, which could result in multiple fan blade releases, uncontained engine failure, and possible damage to the airplane.

Information since Publication of AD 98–19–21

Since the issuance of that AD, the Civil Aviation Authority (CAA) of the United Kingdom and the FAA have received revised analysis from the manufacturer and recent service data from operators. R–R’s analysis provides an improved understanding of the crack propagation mechanism and the service operational data since institution of the inspection program required by the current AD indicates that the initial compliance threshold and repetitive inspection intervals must be decreased in order to maintain an acceptable level of safety.

Service Bulletin (SB)

R–R has issued SB RB211–72–C445, Revision 6, dated September 3, 1999, that describes the initial inspection threshold and repetitive inspection intervals for Trent 800 series turboprop engines. The SB also describes the procedures for ultrasonic inspections of fan blade roots for cracks, and provides part rejection data.
Proposed Actions

Since an unsafe condition has been identified that is likely to exist or develop on other products of this same type design, the proposed AD would supersede AD 98–19–21 to reduce initial compliance thresholds and repetitive cyclic inspection intervals. This proposal would also allow inspections to be accomplished within 100 cycles-in-service if the initial or repetitive thresholds are exceeded on the effective date of the AD. The actions would be required to be accomplished in accordance with the SB listed above.

Economic Analysis

The FAA estimates that 24 engines installed on aircraft of US registry would be affected by this proposed AD, that it would take approximately 8 work hours per engine to accomplish the proposed actions, and that the average labor rate is $60 per work hour. Based on these figures, the total cost impact of the proposed AD on US operators is estimated to be $11,520.

Regulatory Impact

This proposal does not have federalism implications, as defined in Executive Order No. 13132, because it 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.

Accordingly, the FAA has not consulted with state authorities prior to publication of this proposal. For the reasons discussed above, I certify that 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) if promulgated, will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A copy of the draft regulatory evaluation prepared for this action is contained in the Rules Docket. A copy of it may be obtained by contacting the Rules Docket at the location provided under the caption ADDRESSES.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

2. Section 39.13 is amended by removing amendment 39–10762 (63 FR 50484, September 22, 1998) by adding a new airworthiness directive to read as follows:


Applicability: Rolls-Royce, plc (R–R) RB211 Trent 875, RB211 Trent 877, RB211 Trent 884, RB211 Trent 892, and Trent 892B series turboshaft engines, except if the fan blades in R–R Service Bulletin (SB) RB211–72–C629 were installed as complete sets.

The proposed AD affects aircraft certified, modified, altered, or repaired for service in the US or in other countries.

Applicability: Rolls-Royce, plc (R–R)

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

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

§ 39.13 [Amended]

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§ 39.13 [Amended]

2. Section 39.13 is amended by removing amendment 39–10762 (63 FR 50484, September 22, 1998) by adding a new airworthiness directive to read as follows:


Applicability: Rolls-Royce, plc (R–R) RB211 Trent 875, RB211 Trent 877, RB211 Trent 884, RB211 Trent 892, and Trent 892B series turboshaft engines, except if the fan blades in R–R Service Bulletin (SB) RB211–72–C629 were installed as complete sets.

The proposed AD affects aircraft certified, modified, altered, or repaired for service in the US or in other countries.

Applicability: Rolls-Royce, plc (R–R)

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

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

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The proposed AD affects aircraft certified, modified, altered, or repaired for service in the US or in other countries.

Applicability: Rolls-Royce, plc (R–R)
ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This document proposes the supersede of an existing airworthiness directive (AD), applicable to certain Boeing Model 737–100, –200, –200C, –300, –400, and –500 series airplanes, that currently requires a one-time inspection of the attachment nuts at each end attachment of the elevator tab push rods to measure run-on torque values, and corrective actions, if necessary. This action would add a requirement to replace all existing bolts and attachment nuts at the forward and aft end attachment of each elevator tab push rod with new bolts and self-locking castellated nuts with cotter pins. This proposal is prompted by reports of excessive high-frequency airframe vibration during flight, with consequent structural damage to the elevator tab, elevator, and stabilizer. The actions specified in this AD are intended to prevent detachment of an elevator tab push rod due to a detached nut at either end attachment of a push rod, which could result in excessive high-frequency airframe vibration during flight; consequent structural damage to the elevator tab, elevator, and horizontal stabilizer; and reduced controllability of the airplane.

DATES: Comments must be received by January 18, 2000.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Transport Airplane Directorate, ANM–114, Attention: Rules Docket No. 99–NM–69–AD, 1601 Lind Avenue, SW., Renton, Washington 98055–4056. Comments may be inspected at this location between 9:00 a.m. and 3:00 p.m., Monday through Friday, except Federal holidays.

The service information referenced in the proposed rule may be obtained from Boeing Commercial Airplane Group, P.O. Box 3707, Seattle, Washington 98124–2207. This information may be examined at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington.


SUPPLEMENTARY INFORMATION: Comments Invited

Interested persons are invited to participate in the making of the proposed rule by submitting such written data, views, or arguments as they may desire. Communications shall identify the Rules Docket number and be submitted in triplicate to the address specified above. All communications received on or before the closing date for comments, specified above, will be considered before taking action on the proposed rule. The proposals contained in this notice may be changed in light of the comments received.

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

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this notice must submit a self-addressed, stamped postcard on which the following statement is made: “Comments to Docket Number 99–NM–69–AD.” The postcard will be date stamped and returned to the commenter.

Availability of NPRMs


Discussion

On February 26, 1999, the FAA issued AD 99–05–15, amendment 39–11063 (64 FR 10935, March 8, 1999), applicable to certain Boeing Model 737–100, –200, –200C, –300, –400, and –500 series airplanes, to require a one-time inspection of the attachment nuts at each end attachment of the elevator tab push rods to measure run-on torque values, and corrective actions, if necessary. That action was prompted by reports of excessive high-frequency airframe vibration during flight, with consequent structural damage to the elevator tab, elevator, and stabilizer. The requirements of that AD are intended to prevent detachment of an elevator tab push rod due to a detached nut at either end attachment of a push rod, which could result in excessive high-frequency airframe vibration during flight; consequent structural damage to the elevator tab, elevator, and horizontal stabilizer; and reduced controllability of the airplane.

In the preamble to AD 99–05–15, the FAA indicated that the actions required by that AD were considered “interim action” until final action is identified, at which time the FAA may consider further rulemaking. Final action has been identified, and the FAA has determined that further rulemaking action is indeed necessary; this AD follows from that determination.

Actions Since Issuance of Previous Rule

Based upon a report of airframe vibration which resulted in severe damage to the elevator, elevator tab push rods, and elevator tab, the FAA has determined that a fastener installation which incorporates a secondary locking feature should be installed at the elevator tab push rod end attachments. The report indicated that airframe vibration was initially caused by the absence of a bushing, which was not installed during maintenance, in one of the elevator push rod attachments. Based on this finding, it is concluded that vibration may occur as a result of a single elevator tab push rod becoming disconnected. In addition, a review of numerous reports has revealed that airframe vibration has been caused by worn, loose, or missing parts at the elevator tab attachments. To positively address the problem with the elevator tab push rod end attachments becoming loose, the FAA finds it necessary to mandate the new bolt, castellated nut, and cotter pin installation.

Explanation of Requirements of Proposed Rule

Since an unsafe condition has been identified that is likely to exist or develop on other products of this same type design, the proposed AD would supersede AD 99–05–15 to continue to require a one-time inspection of the attachment nuts at each end attachment of the elevator tab push rods to measure run-on torque values. The proposed AD would also require replacement of existing bolt and attachment nuts with new bolts and self-locking castellated nuts that incorporate cotter pins as a secondary locking feature. The actions would be required to be accomplished in accordance with the service information described previously in AD 99–05–15, except as discussed below.

Differences Between Proposed Rule and Service Letter

 Operators should note that Boeing Service Letter 737–SL–27–118–A, dated November 14, 1997, describes the actions specified by the proposed AD as a design improvement that may be accomplished at any time by the
operator. The service letter, therefore, does not provide a recommended timeframe for accomplishing the replacement of the existing bolts and attachment nuts with new bolts and self-locking castellated nuts that incorporate the installation of cotter pins as a secondary locking feature. The FAA has determined that an unspecified interval would not address the identified unsafe condition in a timely manner. In developing an appropriate compliance time for this AD, the FAA considered not only the manufacturer’s recommendation, but the degree of urgency associated with addressing the subject unsafe condition, the average utilization of the affected fleet, and the time necessary to perform the replacement (4 hours). In light of all of these factors, the FAA finds a 12-month compliance time for completing the required actions to be warranted, in that it represents an appropriate interval of time allowable for affected airplanes to continue to operate without compromising safety.

Cost Impact

There are approximately 2,742 airplanes of the affected design in the worldwide fleet. The FAA estimates that 1,106 airplanes of U.S. registry would be affected by this proposed AD.

The new replacement that is proposed in this AD action would take approximately 4 work hours per airplane to accomplish, at an average labor rate of $60 per work hour. Required parts would cost approximately $560 per airplane. Based on these figures, the cost impact of the proposed requirements of this AD on U.S. operators is estimated to be $884,800, or $800 per airplane.

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

The one-time inspection required by AD 99–05–15 was required to be accomplished within 90 days after the effective date of that AD (March 23, 1999). Since the 90-day compliance time has past, the FAA assumes that all airplanes currently on the U.S. Register have been inspected. Therefore, there is no future cost impact of this requirement on current U.S. operators of these airplanes.

However, should an affected airplane be imported and placed on the U.S. Register in the future, it would take approximately 4 work hours per airplane to accomplish the one-time inspection, at an average labor rate of $60 per work hour. Based on these figures, the cost impact of the proposed inspection requirement on U.S. operators is estimated to be $240 per airplane.

Regulatory Impact

The regulations proposed herein would not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 12866, it is determined that this proposal would not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

For the reasons discussed above, I certify that 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) if promulgated, will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A copy of the draft regulatory evaluation prepared for this action is contained in the Rules Docket. A copy of it may be obtained by contacting the Rules Docket at the location provided under the caption ADDRESSES.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§39.13 [Amended]

2. Section 39.13 is amended by removing amendment 39–11063 (64 FR 10935, March 8, 1999), and by adding a new airworthiness directive (AD), to read as follows:


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

Compliance: Required as indicated, unless accomplished previously.

To prevent detachment of an elevator tab push rod due to a detached nut at either end attachment of a push rod, which could result in excessive high-frequency airframe vibration during flight; consequent structural damage to the elevator tab, elevator, and horizontal stabilizer; and reduced controllability of the airplane; accomplish the following:

Restatement of Requirements of AD 99–05–15

One-Time Inspection

(a) Within 90 days after March 23, 1999 (the effective date of AD 99–05–15, amendment 39–11063), perform a one-time inspection of all attachment nuts at each end of each elevator tab push rod to measure the run-on torque values of the nuts, in accordance with Boeing Alert Service Bulletin 737–27A1205, dated August 28, 1997.

(b) Within 12 months after the effective date of this AD, replace all existing bolts and attachment nuts at each end of each elevator tab push rod to measure the run-on torque values of the nuts, in accordance with Boeing Alert Service Bulletin 737–27A118A–A, dated November 14, 1997, and ensure that the final seating torque of the attachment nuts is within the torque values specified in the service letter.

Repeal

Note 2: Accomplishment of the inspection and ensuring adequate final seating torque values, prior to the effective date of this AD, in accordance with Boeing All-Base Telex M–7272–97–0897, dated February 13, 1997, are considered acceptable for compliance with the actions specified in paragraphs (a) and (b)(1) of this AD for only the forward attachment nuts.

Replacement

(b) Within 12 months after the effective date of this AD, replace all existing bolts and attachment nuts at the forward and aft end attachment of each elevator tab push rod

Alternative Methods of Compliance
(c)(1) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, Seattle Aircraft Certification Office (ACO), FAA, Transport Airplane Directorate. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, Seattle ACO.

(2) Alternate methods of compliance, approved previously in accordance with AD 99–05–15, amendment 99–11063, are not considered to be approved as alternate methods of compliance with this AD.

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

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

Issued in Renton, Washington, on November 29, 1999.

D.L. Riggin,
Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

DEPARTMENT OF TRANSPORTATION
Federal Aviation Administration

14 CFR Part 71
[Airspace Docket No. 99–AGL–56]

Proposed Modification of Class D Airspace; Grand Forks AFB, ND

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking.

SUMMARY: This action proposes to modify Class D airspace at Grand Forks AFB, ND. This action would amend the effective hours at the Class D surface area to coincide with the airport traffic control tower (ATCT) hours of operation for Grand Forks AFB. The purpose of this action is to clarify when two-way radio communication with the ATCT is required.

DATES: Comments must be received on or before January 14, 2000.

ADDRESSES: Send comments on the proposed rule in triplicate to: Federal Aviation Administration, Office of the Assistant Chief Counsel, AGL–7, Rules Docket No. 99–AGL–56, 2300 East Devon Avenue, Des Plaines, IL 60018.

The official docket may be examined in the Office of the Assistant Chief Counsel, Federal Aviation Administration, 2300 East Devon Avenue, Des Plaines, IL. An informal docket may also be examined during normal business hours at the Air Traffic Division, Airspace Branch, Federal Aviation Administration, 2300 East Devon Avenue, Des Plaines, IL.

FOR FURTHER INFORMATION CONTACT:
Denis C. Burke, Air Traffic Division, AGL–520, Federal Aviation Administration, 2300 East Devon Avenue, Des Plaines, IL 60018, telephone (847) 294–7658.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related species aspects of the proposal. Communications should identify the airspace docket number and be submitted in triplicate to the address listed above.

Committers wishing the FAA to acknowledge receipt of their comments on this action must submit with those comments a self-addressed, stamped postcard on which the following statement is made: “Comments to Airspace Docket No. 99–AGL–56.” The postcard will be date/time stamped and returned to the commenter. All communications received on or before the specified closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this action may be changed in light of comments received. All comments submitted will be available for examination in the Rules Docket, FAA, Great Lakes Region, Office of the Assistant Chief Counsel, 2300 East Devon Avenue, Des Plaines, IL, both before and after the closing date for comments. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRM’s

Any person may obtain a copy of this Notice of Proposed Rulemaking (NPRM) by submitting a request to the Federal Aviation Administration, Office of Public Affairs, Attention: Public Inquiry Center, APA–230, 800 Independence Avenue, SW, Washington, DC 20591, or by calling (202) 267–3484. Communications must identify the docket number of this NPRM. Persons interested in being placed on a mailing list for future NPRM’s should also request a copy of Advisory Circular No. 11–2A, which describes the application procedure.

The Proposal

The FAA is considering an amendment to 14 CFR part 71 to modify Class D airspace at Grand Forks AFB, ND, by amending the effective hours to coincide with the ATCT hours of operation for Grand Forks AFB.

Controlled airspace extending upward from the surface is needed to contain aircraft executing instrument approach procedures. The area would be depicted on appropriate aeronautical charts.

Class D airspace designations are published in paragraph 5000 of FAA Order 7400.9C dated September 1, 1999, and effective September 16, 1999, which is incorporated by reference in 14 CFR 71.1. The Class D designations listed in this document would be published subsequently in the Order.

The FAA has determined that this proposed regulation only involves an establishment body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. Therefore this proposed regulation—(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) 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 proposed rule will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:
PART 71—DESIGNATION OF CLASS A, CLASS B, CLASS C, CLASS D, AND CLASS E AIRSPACE AREAS; AIRWAYS; ROUTES; AND REPORTING POINTS

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


§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of the Federal Aviation Administration Order 7400.9G, airspace designations and reporting points, dated September 1, 1999, and effective September 16, 1999, is amended as follows:

Paragraph 5000 Class D airspace

AGI. ND D Grand Forks AFB, ND [Revised]

Grand Forks AFB, ND

(Lat. 47°57′40″N., long. 97°24′04″W.)

That airspace extending upward from the surface to and including 3,400 feet MSL within an 4.9-mile radius of Grand Forks AFB, and within 2.3 miles each side of the 174° bearing from the AFB extending from the 4.9-mile radius of the AFB to 5.6 miles south of the AFB, excluding that airspace within the Grand Forks, ND, Class D airspace area. This Class D airspace area is effective during the specific dates and times established in advance by Notice to Airmen. The effective date and time will thereafter be continuously published in the Airport/Facility Directory.


Christopher R. Blum,
Manager, Air Traffic Division.

[FR Doc. 99–31404 Filed 12–2–99; 8:45 am]

BILLING CODE 4910–13–M

Railroad Retirement Board

20 CFR Parts 325, 330, 335, and 336

RIN 3220–AB39

Registration for Railroad Unemployment Benefits; Sickness Benefits; Determination of Daily Benefit Rates; Duration of Normal and Extended Benefits

AGENCY: Railroad Retirement Board.

ACTION: Proposed rule.

SUMMARY: The Railroad Retirement Board (Board) proposes to amend its regulations to incorporate amendments made to the Railroad Unemployment Insurance Act, which shortened the waiting period for receipt of benefits under the RUIA, changed the method of computing the daily benefit rate, and eliminated certain extended benefits.

DATES: Comments should be submitted on or before February 1, 2000.

ADDRESSES: Secretary to the Board, Railroad Retirement Board, 844 North Rush Street, Chicago, Illinois 60611.

FOR FURTHER INFORMATION CONTACT: Thomas W. Sadler, Senior Attorney, (312) 751–4513, TDD (312) 751–4701.

SUPPLEMENTARY INFORMATION: Public Law 104–251 (110 Stat. 3161), commonly known as the Railroad Unemployment Insurance Act Amendments of 1996, amended the Railroad Unemployment Insurance Act (RUIA) to shorten the waiting period for receipt of unemployment and sickness benefits payable under that statute, to change the method of computing the daily benefit rate, and to eliminate certain extended payments of benefits, and the Board proposes to amend its regulations under the RUIA to conform to those amendments.

Section 325.1 is proposed to be amended to reflect the change in the waiting period for unemployment benefits from 14 days to seven days. As amended, § 325.1 would provide that unemployment benefits are payable to any qualified employee for each day of unemployment in excess of seven in his or her first two-week registration period, and then for up to ten days of unemployment in any subsequent registration period within the same period of continuing unemployment. However, if the unemployment is the result of a strike, no benefits are payable for the first day 14 days of unemployment. For purposes of applying the seven-day waiting period, a period of continuing unemployment would end when an employee exhausts his or her unemployment benefits for a benefit year. Section 325.1 would also be amended to incorporate a definition of “period of continuing unemployment”, a concept added by the 1996 amendments. The concept of a period of continuing unemployment was added to the RUIA so as to permit the continued payment of benefits from one benefit year to the next without a new waiting period if the period of unemployment runs from one year to the next. Finally, § 325.1 is proposed to be amended to provide that if an employee’s earnings in a registration period exceed the monthly compensation base for the applicable base year, then no unemployment benefits are payable in that registration period. For example, for benefit year 1998 the base year is calendar year 1997 in which the monthly compensation base was $890. No benefits are payable for any days of unemployment in the benefit year beginning July 1, 1998, for any registration period in which the employee earns more than $890. An employee who declines suitable work during a registration period is treated as having earned the amount of earnings he would have received had he not declined employment.

Section 330.2 is proposed to be amended to provide that the maximum daily benefit rate under the RUIA is the monthly compensation base, as computed under 20 CFR part 302, multiplied by 5%, rounded down to the nearest $1. This change is the result of a change in the RUIA enacted under the 1996 amendments. The Board will publish the maximum daily benefit rate for the upcoming benefit year by June 1 of each year.

Section 335.6 is proposed to be revised to reflect the same changes with respect to the waiting period for sickness benefits that the proposed amendments to § 325.1 make with respect to unemployment benefits.

Finally, § 336.13 is revised, and § 336.14 is amended to reflect a change in the payment of extended benefits made by the 1996 amendments. Under the RUIA, as amended, an employee with ten or more years of service will receive a maximum of 65 days of extended unemployment or sickness benefits after the employee has exhausted his or her normal 130 days of unemployment or sickness.

The Board, with the concurrence of the Office of Management and Budget, has determined that this is not a significant regulatory action under Executive Order 12866; therefore no regulatory impact analysis is required. There are no information collections associated with these rules.

List of Subjects in 20 CFR Parts 325, 330, 335, and 336

Railroad employees, Railroad unemployment insurance, Reporting and recordkeeping requirements.

For the reasons set out in the preamble, the Railroad Retirement Board proposes to amend chapter II, title 20 of the Code of Federal Regulations as follows:

PART 325—REGISTRATION FOR RAILROAD UNEMPLOYMENT BENEFITS

1. The authority for part 325 continues to read as follows:

Authority: 45 U.S.C. 362(f) and 362(l).

2. Paragraphs (a) through (d) of § 325.1 are revised, paragraph (e) is redesignated as paragraph (h), and new
§ 325.1 General.

(a) Day of unemployment. A “day of unemployment” is a calendar day on which an employee, although ready and willing to work, is unemployed, and on which no remuneration is payable and for which the employee has registered, as required by this part. The amount of compensable days of unemployment shall be computed in accordance with this section.

(b) Registration period. Except for registration periods in extended unemployment benefit periods, a “registration period” means a period of 14 consecutive days beginning with the first day for which an employee registers following:

(1) His or her last day of work, or
(2) The last day of the employee’s last preceding registration period, and with respect to which the employee properly files a claim for benefits on such form and in such manner as the Board prescribes.

(c) General waiting period. Benefits are payable to any qualified employee for each day of unemployment in excess of seven during his or her first registration period in a period of continuing unemployment if such period of continuing unemployment is his or her initial period of continuing unemployment beginning in the benefit year, and then for each day of unemployment in excess of four during any subsequent registration period within the same period of continuing unemployment. A strike waiting period, described in paragraph (d) of this section, will satisfy a general waiting period with respect to a benefit year.

(d) Strike waiting period. If a qualified employee has a period of continuing unemployment that includes days of unemployment due to a stoppage of work because of a strike in the establishment, premises, or enterprise at which he or she was last employed, no benefits are payable for his or her first 14 days of unemployment due to such stoppage of work. For subsequent days of unemployment due to the same stoppage of work, benefits are payable for days of unemployment in excess of four in each subsequent registration period within the same period of continuing unemployment. If such period of continuing unemployment ends because the employee has exhausted his or her benefits as provided for under part 336 of this chapter, but the stoppage of work continues, benefits are payable for days of unemployment in excess of seven in the employee’s first registration period in a new period of continuing unemployment based upon the same stoppage of work and for days of unemployment in excess of four in subsequent registration periods in the same period of continuing unemployment.

(e) Period of continuing unemployment. A “period of continuing unemployment” means a single registration period that includes more than four days of unemployment or a series of consecutive periods each of which includes more than four days of unemployment, or a series of successive registration periods, each of which includes more than four days of unemployment, if each succeeding registration period begins within 15 days after the last day of the immediately preceding registration period. An employee’s period of continuing unemployment ends on the last day of a benefit year in which he or she exhausts rights to unemployment benefits as provided for in part 336 of this chapter.

(f) Computation of compensable days. (1) Example 1. An employee has an initial period of continuing unemployment from June 14 through July 25 and is unemployed on all days in that period. The employee’s first registration period covers June 14 to June 27, and his subsequent registration periods cover June 28 to July 11 and July 12 to July 25. Under paragraph (c) of this section, a one-week waiting period applies to his first registration period and the employee is therefore paid benefits for days of unemployment in excess of four in that period. The employee is then paid benefits for days of unemployment in excess of four in each of the two ensuing registration periods. [Note: if this employee’s period of continuing unemployment had been the result of a strike in the establishment, premises, or enterprise at which the employee was last employed, then under paragraph (d) of this section, no benefits would be payable for the period June 14 to June 27, and benefits would then be payable for days of unemployment in excess of four in each of the ensuing registration periods.] (2) Example 2. Same facts as in example 1, but the employee is unemployed again beginning August 18. Since August 18 is more than 15 days after July 25, the end of his last registration period, the employee begins a new period of continuing unemployment. The employee’s first registration period in the new period of continuing unemployment covers August 18 to August 31. The employee is paid benefits for days of unemployment in excess of seven in that registration period because that period is the employee’s first registration period in a new period of continuing unemployment commencing in the benefit year beginning July 1, and he or she did not previously have a waiting period in any registration period earlier in that benefit year. The employee’s next registration period covers September 1 to September 14, and the employee returned to work on September 12. In that registration period, the employee has 11 days of unemployment and is therefore paid benefits for days of unemployment in excess of four.

(g) Remuneration exceeds base year compensation. (1) No benefits are payable to any otherwise eligible employee for any day of unemployment in a registration period where the total amount of remuneration, as defined in part 322 of this chapter, payable to the employee during a registration period exceeds the amount of the base year monthly compensation base. For this purpose an employee is considered to have received the amount he would have earned except for the fact that he declined suitable work available to him or her during the registration period.

(2) Days of unemployment which are not compensable by virtue of paragraph (g)(1) of this section shall nevertheless be counted as days of unemployment for purposes of determining whether the general waiting period, as described in paragraph (c) of this section, has been satisfied.

* * * * *

PART 330—DETERMINATION OF DAILY BENEFIT RATES

3. The authority citation for part 330 continues to read as follows:


4. Section 330.1 is revised to read as follows:
§ 330.1 Introduction.
The Railroad Unemployment Insurance Act provides for the payment of benefits, at a specified daily benefit rate, to any qualified employee for his or her days of unemployment or days of sickness, subject to a maximum amount per day. The “daily benefit rate” for an employee is the amount of benefits that he or she may receive for each compensable day of unemployment or sickness in any registration period in a period of continuing unemployment or sickness.

5. Paragraphs (b), (c), and (d) of § 330.2 are revised to read as follows:

§ 330.2 Computation of daily benefit rate.

(b) Maximum daily benefit rate. The maximum daily benefit rate is the product of the monthly compensation base, as computed under part 302 of this chapter, for the base year immediately preceding the beginning of the benefit year, multiplied by five percent. If the maximum daily benefit rate so computed is not a multiple of $1.00, the Board will round it down to the nearest multiple of $1.00.

(c) When increase effective. Whenever the annual application of the formula in paragraph (b) of this section triggers an increase in the maximum daily benefit rate, such increase will apply to days of unemployment or days of sickness in registration periods beginning after June 30 of the calendar year immediately following the base year referred to in paragraph (b) of this section.

(d) Notice. Whenever the annual application of the formula in paragraph (b) of this section triggers an increase in the maximum daily benefit rate, or if the annual application of the formula does not trigger an increase, the Board will publish a notice in the Federal Register explaining how it computed the maximum daily benefit rate for the year. The Board will also notify each employer of the maximum amount of the daily benefit rate. The Board will make the computation as soon as it has computed the amount of the monthly compensation base under part 302 of this chapter and will publish notice as soon as possible thereafter, but in no event later than June 1 of each year. Information as to the current amount of the maximum daily benefit rate will also be available in any Board district or regional office.

§ 330.3 Payment of sickness benefits.

(a) General rule. Except as provided in this section, benefits are payable to any qualified employee for each day of sickness after the fourth consecutive day of sickness in a period of continuing sickness, as defined in § 335.1(c), but excluding four days of sickness in any registration period in such period of continuing sickness.

(b) Waiting period. Benefits are payable to any qualified employee for each day of sickness in excess of seven during his or her initial period of continuing sickness beginning in the benefit year.

(c) Computation of compensable days. (1) Example 1. An employee has an initial period of continuing sickness from June 14 through July 25, and all days in that period are days of sickness. The employee’s first registration period covers June 14 to June 27, and his or her subsequent registration period covers June 28 to July 11, and July 12 to July 25. In the one-week waiting period the employee is paid benefits for days of sickness in excess of seven. In each of the two ensuing registration periods the employee is paid benefits for days of sickness in excess of four.

(2) Example 2. Same facts as in Example 1, but the employee later has a new period of continuing sickness based upon a different illness or impairment beginning September 17. The employee’s first registration period in his or her new period of continuing sickness covers September 17 to September 30. The employee is paid benefits for days of sickness in excess of seven in that 14-day period because that period is his or her first registration period in a new period of continuing sickness commencing in the benefit year beginning July 1, and he or she did not previously have a waiting period in any registration period earlier in the benefit year.

(3) Example 3. Same facts as in examples 1 and 2, but the employee then has a new period of continuing sickness beginning January 1 in the same benefit year. January 1 to January 14 is the employee’s first registration period in that period of continuing sickness. The employee is paid benefits for days of sickness in excess of four in that registration period because earlier in the benefit year he or she had a registration period, September 17 to September 30, in which he or she satisfied the initial seven-day waiting period.

(d) Amount payable. The gross amount of sickness benefits for any registration period in a period of continuing sickness shall be computed by multiplying the number of compensable days of sickness in such registration period by the employee’s daily benefit rate, as computed under part 330 of this chapter.

PART 335—SICKNESS BENEFITS

6. The authority citation for part 335 continues to read as follows:

Authority: 45 U.S.C. 362(j) and 362(l).

7. Section 335.6 is revised to read as follows:

§ 335.6 Payment of sickness benefits.

(a) General rule. Except as provided in this section, benefits are payable to any qualified employee for each day of sickness after the fourth consecutive day of sickness in a period of continuing sickness, as defined in § 335.1(c), but excluding four days of sickness in any registration period in such period of continuing sickness.

(b) Waiting period. Benefits are payable to any qualified employee for each day of sickness in excess of seven during his or her initial period of continuing sickness beginning in the benefit year.

(c) Computation of compensable days. (1) Example 1. An employee has an initial period of continuing sickness from June 14 through July 25, and all days in that period are days of sickness. The employee’s first registration period covers June 14 to June 27, and his or her subsequent registration period covers June 28 to July 11, and July 12 to July 25. In the one-week waiting period the employee is paid benefits for days of sickness in excess of seven. In each of the two ensuing registration periods the employee is paid benefits for days of sickness in excess of four.

(2) Example 2. Same facts as in Example 1, but the employee later has a new period of continuing sickness based upon a different illness or impairment beginning September 17. The employee’s first registration period in his or her new period of continuing sickness covers September 17 to September 30. The employee is paid benefits for days of sickness in excess of seven in that 14-day period because that period is his or her first registration period in a new period of continuing sickness commencing in the benefit year beginning July 1, and he or she did not previously have a waiting period in any registration period earlier in the benefit year.

(3) Example 3. Same facts as in examples 1 and 2, but the employee then has a new period of continuing sickness beginning January 1 in the same benefit year. January 1 to January 14 is the employee’s first registration period in that period of continuing sickness. The employee is paid benefits for days of sickness in excess of four in that registration period because earlier in the benefit year he or she had a registration period, September 17 to September 30, in which he or she satisfied the initial seven-day waiting period.

(d) Amount payable. The gross amount of sickness benefits for any registration period in a period of continuing sickness shall be computed by multiplying the number of compensable days of sickness in such registration period by the employee’s daily benefit rate, as computed under part 330 of this chapter.

PART 336—DURATION OF NORMAL AND EXTENDED BENEFITS

8. The authority citation for part 336 continues to read as follows:


9. Section 336.13 is revised to read as follows:

§ 336.13 Years of service requirement.

(a) Eligibility. For the purposes of this part, an employee is not eligible for extended unemployment or sickness benefits if he or she does not have at least 10 years of railroad service. An employee who has 120 service months, as defined in part 210 of this chapter, whether or not consecutive, is considered to have 10 years of railroad service.

(b) Initial determination. The Board will determine whether an employee has 10 years of railroad service on the basis of reports filed by employers pursuant to part 209 of this chapter. The number of years of service shown in the Board’s records will be accepted as correct for the purposes of this part, unless the employee claims credit for more service than that shown in the Board’s records and such additional service is verified, subject to part 211 of this chapter.

(c) Effective date. An employee acquires ten years of railroad service as of the first day with respect to which creditable compensation is attributable in his 120th month of service.

10. In § 336.14, paragraphs (a), (c), and (d) are revised to read as follows:

§ 336.14 Extended benefit period.

(a) Defined. An extended benefit period consists of seven consecutive 14-day registration periods.
DEPARTMENT OF DEFENSE

48 CFR Part 30

Changes in Cost Accounting Practices

AGENCY: Department of Defense (DoD).

ACTION: Notice of public meeting.

SUMMARY: The Office of the Director of Defense Procurement, in conjunction with the National Contract Management Association, is sponsoring a public meeting to discuss alternatives to the Cost Accounting Standard Board’s Supplemental Notice of Proposed Rulemaking (SNPRM–II) regarding “Changes in Cost Accounting Practices,” published in the Federal Register at 64 FR 45700 on August 20, 1999. The Office of the Director of Defense Procurement would like to hear the views of interested parties on potential alternatives to the approach proposed by the Cost Accounting Standards Board in SNPRM–II. One such alternative is available on the Internet Home Page of the Office of Cost, Pricing, and Finance at http://www.acq.osd.mil/dp/cpf.

The Office of the Director of Defense Procurement is particularly concerned about the complexity and level of detail contained in SNPRM–II, and the additional administrative burden for contractors and contracting officers that would result from its implementation. The Office is also concerned that the addition of unnecessary and cumbersome requirements for contractor submissions and government reviews would lengthen the process for resolving the cost impact of a change in cost accounting practice and increase the potential for disputes.

If feasible alternatives to SNPRM–II can be identified, working groups may be formed to refine the alternatives if necessary. The alternatives would then be provided to the Chairman of the Cost Accounting Standards Board for the Board’s consideration.

DATES: The meeting will be held on December 17, 1999, from 9 a.m. until 1 p.m.

ADDRESSES: The meeting will be held at the National Contract Management Association, 1912 Woodford Drive, Vienna, VA 22182. Directions may be found on the Internet at http://www.acq.osd.mil/dp/cpf.

FOR FURTHER INFORMATION CONTACT: Claudia Low, National Contract Management Association, by telephone (703) 693–9616, or by e-mail at capitadj@acq.osd.mil; or Ms. Claudia Low, National Contract Management Association, by telephone at (703) 734–5440.

Michele P. Peterson, Executive Editor, Defense Acquisition Regulations Council.

BILLING CODE 5000–04–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

RIN 1018–AF79

Endangered and Threatened Wildlife and Plants; Proposed Threatened Status for the Plant Silene spaldingii (Spalding’s Catchfly)

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Proposed rule and notice of petition finding.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), propose to list Silene spaldingii (Spalding’s catchfly) as threatened pursuant to the Endangered Species Act of 1973, as amended (Act). Silene spaldingii is currently known from a total of 52 populations. Seven populations occur in west-central Idaho, 7 in northeastern Oregon, 9 in western Montana, 28 in eastern Washington, and 1 in adjacent British Columbia, Canada. This taxon is threatened by a variety of factors including habitat destruction and fragmentation from agricultural and urban development, grazing and trampling by domestic livestock and native herbivores, herbicide treatment, and competition from non-native plant species. This proposal, if made final, would implement the Federal protection and recovery provisions afforded by the Act for the plant.

DATES: Comments from all interested parties must be received by February 1, 2000. Public hearing requests must be received by January 18, 2000.

ADDRESSES: Comments and materials concerning this proposal should be sent to the Supervisor, Snake River Basin Office, U.S. Fish and Wildlife Service, 1387 S. Vinnell Way, Room 368, Boise, Idaho 83709. Comments and materials received will be available for public inspection, by appointment, during normal business hours at the above address.

FOR FURTHER INFORMATION CONTACT: Robert Ruesink, Supervisor, at the above address (telephone 208/378–5243; facsimile 208/378–5262).

SUPPLEMENTARY INFORMATION:

Background

A member of the pink or carnation family (Caryophyllaceae), Silene spaldingii Watson is a long-lived perennial herb with four to seven pairs of lance-shaped leaves and a spirally arranged inflorescence (group of flowers) consisting of small greenish-white flowers. The foliage is lightly to densely covered with sticky hairs. Reproduction is by seed only; S. spaldingii does not possess rhizomes or other means of vegetative reproduction (Lesica 1992). Plants range from approximately 2 to 6 decimeters (dm) (8 to 24 inches (in)) in height (Lichthardt 1997).

First collected in the vicinity of the Clearwater River, Idaho, between 1836 and 1847, Silene spaldingii was originally described by Watson (Watson 1875). This taxon was retained as a full species in a recent, comprehensive regional flora (Hitchcock and Cronquist 1973). Silene spaldingii differs from the related, common species S. scouleri by having petal blades 2 millimeters (mm) (0.06 in) in length; S. scouleri has deeply lobed petal blades that are 6 to 7 mm (0.24 to 0.28 in) long. Silene douglasii also occurs with S. spaldingii in some areas but typically has multiple, slender stems, narrower leaves, and is rarely sticky-pubescent (Lichthardt 1997).
The distribution and habitat of \textit{Silene spaldingii} are limited. The total number of sites discussed in the 90-day finding for \textit{S. spaldingii} (63 FR 63661) was 94, which is larger than the number of populations identified in this proposed rule. The number of sites stated in the 90-day finding was based primarily on information (generally known as element occurrence records) available in State natural heritage data bases. During the preparation of this proposed rule, we felt it was appropriate to group certain element occurrence records for \textit{S. spaldingii} together when the sites were located approximately 1.6 kilometer (km) (1 mile (mi)) or less apart. Thus, the difference in the number of \textit{S. spaldingii} locations described in this proposed rule and the 90-day finding does not reflect the actual loss or extirpation of sites.

This species is currently known from a total of 52 populations in the United States and British Columbia, Canada. Of the 51 \textit{Silene spaldingii} populations in the United States, 7 occur in Idaho (Idaho, Lewis, and Nez Perce Counties), 7 in Oregon (Wallowa County), 9 in Montana (Flathead, Lake, Lincoln, and Sanders Counties), and 28 in Washington (Asotin, Lincoln, Spokane, and Whitman Counties). A population consists of one to several sites that are generally located less than 1.6 km (1 mi) apart. The number of \textit{S. spaldingii} individuals within each population ranges from one to several thousand.

Eighteen populations contain more than 50 individuals; only 6 of these populations are moderately large (i.e., contain more than 500 plants). Of the six largest populations, two are found in Oregon (Wallowa County), one in Idaho (Nez Perce County), one in Montana (Lincoln County), and two in Washington (Asotin and Lincoln Counties). The 6 moderately large populations contain approximately 84 percent (i.e., 13,800 individuals) of the total number of \textit{S. spaldingii}. The total number of \textit{S. spaldingii} individuals for all 52 populations is about 16,500 (Edna Rey-Vizgirdas, Service, in litt. 1999).

Much of the remaining habitat occupied by \textit{Silene spaldingii} is fragmented. For example, \textit{S. spaldingii} sites in Oregon are located at least 64 km (40 mi) from the nearest known sites in eastern Washington. \textit{Silene spaldingii} sites in Montana are approximately 190 km (120 mi) from occupied habitat in Idaho and Washington. Approximately 52 percent of extant \textit{S. spaldingii} populations occur on private land, 10 percent on State land, 33 percent on Federal land, and 5 percent on Tribal land (E. Rey-Vizgirdas, in litt. 1999).

This species is primarily restricted to mesic (not extremely wet nor extremely dry) grasslands (prairie or steppe vegetation) that make up the Palouse region in southeastern Washington, northwestern Montana, and adjacent portions of Idaho and Oregon. In addition, approximately 100 plants were located in British Columbia (Geraldine Allen, University of Victoria, in litt. 1996). Palouse habitat is considered to be a subset of the Pacific Northwest bunchgrass habitat type (Tisdale 1986). In Idaho, Palouse habitat is confined to a narrow band along the western edge of central and north-central Idaho, centering on Latah County (Tisdale 1986; Erter and Moseley 1992). Large-scale ecological changes in the Palouse region over the past several decades, including agricultural conversion, changes in fire frequency, and alterations of hydrology, have resulted in the decline of numerous sensitive plant species including \textit{Silene spaldingii} (Tisdale 1961). More than 98 percent of the original Palouse prairie habitat has been lost or modified by agricultural conversion, grazing, invasion of non-native species, altered fire regimes, and urbanization (Noss et al. 1995).

\textit{Silene spaldingii} is typically associated with grasslands dominated by native perennial grasses such as \textit{Festuca idahoensis} (Idaho fescue) or \textit{F. scabrella} (rough fescue). Other associated species include bluebunch wheatgrass (\textit{Agropyron spicatum}), snowberry (\textit{Symphoricarpos albus}), Nootka rose (\textit{Rosa nutkana}), yarrow (\textit{Achillea millefolium}), prairie smoke avens (\textit{Geum triflorum}), sticky purple geranium (\textit{Geranium viscisissum}), and arrowleaf balsamroot (\textit{Balsamorhiza sagitata}) (Lichhardt 1997; Montana Natural Heritage Program (MNHP) 1998). Scattered individuals of Ponderosa pine (\textit{Pinus ponderosa}) may also be found in or adjacent to \textit{S. spaldingii} habitat. \textit{S. spaldingii} sites range from approximately 530 m (1,750 feet (ft)) to 1,600 m (5,100 ft) elevation (Oregon Natural Heritage Program (ONHP) 1994; Washington Natural Heritage Program (WNHP) 1998).

**Previous Federal Action**

Federal government actions for the plant began as a result of section 12 of the Act (16 U.S.C. 1531 et seq.), which directed the Secretary of the Smithsonian Institution to prepare a report on those plants considered to be endangered, threatened, or extinct in the United States. This report, designated as House Document No. 94±51, was presented to Congress on January 9, 1975, and included \textit{Silene spaldingii} as an endangered species. We published a notice on July 1, 1975, in the \textit{Federal Register} (40 FR 27823) of our acceptance of the report of the Smithsonian Institution as a petition within the context of section 4(c)(2) (petition provisions are now found in section 4(b)(3) of the Act) and our intention to review the status of the plant taxa named in the report. The July 1, 1975, notice included the above taxon. On June 16, 1976, we published a proposal (41 FR 24523) to determine approximately 1,700 vascular plant species to be endangered species pursuant to section 4 of the Act. The list of 1,700 plant taxa was assembled on the basis of comments and data received by the Smithsonian Institution and us in response to House Document No. 94±51 and the July 1, 1975, \textit{Federal Register} publication. \textit{Silene spaldingii} was included in the June 16, 1976, proposal.

In 1978, amendments to the Act required that all proposals over two years old be withdrawn. On December 10, 1979, we published a notice withdrawing that portion of the June 16, 1976, proposal that had not been made final, including the proposal to list \textit{Silene spaldingii} (45 FR 82480). We published an updated Notice of Review for plants on December 15, 1980 (45 FR 82480). This notice included \textit{S. spaldingii} as a category 1 candidate. Category 1 candidates were those for which we had sufficient information on biological vulnerability and threats to support proposals to list them as endangered or threatened species. \textit{Silene spaldingii} was included as a category 2 candidate in the November 28, 1983, supplement to the Notice of Review (48 FR 53640), as well as subsequent revisions on September 27, 1985 (50 FR 39526), February 21, 1990 (55 FR 6184), and September 30, 1993 (58 FR 51413). Category 2 candidates were those for which information in our possession indicated that proposing to list as endangered or threatened was possibly appropriate, but sufficient data to support proposed rules was not currently available. Upon publication of the February 28, 1996, Notice of Review (61 FR 7596), we ceased using category designations. \textit{Silene spaldingii} was not included as a candidate species in this notice.

Section 4(b)(3)(B) of the Act requires the Secretary to make findings as to whether the petitioned action is warranted on petitions that present substantial information indicating the petitioned action may be warranted. Section 2(b)(1) of the 1982 amendments further required that all petitions pending on October 13, 1982, be treated as having been newly submitted on that
date. This provision applied to *Silene spaldingii* because the 1975 Smithsonian report had been accepted as a petition. On October 13, 1983, we found that the listing of the species was warranted but precluded by other pending listing actions, in accordance with section 4(b)(3)(B)(iii) of the Act. We published notification of this finding on January 20, 1984 (49 FR 57114). The guidance clarifies the order in which we will process rulemakings. Highest priority is processing emergency listing rules for any species determined to face a significant and imminent risk to its well-being (Priority 1). Second priority (Priority 2) is processing final determinations on proposed additions to the lists of endangered and threatened wildlife and plants. Third priority (Priority 3) is processing new proposals to add species to the lists. The processing of administrative petition findings (petitions filed under section 4 of the Act) is the fourth priority (Priority 4). The processing of critical habitat determinations (prudency and determinability decisions) and proposed or final designations of critical habitat will no longer be subject to prioritization under the Listing Priority Guidance. This proposed rule is a Priority 3 action and is being completed in accordance with the current Listing Priority Guidance.

**Summary of Factors Affecting the Species**

Section 4 of the Act and regulations (50 CFR part 424) promulgated to implement the listing provisions of the Act set forth the procedures for adding species to the Federal lists. A species may be determined to be an endangered or threatened species due to one or more factors described in section 4(a)(1) of the Act. These factors and their application to *Silene spaldingii* are as follows.

A. The Present or Threatened Destruction, Modification, or Curtailment of Its Habitat or Range

As discussed in the “Background” section above, the distribution and habitat of *Silene spaldingii* are limited. This species is primarily restricted to slopes, flats, or swales (marshy lands) in mesic grasslands or steppe vegetation of the Palouse region in southeastern Washington, northwestern Montana, and adjacent portions of Idaho and Oregon. One site is located in British Columbia, Canada, directly adjoining a Montana population. In Idaho, Palouse habitat is confined to a narrow band along the western edge of central and north-central Idaho, centering on Latah County (Tisdale 1986; Erter and Moseley 1992). The Palouse prairie is extensively cultivated, with few remnants of native habitat (Tisdale 1986). Large-scale ecological changes have occurred in the Palouse region over the past several decades. More than 98 percent of the original Palouse prairie habitat has been lost or modified by agricultural conversion, grazing, invasion of non-native species, altered fire regimes, and urbanization (Noss *et al.* 1995). This loss of habitat has resulted in the decline of numerous sensitive plant species including *S. spaldingii* (Tisdale 1961).

Although historical data on *Silene spaldingii* distribution and population size are incomplete, this species was likely much more widespread in the past, based on the former distribution on suitable Palouse habitat. According to Erter and Moseley (1992), “because of the exceptionally rich soil, a deep layer of loess, most of the grasslands have been converted to agriculture.

Most of the Palouse prairie vegetation has, therefore, disappeared, and endemic species such as *Aster jessicae* Piper and *Haplopappus liatriformis* (Greene) St. John are threatened with extinction.” Both *A. jessicae* and *H. liatriformis* may be found within or near habitat occupied by *S. spaldingii* (Lichthardt 1997).

Invasion by non-native plant species, herbicide application, and/or grazing (including trampling and consumption of plants) threaten virtually all of the remaining populations of this species, including those present in areas administered by the Bureau of Land Management (BLM) and U.S. Forest Service (Forest Service) (Biodiversity Legal Foundation *et al.* 1995; Lichthardt 1997; MNHP 1998; ONHP 1998; WNHP 1998).

Non-native plant species are considered to be a major threat at nearly all sites supporting *Silene spaldingii*. Threats to *S. spaldingii* posed by non-native plant species include competition for water, nutrients, and light, in addition to competition for pollinators (Lesica and Heidel 1996). Non-native plant species such as St. John’s-wort (*Hypericum perforatum*), yellow star-thistle (*Centaurea solstitialis*), leafy spurge (*Euphorbia esula*), teasel (*Dipsacus sylvestris*), Canada thistle (*Cirsium arvense*), sulfur cinquefoil (*Potentilla recta*), Russian knapweed (*Acroptilon repens*), Scotch thistle (*Onopordum acanthium*), and cheatgrass (*Bromus tectorum*) threaten *S. spaldingii* in Idaho, Oregon, Montana, and Washington (Lesica and Heidel 1996; Lichthardt 1997; MNHP 1998; ONHP 1998; WNHP 1998; Janice Hill, The Nature Conservancy, *in litt.* 1999).

Some of these non-native species can invade and displace native plant communities in a relatively short period...
of time. For example, at The Nature Conservancy’s Garden Creek Preserve, which contains the largest *Silene spaldingii* population in Idaho (Idaho Conservation Data Center 1998), yellow star-thistle spread from approximately 60 hectares (ha) (150 acres (ac)) in 1987 to 1,200 ha (3,000 ac) in 1998 (J. Hill, in litt. 1999). Another site containing *S. spaldingii* in Idaho (Lawyer’s Creek) was apparently extirpated by highway construction in 1990 and the invasion of yellow star-thistle.

Yellow star-thistle is found in the vicinity of all *Silene spaldingii* populations in Idaho (Lichthardt 1997). This aggressive exotic can form almost complete monocultures, invading and outcompeting native species. Even small areas that experience soil disturbance are almost immediately colonized by yellow star-thistle or other non-native winter annuals (Lichthardt 1997). Seeds of yellow star-thistle can remain dormant in the soil for 10 years (Callihan and Miller 1997), making effective control of this aggressive weed extremely difficult.

Russian knapweed spreads readily by reproducing vegetatively, as well as by seed. Once established, knapweed forms single-species stands by producing chemicals that inhibit the survival of competing plant species, known as allelopathy (U.S. Geological Survey 1999). Knapweed has been noted to displace *Silene spaldingii* plants in Montana. At this site, the number of *S. spaldingii* plants declined from 30 in 1983 to 11 in 1990, due to the invasion of knapweed (MNHP 1998). Noxious weeds also threaten the largest *S. spaldingii* populations in Montana (Biodiversity Legal Foundation et al. 1995; Brian Martin, The Nature Conservancy, in litt. 1998), Oregon (Jimmy Kagan, Oregon Natural Heritage Program, pers. comm. 1998), and Washington (Scott Riley, Umatilla National Forest, pers. comm. 1999). *Silene spaldingii* and other native plants are generally unable to grow or successfully reproduce in areas dominated by yellow star-thistle and knapweed.

*Silene spaldingii* habitat is threatened by herbicide drift. Most remaining *S. spaldingii* populations are adjacent to agricultural fields, which are often treated with herbicides to control weeds. Even *S. spaldingii* sites that are not located immediately adjacent to agricultural areas may be vulnerable to herbicide use due to the presence of weeds (Jerry Hustafa, Wallowa-Whitman National Forest, pers. comm. 1999). Herbicide overspray threatens populations in Idaho (Lichthardt 1997; J. Hill, in litt. 1999), Oregon (J. Hustafa, pers. comm. 1998; J. Kagan, pers. comm. 1998), and Washington (WNHP 1998). The population of *S. spaldingii* at one site in Idaho (Lewis County) decreased by more than 80 percent in the past 11 years, apparently due to weed invasion, herbicide spraying, and development (Lichthardt 1997). One of the two largest *S. spaldingii* sites in Washington (on the Umtilla National Forest, Pomeroy Ranger District) is threatened by herbicide spraying to control weeds (S. Riley, pers. comm. 1999). A recent aerial herbicide spraying incident in Idaho County, Idaho, impacted the threatened plant species, MacFarlane’s four-o’clock (*Mirabilis macfarlanei*). Approximately 2,000 *M. macfarlanei* plants on Federal and private land were accidentally sprayed during treatment for nearby target weed species (Craig Johnson, BLM, in litt. 1997). This species occurs in similar habitats as *S. spaldingii*. At least two *S. spaldingii* sites in Idaho (Nez Perce County) are particularly vulnerable to herbicide drift because of their close proximity to cropland (Lichthardt 1997).

In addition to direct consumption of plants (as discussed under Factor C of this section), grazing animals can also affect *Silene spaldingii* by trampling and changing the community composition by fostering the invasion of non-native species. Impacts from trampling by native ungulates and domestic livestock have been observed at *S. spaldingii* sites in Washington (Gamon 1991; WNHP 1998). Grazing can indirectly affect *S. spaldingii* habitat by altering the species composition (Gamon 1991; Lichthardt 1997; Bonnie Heidel, Montana Natural Heritage Program, in litt. 1999). If grazing is heavy enough to adversely affect native species or allow weed invasion, *S. spaldingii* will likely disappear from sites (Barbara Benner, BLM, in litt. 1993). Biennial and non-native annual plants, adapted to disturbance, have a competitive advantage over *S. spaldingii* because of the soil disturbance associated with grazing (B. Benner, in litt. 1995). Most populations (52 percent) of *Silene spaldingii* occur on privately owned property and are, therefore, threatened by changes in land use practices, including certain livestock grazing practices, agricultural developments, and urbanization. For example, active housing development threatens to eliminate *S. spaldingii* habitat near Redbird Ridge in Idaho (Lichthardt 1997). Over the past 3 years, residential development immediately adjoining land owned by The Nature Conservancy (TNC), which has the largest *S. spaldingii* population in Montana, has destroyed potential habitat, increased the likelihood of uncontrolled, competing noxious weeds, and reduced management options such as controlled burning on the preserve (B. Martin, in litt. 1998).

*Continued development in this area is expected (B. Martin, in litt. 1998).* Habitat for *S. spaldingii* on private land near Wallowa Lake in eastern Oregon, which supports the largest site in Oregon, may be threatened by development because of its proximity to existing recreational facilities and residences (E. Rey-Vizgirdas, pers. obs. 1998). Other *S. spaldingii* sites on private land in Idaho, Montana, and Washington may also be threatened by development.

**B. Overutilization for Commercial, Recreational, Scientific, or Educational Purposes**

The plant is not a source for human food, nor is it currently of commercial horticulture interest. Therefore, overutilization is not considered to be a threat to this species over the past century. However, simply listing a species can precipitate commercial or scientific interest, both legal and illegal, which can threaten the species through unauthorized and uncontrolled collection for scientific and/or commercial purposes. The listing of species as threatened or endangered publicizes their rarity and may make them more susceptible to collection by researchers or curiosity seekers. Some of the populations of *Silene spaldingii* are small enough that even limited collection pressure could have adverse impacts on their reproductive or genetic viability.

**C. Disease or Predation**

Grazing or browsing of *Silene spaldingii* inflorescences by livestock and native herbivores has been observed and is considered a significant threat to the species (Kagan 1989; Lesica 1993; Heidel 1995; B. Benner, in litt. 1999). While grazing or browsing of *S. spaldingii* by native herbivores likely occurred historically, the effects of grazing or browsing becomes even more important as population sizes decrease. Rodent activity is also considered a significant factor affecting the persistence of *S. spaldingii* at several sites in eastern Washington (B. Benner, in litt. 1999). For example, numerous *S. spaldingii* plants were marked with stakes and metal tags as part of a monitoring study on land managed by the BLM in Washington. On a site visit, the BLM botanist discovered that many of these plants were either broken off or missing completely and likely consumed by rodents, as evidenced by
rodent burrowing activity in the area (B. Benner, in litt. 1999). Since *S. spaldingii* reproduces only by seed (Lesica 1992), grazing, browsing, or trampling directly affects reproduction of this species when flowers or seeds are removed or damaged.

Insect predation on flowers and fruits is also a threat for this species (Kagan 1989; Gamon 1991; B. Benner, in litt. 1999). Such predation likely results in reduced reproductive success for *Silene spaldingii* (Heidel 1995). For example, at one of the two largest *S. spaldingii* populations in Washington on land managed by the Forest Service, insect consumption of seeds has been consistently observed by biologists monitoring the plants. This consumption results in empty capsules with no seeds, thereby limiting sexual reproduction of affected *S. spaldingii* plants (S. Riley, pers. comm. 1999). Similarly, in Oregon, a high percentage of *S. spaldingii* seed heads were destroyed by a seed weevil (Kagan 1989). Insect damage to foliage of *S. spaldingii* plants has also been noted (Lichthardt 1997).

**D. The Inadequacy of Existing Regulatory Mechanisms**

*Silene spaldingii* is listed as endangered by the State of Oregon (Oregon Department of Agriculture). However, the State Endangered Species Act does not provide protection for species on private land. Therefore, under State law, any plant protection is at the discretion of the landowner. *Silene spaldingii* is on the Washington Natural Heritage Program’s list of threatened species (Gamon 1991), but this designation offers no statutory protection (Ted Thomas, Service, in litt. 1998). In addition, although State natural heritage programs in Idaho and Montana consider *Spaldingia* to be rare and imperiled these States have no endangered species legislation that protect threatened or endangered plants. The majority of *S. spaldingii* habitat occurs on private land, which is not adequately protected by existing regulatory mechanisms.

In Canada, *Silene spaldingii* is listed on the British Columbia, Ministry of Environment, Lands and Park’s Red List. The Red List includes indigenous species or subspecies (taxa) that are either extirpated, endangered, threatened, or candidates for such status. Endangered taxa are facing imminent extirpation or extinction. Threatened taxa are likely to become endangered if limiting factors are not reversed. *S. spaldingii* is a candidate for legal designation as an endangered or threatened species.

**E. Other Natural or Manmade Factors Affecting Its Continued Existence**

Competition with other species for a limited number of pollinators (e.g., bumblebees (*Bombus fervidus*)) has the potential to adversely affect both fecundity and individual fitness in *Silene spaldingii* (Lesica and Heidel 1996). Competition for pollinators occurs primarily at *S. spaldingii* sites with large populations of other flowering plants, and the competition can affect the survival of these small populations of *S. spaldingii*. For example, the non-native flowering plant St. John’s-wort competes for pollinators where this plant occurs with *S. spaldingii* in Idaho (Lesica and Heidel 1996; Janice Hill, TNC, in litt. 1999; Karen Gray, botanist, in litt. 1999).

Reduced pollinator activity is associated with poor reproductive success of *Silene spaldingii*, particularly in small populations (Lesica 1993; Lesica and Heidel 1996). Agricultural fields do not provide suitable habitat for pollinators of *S. spaldingii*, which requires pollination by insects for maximum seed set and population viability (Lesica and Heidel 1996). Populations of *S. spaldingii* that occupy small areas surrounded by land that does not support bumblebee colonies (e.g., crop lands) are not likely to persist over the long term, and the presence of pollinators is considered to be critical for the persistence of *S. spaldingii* (Lesica 1993; Lesica and Heidel 1996).

In addition to agricultural conversion and pesticides, pollinators are vulnerable to herbicide application, domestic livestock grazing, and fire (Gamon 1991; Lesica 1993).

Climatic fluctuations can adversely affect this species and may contribute to the extirpation of small populations. For example, a population of *Silene spaldingii* at Wild Horse Island (Montana) declined from approximately 250 to 10 plants, due primarily to drought conditions in the late 1980s (Lesica 1988; Heidel 1995). Such reductions in population size are often exacerbated by other factors including pollinator competition and poor reproductive success.

Habitat changes associated with fire suppression threaten this species, even at sites on public lands and those with some protective status (e.g., managed by TNC). Fire suppression can result in an overall decline in suitable habitat conditions for *Silene spaldingii* by facilitating encroachment by woody vegetation and other plant species and contributing to a build-up in the litter or duff layer. Competition from woody plants is frequently considered to reduce fecundity or recruitment of native prairie species (Menges 1995). In areas where fire regimes have been altered or excluded, shrubs and trees can encroach on grassland habitats that support *S. spaldingii* and inhibit seed germination. For example, *S. spaldingii* in the Kramer Palouse Biological Study Area in Washington declined from 147 to 10 individuals during the period from 1981 to 1994, apparently due to encroachment by the non-native yellow star-thistle and woody vegetation (Heidel 1995). Prescribed fire may have a positive effect on *S. spaldingii* by removing litter and creating suitable
sites for recruitment (Lesica, in press). Recruitment of *Silene spaldingii* at study sites in Montana was enhanced following prescribed fire (Lesica 1992; in press). However, the effects of fire will vary at different sites within the range of this species due to factors such as fuel moisture content, species composition, and season and intensity of burning (Lesica 1997).

Most populations of *Silene spaldingii* are restricted to small, remnant patches of native habitat (Gamon 1991; Lichthardt 1997; B. Heidel, in litt. 1999; S. Riley, pers. comm. 1999). When the number of populations or species in an area is small, the remaining populations (or portions of populations) have a higher probability of extinction from random events. Small populations are vulnerable to even relatively minor disturbances such as fire, herbicide drift, and weed invasions, which could result in the loss of *S. spaldingii* populations (Gamon 1991). Small populations of *Silene regia*, a rare prairie species native to the Midwest, have low seed germination presumably due to reduced pollinator visitation and other factors (Menges 1995). Small fragments of habitat that contain *S. spaldingii* may not be large enough to support viable populations of pollinators (Lesica 1993). Small populations are vulnerable to natural and manmade disturbances and may lose a large amount of genetic variability because of genetic drift (loss of genetic variability that takes place as a result of chance), reducing their long-term viability. Many *S. spaldingii* populations are isolated from other populations by large distances, and the majority of the populations occur at scattered localities separated by habitat that is not suitable for this species, such as agricultural fields. Extinction appears to be imminent for at least two *S. spaldingii* populations in Idaho due to their small size and habitat degradation (Lichthardt 1997). One of these populations consists of four individuals, and the other population has only one *S. spaldingii* plant. With these very small populations, even if the habitat was completely undisturbed, these populations would not be considered viable.

We have carefully assessed the best scientific and commercial information available regarding the past, present, and future threats faced by the species in determining to issue this proposed rule. Most of the remaining sites that support *Silene spaldingii* are small and fragmented, and existing sites are vulnerable to impacts from factors including grazing, trampling, herbicide use, and non-native vegetation, in addition to urban and agricultural development. The majority of this species (52 percent) occurs on private land with little or no protection. Only one-third (33 percent) of *S. spaldingii* populations occur on Federal land (managed primarily by the BLM and Forest Service) and may, therefore, be afforded some level of protection. As previously described, only 6 *S. spaldingii* populations (12 percent) contain more than 500 plants, and even these relatively large populations (which occur on private and Federal land) are variously threatened by the above factors.

**Critical Habitat**

We are not at this time making a critical habitat determination for *Silene spaldingii*. The Final Listing Priority Guidance for FY 1999/2000 (64 FR 57114) states, that the processing of critical habitat determinations (prudency and determinability decisions) and proposed or final designations “will no longer be subject to prioritization under the Listing Priority Guidance. Critical habitat determinations, which were previously included in final listing rules published in the Federal Register, may now be processed separately, in which case stand-alone critical habitat determinations will be published as notices in the Federal Register. We will undertake critical habitat determinations and designations during FY 1999 and FY 2000 as allowed by our funding allocation for that year.” As explained in detail in the Listing Priority Guidance, our listing budget is currently insufficient to allow us to immediately complete all of the listing actions required by the Act. Deferral of the critical habitat determination for *S. spaldingii* will allow us to concentrate our limited resources on higher priority critical habitat and other listing actions, while allowing us to pursue protections needed for the conservation of *S. spaldingii* without further delay. We will publish a critical habitat determination for *S. spaldingii* in the Federal Register subsequent to this rule.

**Available Conservation Measures**

Conservation measures provided to species listed as endangered or threatened under the Act include recognition, recovery actions, requirements for Federal protection, and prohibitions against certain activities. Recognition through listing encourages public awareness and results in conservation actions by Federal, State, and private agencies and individuals. The Act provides for possible land acquisition and cooperation with the State and requires that recovery plans be developed for all listed species. The protection required of Federal agencies and the prohibitions against certain activities involving listed plants are discussed, in part, below.

Section 7(a) of the Act requires Federal agencies to evaluate their actions with respect to any species that is proposed or listed as endangered or threatened and with respect to its critical habitat, if any is being designated. Regulations implementing this interagency cooperation provision of the Act are codified at 50 CFR Part 402. Section 7(a)(4) of the Act requires Federal agencies to confer with us on any action that is likely to jeopardize the continued existence of a proposed species or result in destruction or adverse modification of proposed critical habitat. If a species is subsequently listed, section 7(a)(2) requires Federal agencies to ensure that activities they authorize, fund, or carry out are not likely to jeopardize the continued existence of such a species or to destroy or adversely modify its critical habitat. If a Federal action may affect a listed species or its critical habitat, the responsible Federal agency must enter into formal consultation with us, unless we concur that the action is not likely to adversely affect the species.

Federal agencies that may have involvement with *Silene spaldingii* include the Federal Housing Administration and the Farm Services Agency, which may be subject to section 7 consultation through potential funding of housing and farm loans where this species or its habitat occurs. Highway construction and maintenance projects that receive funding from the U.S. Department of Transportation for Federal highways will also be subject to review under section 7 of the Act. In addition, activities that may affect populations of *S. spaldingii* that occur on Federal lands (e.g., managed by the BLM, Department of Defense, or Forest Service) will be subject to section 7 review.

The Act and its implementing regulations set forth a series of general prohibitions and exceptions that apply to all threatened plants. Pursuant to 50 CFR 17.71, generally all prohibitions of 50 CFR 17.61 apply to threatened plants. These prohibitions, in part, make it illegal for any person subject to the jurisdiction of the United States to import or export, transport or ship any endangered or threatened plant species in interstate or foreign commerce in the course of a commercial activity, sell or offer for sale such species in interstate or foreign commerce, or remove and reduce such species to possession from
areas under Federal jurisdiction. Certain exceptions apply to our agents and State conservation agencies.

The Act and 50 CFR 17.72 also provide for the issuance of permits to carry out otherwise prohibited activities involving threatened plant species under certain circumstances. Such permits are available for scientific purposes and to enhance the propagation or survival of the species. For threatened plants, permits also are available for botanical or horticultural exhibition, educational purposes, or special purposes consistent with the purposes of the Act. We anticipate few trade permits would ever be sought or issued for this species because the plant is not common in cultivation or in the wild.

Our policy is as published in the Federal Register on July 1, 1994 (59 FR 34272), to identify, to the maximum extent practicable at the time a species is listed, those activities that would or would not constitute a violation of section 9 of the Act. The intent of this policy is to increase public awareness of the effects of the listing on proposed and ongoing activities within the species' range.

We believe that, based upon the best available information, the following activities will not result in a violation of section 9, provided these activities are carried out in accordance with existing regulations and permit requirements:

1. Activities authorized, funded, or carried out by Federal agencies (e.g., grazing management, agricultural conversions, wetland and riparian habitat modification, flood and erosion control, residential development, recreational trail development, road construction, hazardous material containment and cleanup activities, prescribed burns, pesticide/herbicide application, and pipeline or utility line construction crossing suitable habitat), when such activity is conducted in accordance with any reasonable and prudent measures given by us in a consultation conducted under section 7 of the Act;

2. Casual, dispersed human activities on foot or horseback (e.g., bird watching, sightseeing, photography, camping, hiking);

3. Activities on private lands that do not require Federal authorization and do not involve Federal funding, such as grazing management, agricultural conversions, flood and erosion control, residential development, road construction, and pesticide/herbicide application;

4. Residential landscape maintenance, including the clearing of vegetation around one's personal residence as a fire break.

We believe that the following might potentially result in a violation of section 9; however, possible violations are not limited to these actions alone:

1. Unauthorized collecting of the species on Federal lands; and

2. Interstate or foreign commerce and import/export without previously obtaining an appropriate permit.

Questions regarding whether specific activities risk violating section 9 should be directed to the Field Supervisor of the Snake River Basin Office (see ADDRESSES section). Requests for copies of the regulations on listed plants and animals, and general inquiries regarding prohibitions and permits, may be addressed to the U.S. Fish and Wildlife Service, Ecological Services, Endangered Species Permits, 911 N.E. 11th Ave., Portland, Oregon 97232-4181 (telephone 503/231-2063; facsimile 503/231-6243).

Public Comments Solicited

We intend that any final action resulting from this proposal will be as accurate and as effective as possible. Therefore, we are soliciting comments or suggestions from the public, other concerned governmental agencies, the scientific community, industry, or any other interested party concerning this proposed rule. We are particularly seeking comments concerning:

1. Biological, commercial trade, or other relevant data concerning any threat (or lack thereof) to this species;

2. The location of any additional populations of this species and the reasons why any habitat should or should not be determined to be critical habitat pursuant to section 4 of the Act;

3. Additional information concerning the range, distribution, and population size of this species; and

4. Current or planned activities in the subject area and their possible impacts on this species.

We will take into consideration for any decision on this proposal the comments and additional information we receive, and such communications may lead to a final regulation that differs from this proposal.

Executive Order 12866

Executive Order 12866 requires agencies to write regulations that are easy to understand. We invite your comments on how to make this proposal easier to understand including answers to questions such as the following:

1. Is the discussion in the "Supplementary Information" section of the preamble helpful in understanding the proposal?

2. Does the proposal contain technical language or jargon that interferes with its clarity?

3. Does the format of the proposal (grouping and order of sections, use of headings, paragraphing, etc.) aid or reduce its clarity? What else could we do to make the proposal easier to understand?

Send a copy of any comments that concern how we could make this rule easier to understand to the office identified in the ADDRESSES section at the beginning of this document.

National Environmental Policy Act

We have determined that an environmental assessment and environmental impact statement, as defined under the authority of the National Environmental Policy Act of 1969, need not be prepared in connection with regulations adopted pursuant to section 4(a) of the Act. We published a notice outlining our reasons for this determination in the Federal Register on October 25, 1983 (48 FR 49244).

Required Determinations

This rule does not contain any information collection requirements for which Office of Management and Budget (OMB) approval under the Paperwork Reduction Act, 44 U.S.C. 3501 et seq., is required. An information collection related to the rule pertaining to permits for endangered and threatened species has OMB approval and is assigned clearance number 1018-0094. This rule does not alter that information collection requirement. For additional information concerning permits and associated requirements for threatened plants, see 50 CFR 17.72.

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:

The primary author of this proposed rule is Edna Rey-Vizgirdas, U.S. Fish and Wildlife Service, Snake River Basin Office (see ADDRESSES section).

List of Subjects in 50 CFR Part 17

Endangered and threatened species, Exports, Imports, Reporting and recordkeeping requirements, Transportation.

Regulations Promulgation

Accordingly, we propose to amend part 17, subchapter B of chapter I, title 50 of the Code of Federal Regulations as set forth below:
PART 17—[AMENDED]

1. The authority citation for part 17 continues to read as follows:


2. Section 17.12(h) is amended by adding the following, in alphabetical order under FLOWERING PLANTS, to the List of Endangered and Threatened Plants:

<table>
<thead>
<tr>
<th>Species</th>
<th>Historic range</th>
<th>Family</th>
<th>Status</th>
<th>When listed</th>
<th>Critical habitat</th>
<th>Special rules</th>
</tr>
</thead>
<tbody>
<tr>
<td>Silene spaldingii</td>
<td>U.S.A. (OR, ID, MT, WA), Canada (B.C.)</td>
<td>Caryophyllaceae</td>
<td>T</td>
<td>NA</td>
<td>NA</td>
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</tr>
</tbody>
</table>


Jamie Rappaport Clark,
Director, Fish and Wildlife Service.

[FR Doc. 99–31387 Filed 12–2–99; 8:45 am]

BILLING CODE 4310–55–P
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.

AFRICAN DEVELOPMENT FOUNDATION

Sunshine Act Meeting; Board of Directors Meeting

This supersedes the announcement published on December 1, 1999.

TIME: 10:00 a.m.–12:30 p.m.
PLACE: ADF Headquarters.
DATE: Tuesday, December 7, 1999.
STATUS: Open.

Agenda
10:00 a.m.: Chairman’s Report
10:30 a.m.: President’s Report, New Business
12:30 p.m.: Adjournment

If you have any questions or comments, please direct them to Dick Day, Coordinator, Office of Policy, Planning and Outreach, who can be reached at (202) 673–3916.

William R. Ford,
President.

[FR Doc. 99–31512 Filed 12–1–99; 1:43 pm]
BILLING CODE 6116–01–P

DEPARTMENT OF AGRICULTURE
Forest Service
National Forest System Roadless Areas

AGENCY: Forest Service, USDA.
ACTION: Notice of additional scoping meetings.

SUMMARY: On October 19, 1999, the Forest Service published in the Federal Register a Notice of Intent to prepare an environmental impact statement for a proposed rule for the protection of roadless areas. The notice requested public comment on the scope of the analysis, on possible alternatives, and on whether an exemption should be granted to the Tongass National Forest. On November 10, 1999, the Forest Service published a meeting notice of 10 public scoping meetings around the country. The agency now gives notice of additional local public scoping meetings to be hosted by National Forest offices throughout the United States. A schedule of meeting locations, dates, and times is set out in the SUPPLEMENTARY INFORMATION section of this notice. The deadline for responding to the notice of intent remains December 20, 1999.

DATES: The dates of these additional scoping meetings are listed in a table in the SUPPLEMENTARY INFORMATION section of this notice. The deadline for responding to the notice of intent remains December 20, 1999.

ADDRESSES: The planned locations and dates for the ongoing National Forest-level scoping meetings are set out in the SUPPLEMENTARY INFORMATION section of this notice. All written comments on the Notice of Intent should be mailed to: USDA Forest Service-CAET, Attention: Roadless Areas NOI, P.O. Box 221090, Salt Lake City, Utah 84122 or faxed to 801–517–1021. Comments may be sent to Roadless/wo_caet-slc@fs.fed.us via electronic mail.

FOR FURTHER INFORMATION CONTACT: Leslie Watson, Content Analysis Enterprise Team, telephone: 801–517–1020, or send comments to Roadless/wo_caet-slc@fs.fed.us via electronic mail. Those interested in attending the meetings may also contact the hosting Forest Supervisor’s Office. The Forest Service’s home page at www.fs.fed.us/link/other.shtml contains a list of Forest Service offices by name, State, and Region.

SUPPLEMENTARY INFORMATION: In addition to previously announced regional meetings, the Forest Service is providing additional opportunities for the public to participate in local scoping meetings on the proposal for protecting the remaining roadless areas within the National Forest System. The scoping meetings are scheduled at the times and places shown the following list. Those wishing to attend from outside the immediate area served by the National Forest are cautioned to check with the Forest Supervisor’s Office before departing for the meeting.

BILLING CODE 3410–11–M
### Northern Region (Region 1)

<table>
<thead>
<tr>
<th>Administrative Unit</th>
<th>Date (1999)</th>
<th>Meeting Location</th>
<th>Meeting Time</th>
<th>Contact Person</th>
</tr>
</thead>
<tbody>
<tr>
<td>Regional Office</td>
<td>November 17</td>
<td>Missoula, Montana University of Montana</td>
<td>6:00 to 9:00 p.m.</td>
<td>Tom Rhode (406) 329-3196</td>
</tr>
<tr>
<td>Lolo NF</td>
<td>November 17</td>
<td>Missoula, Montana University of Montana</td>
<td>6:00 to 9:00 p.m.</td>
<td>Barb Beckes (406) 329-3750</td>
</tr>
<tr>
<td>Nez Perce NF</td>
<td>December 1</td>
<td>Grangeville, Idaho Supervisor's Office</td>
<td>6:30 to 9:00 p.m.</td>
<td>Ihor Moreszczak (208) 983-4055</td>
</tr>
<tr>
<td>Lewis and Clark NFs</td>
<td>December 2</td>
<td>Great Falls, Montana Supervisor's Office</td>
<td>4:00 to 7:00 p.m.</td>
<td>Robin Strathy (406) 791-7700</td>
</tr>
<tr>
<td>Kootenai NF</td>
<td>December 7</td>
<td>Libby, Montana City Hall</td>
<td>6:00 to 9:00 p.m.</td>
<td>Joan Dickerson (406) 293-6211</td>
</tr>
<tr>
<td>Bitteroot NF</td>
<td>December 8</td>
<td>Hamilton, Montana Senior Center</td>
<td>4:00 to 8:00 p.m.</td>
<td>Sue Heald (406) 363-7121</td>
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<tr>
<td>Administrative Unit</td>
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<td>Meeting Location</td>
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<tr>
<td>Clearwater NF</td>
<td>December 8</td>
<td>Orofino, Idaho</td>
<td>6:00 to 10:00 p.m.</td>
<td>Cliff Mitchell</td>
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<td></td>
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<td>Orofino High School</td>
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<td>(208) 476-4541</td>
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<tr>
<td>Flathead NF</td>
<td>December 8</td>
<td>Kalispell, Montana</td>
<td>6:30 to 9:00 p.m.</td>
<td>Allen Rowley</td>
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<td></td>
<td></td>
<td>Outlaw Inn</td>
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<td>(406) 758-5200</td>
</tr>
<tr>
<td>Custer NF</td>
<td>December 14</td>
<td>Billings, Montana</td>
<td>5:30 to 8:30 p.m.</td>
<td>Cheri Bashor</td>
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<td>Custer Supervisor's Office</td>
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<td>(406) 657-6200</td>
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<tr>
<td>Helena NF</td>
<td>December 14</td>
<td>Helena, Montana</td>
<td>4:00 to 8:00 p.m.</td>
<td>Maggie Pitman</td>
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<td>Supervisor's Office</td>
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<td>(406) 449-5201</td>
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<tr>
<td>Idaho Panhandle NF</td>
<td>December 14</td>
<td>Coeur d'Alene, Idaho</td>
<td>3:00 to 8:00 p.m.</td>
<td>Anthony Matthews</td>
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<td>Supervisor's Office</td>
<td></td>
<td>(208) 765-7223</td>
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<tr>
<td>Dakota Prairie NG</td>
<td>December 15</td>
<td>Bismarck, North Dakota</td>
<td>4:00 to 8:00 p.m.</td>
<td>Steve Williams</td>
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<td>Dakota Supervisor's Office</td>
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<td>(701) 250-4443</td>
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<tr>
<td>Gallatin NF</td>
<td>December 15</td>
<td>Bozeman, Montana</td>
<td>6:00 to 9:00 p.m.</td>
<td>Jim Devitt</td>
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<td></td>
<td></td>
<td>Holiday Inn</td>
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<td>(406) 587-6702</td>
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<tr>
<td>Beaverhead Deerlodge NFs</td>
<td>December 16</td>
<td>Dillon, Montana</td>
<td>4:00 to 8:00 p.m.</td>
<td>Diane Petroni</td>
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<td></td>
<td></td>
<td>Western Montana College</td>
<td></td>
<td>(406) 683-3900</td>
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**Rocky Mountain Region (Region 2)**

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<tr>
<td>Pike San Isabel NFs</td>
<td>December 2</td>
<td>Pueblo, Colorado Forest Supervisor's Office</td>
<td>5:30 to 7:30 p.m.</td>
<td>Barb Timock</td>
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<tr>
<td></td>
<td></td>
<td>1920 Valley Drive</td>
<td></td>
<td>(719) 545-8737</td>
</tr>
<tr>
<td>White River NF</td>
<td>December 6</td>
<td>Glenwood Springs, Colorado First Choice Inn</td>
<td>6:30 to 8:00 p.m.</td>
<td>Lynn Kolund</td>
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<td></td>
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<td></td>
<td>(970) 242-8211 ext. 4116</td>
</tr>
<tr>
<td>Grand Mesa, Uncompaghre,</td>
<td>December 8</td>
<td>Grand Junction, Colorado Grand Vista Inn</td>
<td>6:30 to 8:30 p.m.</td>
<td>Pam Wilson</td>
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<td>and Gunnison NFs</td>
<td></td>
<td>2790 Crossroads Boulevard</td>
<td></td>
<td>(970) 874-6600</td>
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<tr>
<td>Rio Grande NF</td>
<td>December 8</td>
<td>Del Norte, Colorado Court House Annex</td>
<td>6:00 to 8:00 p.m.</td>
<td>Ron Jablonski</td>
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<td>(719) 852-5941</td>
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<td>Forest</td>
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<tr>
<td>San Juan NF</td>
<td>December 13</td>
<td>Durango, Colorado San Juan Public Lands Center 15 Burnett Court</td>
<td>6:30 to 8:30 p.m.</td>
<td>Ann Bond (970) 355-1219</td>
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<tr>
<td>Medicine Bow NF</td>
<td>December 13</td>
<td>Casper, Wyoming Parkway Plaza, Ballroom A</td>
<td>6:30 to 8:30 p.m.</td>
<td>Pat Harrison (307) 745-2378</td>
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<tr>
<td>Shoshone NF</td>
<td>December 13</td>
<td>Cody, Wyoming Holiday Inn 1701 Sheridan</td>
<td>4:00 to 7:00 p.m.</td>
<td>Gordon Warren (307) 578-1258</td>
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<tr>
<td>Shoshone NF</td>
<td>December 14</td>
<td>Riverton, Wyoming Holiday Inn North Federal Boulevard and Sunset Boulevard</td>
<td>4:00 to 7:00 p.m.</td>
<td>Gordon Warren (307) 578-1258</td>
</tr>
<tr>
<td>Bighorn NF</td>
<td>December 14</td>
<td>Sheridan, Wyoming Sheridan Center Best Western 612 North Main</td>
<td>4:00 to 7:00 p.m.</td>
<td>Bernic Bornong (307) 674-2685</td>
</tr>
<tr>
<td>Routt NF</td>
<td>December 14</td>
<td>Steamboat Springs, Colorado Supervisor's Office</td>
<td>6:30 to 8:30 p.m.</td>
<td>Denise Germann (970) 870-2214</td>
</tr>
<tr>
<td>Black Hills - Nebraska NFs</td>
<td>December 14</td>
<td>Rapid City, South Dakota Hotel Alex Johnson 523 6th Street</td>
<td>5:00 to 9:00 p.m.</td>
<td>Dennis Neill (605) 673-2251 ext. 3117</td>
</tr>
<tr>
<td>Nebraska NF</td>
<td>December 14</td>
<td>Chadron, Nebraska Supervisor's Office 125 North Main Street</td>
<td>7:00 to 9:00 p.m.</td>
<td>Jerry Schumacher (308) 432-0324</td>
</tr>
<tr>
<td>Nebraska NF</td>
<td>December 15</td>
<td>Grand Island, Nebraska Mid-Town Holiday Inn 2503 South Locust Street</td>
<td>7:00 to 9:00 p.m.</td>
<td>Jerry Schumacher (308) 432-0324</td>
</tr>
<tr>
<td>Medicine Bow NF</td>
<td>December 15</td>
<td>Laramie, Wyoming Holiday Inn</td>
<td>6:30 to 8:30 p.m.</td>
<td>Pat Harrison (307) 745-2378</td>
</tr>
<tr>
<td>Arapaho - Roosevelt NFs</td>
<td>December 15</td>
<td>Golden, Colorado Regional Office 740 Simms Street</td>
<td>4:30 to 7:30 p.m.</td>
<td>Karen Roth (970) 498-1100</td>
</tr>
<tr>
<td>Administrative Unit</td>
<td>Date (1999)</td>
<td>Meeting Location</td>
<td>Meeting Time</td>
<td>Contact Person</td>
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</tr>
<tr>
<td>Regional Office - Cibola NF</td>
<td>November 16</td>
<td>Albuquerque, New Mexico</td>
<td>4:00 to 7:00 p.m.</td>
<td>Vicky Estrada (505) 346-2650</td>
</tr>
<tr>
<td>Gila NF</td>
<td>December 13</td>
<td>Silver City, New Mexico Supervisor's Office</td>
<td>4:00 to 7:00 p.m.</td>
<td>Laura Browning (505) 388-8391</td>
</tr>
<tr>
<td>Coconino Kaibab NFs</td>
<td>December 13</td>
<td>Flagstaff, Arizona Supervisor's Office</td>
<td>4:00 to 7:00 p.m.</td>
<td>Roger Zanotto (520) 527-3440 or Bruce Higgins (520) 635-8210</td>
</tr>
<tr>
<td>Coronado NF</td>
<td>December 13</td>
<td>Tucson, Arizona</td>
<td>6:00 to 7:30 p.m.</td>
<td>Ron Senn (520) 679-4575</td>
</tr>
<tr>
<td>Santa Fe NF</td>
<td>December 14</td>
<td>Espanola, New Mexico</td>
<td>7:00 to 9:00 p.m.</td>
<td>Allen Fowler (505) 428-7821</td>
</tr>
<tr>
<td>Lincoln NF</td>
<td>December 14</td>
<td>Ruidoso, New Mexico</td>
<td>4:00 to 7:00 p.m.</td>
<td>Ron Hannon (505) 434-7200</td>
</tr>
<tr>
<td>Tonto NF</td>
<td>December 15</td>
<td>Phoenix, Arizona Embassy Suites 44th and McDowell</td>
<td>6:00 to 9:00 p.m.</td>
<td>Paul Stewart (602) 225-5200</td>
</tr>
<tr>
<td>Santa Fe - Carson NFs</td>
<td>December 15</td>
<td>Pecos, New Mexico</td>
<td>7:00 to 9:00 p.m.</td>
<td>Allen Fowler (505) 428-7821</td>
</tr>
<tr>
<td>Prescott NF</td>
<td>December 15</td>
<td>Prescott, Arizona</td>
<td>4:00 to 7:00 p.m.</td>
<td>Cynthia Moody (520) 527-4874</td>
</tr>
<tr>
<td>Lincoln NF</td>
<td>December 15</td>
<td>Cloudcroft, New Mexico</td>
<td>4:00 to 7:00 p.m.</td>
<td>Ron Hannon (505) 434-7200</td>
</tr>
<tr>
<td>Apache Sitgreaves NFs</td>
<td>December 16</td>
<td>Springerville, Arizona Supervisor's Office</td>
<td>6:30 to 8:30 p.m.</td>
<td>Jim Anderson (520) 333-6370</td>
</tr>
<tr>
<td>Administrative Unit</td>
<td>Date (1999)</td>
<td>Meeting Location</td>
<td>Meeting Time</td>
<td>Contact Person</td>
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</tr>
<tr>
<td>Wasatch Cache NFs</td>
<td>November 17</td>
<td>Salt Lake City, Utah&lt;br&gt;Salt Palace</td>
<td>6:00 to 9:00 p.m.</td>
<td>Michael Barry (801) 524-3900</td>
</tr>
<tr>
<td>Humboldt Toiyabe NFs</td>
<td>December 6</td>
<td>Las Vegas, Nevada&lt;br&gt;Sahara West Library&lt;br&gt;9500 West Sahara Avenue</td>
<td>6:00 to 8:00 p.m.</td>
<td>Rick Connell (775) 331-6444</td>
</tr>
<tr>
<td>Caribou Targhee NFs</td>
<td>December 6</td>
<td>Idaho Falls, Idaho&lt;br&gt;Idaho Falls Public Library</td>
<td>6:00 to 9:00 p.m.</td>
<td>Paul Oakes (208) 236-7500 or&lt;br&gt;Alan Silker (208) 624-3151</td>
</tr>
<tr>
<td>Salmon Challis NFs</td>
<td>December 6</td>
<td>Challis, Idaho</td>
<td>7:00 to 9:00 p.m.</td>
<td>Bob Russell or Pat Ulik (208) 756-5100</td>
</tr>
<tr>
<td>Manti LaSal NFs</td>
<td>December 7</td>
<td>Price, Utah</td>
<td>7:00 to 9:00 p.m.</td>
<td>Aaron Howe or Dave Hatfield (435) 637-2817</td>
</tr>
<tr>
<td>Ashley NF</td>
<td>December 7</td>
<td>Green River, Wyoming&lt;br&gt;Sweetwater County Building&lt;br&gt;80 West Flaming Gorge Way</td>
<td>12:00 to 3:00 p.m.</td>
<td>LauraJo West (435) 789-1181</td>
</tr>
<tr>
<td>Salmon Challis NFs</td>
<td>December 7</td>
<td>Arco, Idaho&lt;br&gt;Arco Business Incubation Center&lt;br&gt;159 North Idaho Avenue</td>
<td>7:00 to 9:00 p.m.</td>
<td>Bob Russell or Pat Ulik (208) 756-5100</td>
</tr>
<tr>
<td>Humboldt Toiyabe NFs</td>
<td>December 8</td>
<td>Reno, Nevada&lt;br&gt;Reno-Sparks Convention Center South Meeting Hall&lt;br&gt;4590 South Virginia Street</td>
<td>6:00 to 8:00 p.m.</td>
<td>Rick Connell (775) 331-6444</td>
</tr>
<tr>
<td>National Forest</td>
<td>Date</td>
<td>Location Information</td>
<td>Time</td>
<td>Contact Person and Phone Numbers</td>
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<tr>
<td>Humboldt-Toiyabe NFs</td>
<td>December 8</td>
<td>Reno, Nevada Galena High School Cafeteria 3600 Butch Cassidy Way</td>
<td>7:00 to 9:00 p.m.</td>
<td>Rick Connell (775) 355-5388</td>
</tr>
<tr>
<td>Fishlake NF</td>
<td>December 8</td>
<td>Richfield, Utah</td>
<td>7:00 to 9:00 p.m.</td>
<td>Linda Jackson (435) 896-9233</td>
</tr>
<tr>
<td>Humboldt Toiyabe NFs</td>
<td>December 9</td>
<td>Hadley, Nevada (between Austin and Tonopah on Highway 376) Hadley Community Center</td>
<td>6:30 to 8:30 p.m.</td>
<td>Rick Connell (775) 331-6444</td>
</tr>
<tr>
<td>Uinta NF</td>
<td>December 9</td>
<td>Provo, Utah</td>
<td>7:00 to 9:00 p.m.</td>
<td>Reese Pope (801) 342-5100</td>
</tr>
<tr>
<td>Salmon Challis NFs</td>
<td>December 9</td>
<td>Salmon, Idaho Supervisor's Office</td>
<td>7:00 to 9:00 p.m.</td>
<td>Bob Russell or Pat Ulik (208) 756-5100</td>
</tr>
<tr>
<td>Ashley NF</td>
<td>December 13</td>
<td>Duchesne, Utah Duchesne County Building</td>
<td>4:00 to 7:00 p.m.</td>
<td>LauraJo West (435) 789-1181</td>
</tr>
<tr>
<td>Boise NF</td>
<td>December 13</td>
<td>Boise, Idaho Owyhee Plaza Hotel 11th and Main Streets</td>
<td>6:00 to 8:00 p.m.</td>
<td>Jennifer Jones (208) 373-4105</td>
</tr>
<tr>
<td>Sawtooth NF</td>
<td>December 13</td>
<td>Twin Falls, Idaho College of Southern Idaho Taylor Administration Building Cedar Room Room 277 315 Falls Avenue</td>
<td>7:00 to 9:00 p.m.</td>
<td>Sharon LeBreque or Rob Daley (2080 737-3277</td>
</tr>
<tr>
<td>Ashley NF</td>
<td>December 14</td>
<td>Vernal, Utah Supervisor's Office 3555 North Vernal Avenue</td>
<td>4:30 to 6:30 p.m.</td>
<td>LauraJo West (435) 789-1181</td>
</tr>
<tr>
<td>Dixie NF</td>
<td>December 15</td>
<td>Cedar City, Utah</td>
<td>7:00 to 9:00 p.m.</td>
<td>Randy Hayman or Joe Reddan (435) 865-3700</td>
</tr>
<tr>
<td>Administrative Unit</td>
<td>Date (1999)</td>
<td>Meeting Location</td>
<td>Meeting Time</td>
<td>Contact Person</td>
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</tr>
<tr>
<td>Payette NF</td>
<td>December 15</td>
<td>McCall, Idaho Supervisor's Office</td>
<td>6:00 to 8:00 p.m.</td>
<td>Ralph Geibel (208) 634-0703</td>
</tr>
<tr>
<td>Bridger Teton NFs</td>
<td>December 15</td>
<td>Jackson, Wyoming Teton County Library</td>
<td>7:00 to 9:00 p.m.</td>
<td>Rick Anderson (307) 739-5558</td>
</tr>
<tr>
<td>Humboldt Toiyabe NFs</td>
<td>December 16</td>
<td>Elko, Nevada Great Basin Community College Greenhaw Technical Arts Building, Room 130</td>
<td>6:00 to 8:00 p.m.</td>
<td>Rick Connell (775) 331-6444</td>
</tr>
</tbody>
</table>

**Pacific Southwest Region (Region 5)**

<table>
<thead>
<tr>
<th>Administrative Unit</th>
<th>Date (1999)</th>
<th>Meeting Location</th>
<th>Meeting Time</th>
<th>Contact Person</th>
</tr>
</thead>
<tbody>
<tr>
<td>Plumas NF</td>
<td>November 30</td>
<td>Quincy, California Plumas County Library</td>
<td>7:00 to 9:00 p.m.</td>
<td>Lee Anne Schramel Taylor (530) 283-7850</td>
</tr>
<tr>
<td>Lake Tahoe Basin Management Unit</td>
<td>December 1</td>
<td>South Lake Tahoe, California South Lake Tahoe Library</td>
<td>7:00 to 9:00 p.m.</td>
<td>Linda Massey (530) 573-2688</td>
</tr>
<tr>
<td>Lassen NF</td>
<td>December 1</td>
<td>Susanville, California Supervisor's Office</td>
<td>7:00 to 9:00 p.m.</td>
<td>Barbara Massey (530) 252-6604</td>
</tr>
<tr>
<td>Plumas NF</td>
<td>December 1</td>
<td>Chico, California Pleasant Valley Recreation Center</td>
<td>7:00 to 9:00 p.m.</td>
<td>Lee Anne Schramel Taylor (530) 283-7850</td>
</tr>
<tr>
<td>Klamath NF</td>
<td>December 6</td>
<td>Yreka, California Miner's Inn</td>
<td>7:00 to 9:00 p.m.</td>
<td>Jon Silvius (530) 841-4485</td>
</tr>
<tr>
<td>Sierra NF</td>
<td>December 8</td>
<td>North Fork, California North Fork Town Hall</td>
<td>6:30 to 8:30 p.m.</td>
<td>Sue Exline (5590 297-0706 ext. 4804</td>
</tr>
<tr>
<td>Mendicino NF</td>
<td>December 7</td>
<td>Willows, California Supervisor's Office</td>
<td>6:30 to 8:30 p.m.</td>
<td>Phebe Brown (530) 934-3316</td>
</tr>
<tr>
<td>National Forest</td>
<td>Date</td>
<td>Location</td>
<td>Time</td>
<td>Contact Person</td>
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</tr>
<tr>
<td>Stanislaus NF</td>
<td>December 7</td>
<td>Sonora, California Supervisor's Office</td>
<td>7:00 to 8:30 p.m.</td>
<td>Beth Chacon (209) 532-3671 ext. 244</td>
</tr>
<tr>
<td>Los Padres NF</td>
<td>December 8</td>
<td>Santa Barbara, California Santa Barbara County Education Office</td>
<td>7:00 to 9:00 p.m.</td>
<td>Kathy Good (805) 681-2759</td>
</tr>
<tr>
<td>Sierra NF</td>
<td>December 8</td>
<td>Clovis, California Clovis, Memorial Building</td>
<td>6:30 to 8:30 p.m.</td>
<td>Sue Exline (559) 297-0706 ext. 4804</td>
</tr>
<tr>
<td>Mendocino NF</td>
<td>December 8</td>
<td>Ukiah, California Bureau of Land Management Conference Room</td>
<td>6:30 to 8:30 p.m.</td>
<td>Phebe Brown (530) 934-3316</td>
</tr>
<tr>
<td>Los Padres NF</td>
<td>December 9</td>
<td>San Luis Obispo, California Veteran's Hall</td>
<td>7:00 to 9:00 p.m.</td>
<td>Kathy Good (805) 681-2759</td>
</tr>
<tr>
<td>Tahoe NF</td>
<td>December 9</td>
<td>Nevada City, California Nevada County Superintendent of Schools Office</td>
<td>7:00 to 9:00 p.m.</td>
<td>Ann Westling (530) 478-6205</td>
</tr>
<tr>
<td>Eldorado NF</td>
<td>December 14</td>
<td>Placerville, California</td>
<td>7:00 to 9:00 p.m.</td>
<td>Frank Mosbacher (530) 621-5268</td>
</tr>
<tr>
<td>Modoc NF</td>
<td>December 14</td>
<td>Alturas, California Supervisor's Office</td>
<td>2:00 to 3:30 p.m.</td>
<td>Nancy Gardner (530) 233-8713</td>
</tr>
<tr>
<td>Modoc NF</td>
<td>December 14</td>
<td>Alturas, California Supervisor's Office</td>
<td>5:30 to 7:00 p.m.</td>
<td>Nancy Gardner (530) 233-8713</td>
</tr>
<tr>
<td>Sequoia NF</td>
<td>December 14</td>
<td>Porterville, California Supervisor's Office</td>
<td>5:00 to 6:30 p.m.</td>
<td>Julie Allen (559) 784-1500 ext. 1160</td>
</tr>
<tr>
<td>Park Name</td>
<td>Date</td>
<td>Location</td>
<td>Time</td>
<td>Contact Details</td>
</tr>
<tr>
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<tr>
<td>Shasta Trinity NFs</td>
<td>December 14</td>
<td>Redding, California Holiday Inn</td>
<td>7:00 to 9:00 p.m.</td>
<td>Duane Lyon (530) 242-2207 or Bob Ramirez (530) 242-2322</td>
</tr>
<tr>
<td>Six Rivers NF</td>
<td>December 14</td>
<td>Eureka, California Supervisor's Office</td>
<td>7:00 to 9:00 p.m.</td>
<td>Bill Pidanick (707) 441-3673</td>
</tr>
<tr>
<td>Cleveland NF</td>
<td>December 15</td>
<td>San Diego, California Supervisor's Office</td>
<td>7:00 to 8:30 p.m.</td>
<td>Joan Wynn (619) 674-2984</td>
</tr>
<tr>
<td>Inyo NF</td>
<td>December 15</td>
<td>Bishop, California Our Lady of Perpetual Help Catholic Church</td>
<td>6:30 to 8:30 p.m.</td>
<td>Nancy Upham (760) 873-2427</td>
</tr>
<tr>
<td>San Bernardino NF</td>
<td>December 15</td>
<td>San Bernardino, California San Bernardino County Government Center Council Room</td>
<td>7:00 to 9:00 p.m.</td>
<td>Ruth Wenstrom (909) 884-6634 ext. 3130</td>
</tr>
<tr>
<td>Sequoia NF</td>
<td>December 15</td>
<td>Lake Isabella, California Lake Isabella Veteran's Hall</td>
<td>5:00 to 6:30 p.m.</td>
<td>Julie Allen (559) 784-1500 ext. 1160</td>
</tr>
<tr>
<td>Angeles NF</td>
<td>December 16</td>
<td>Glendora, California Glendora Public Library</td>
<td>2:30 to 5:00 p.m.</td>
<td>Gail Wright (626) 574-5205 or Randi Jorgensen (626) 574-5206</td>
</tr>
<tr>
<td>Angeles NF</td>
<td>December 16</td>
<td>Glendora, California Glendora Public Library</td>
<td>7:00 to 9:30 p.m.</td>
<td>Gail Wright (626) 574-5205 or Randi Jorgensen (626) 574-5206</td>
</tr>
<tr>
<td>Inyo NF</td>
<td>December 16</td>
<td>Mammoth, California Mammoth Lakes Visitor Center</td>
<td>6:30 to 8:30 p.m.</td>
<td>Nancy Upham (760) 873-2427</td>
</tr>
<tr>
<td>San Bernardino NF</td>
<td>December 16</td>
<td>Hemet, California James Simpson Center</td>
<td>7:00 to 9:00 p.m.</td>
<td>Ruth Wenstrom (909) 884-6634 ext. 3130</td>
</tr>
<tr>
<td>Administrative Unit</td>
<td>Date (1999)</td>
<td>Meeting Location</td>
<td>Meeting Time</td>
<td>Contact Person</td>
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<tr>
<td>Willamette NF</td>
<td>November 29</td>
<td>Oakridge, Oregon Middle Fork Ranger District</td>
<td>6:30 to 8:30 p.m.</td>
<td>Sue Olson (541) 465-6539 or Julie Cox (541) 465-6524</td>
</tr>
<tr>
<td>Gifford Pinchot NF</td>
<td>November 30</td>
<td>Portland, Oregon Oregon Convention Center 777 Northeast Martin Luther King, Jr. Boulevard</td>
<td>5:00 to 8:30 p.m.</td>
<td>Tom Knappenberger (360) 891-5005</td>
</tr>
<tr>
<td>Willamette NF</td>
<td>November 30</td>
<td>McKenzie Bridge, Oregon McKenzie School District Office</td>
<td>6:30 to 8:30 p.m.</td>
<td>Sue Olson (541) 465-6539 or Julie Cox (541) 465-6524</td>
</tr>
<tr>
<td>Regional Office</td>
<td>November 30</td>
<td>Portland, Oregon Oregon Convention Center</td>
<td>5:00 to 8:00 p.m.</td>
<td>Mary Marrs (541) 858-2211 or (541) 471-6515</td>
</tr>
<tr>
<td>Willamette NF</td>
<td>December 1</td>
<td>Sweet Home, Oregon Sweet Home Ranger District</td>
<td>6:30 to 8:30 p.m.</td>
<td>Sue Olson (541) 465-6539 or Julie Cox (541) 465-6524</td>
</tr>
<tr>
<td>Siskiyou NF</td>
<td>December 2</td>
<td>Coos Bay, Oregon Coos Bay Public Library Main Meeting Room 525 Anderson</td>
<td>6:00 to 9:00 p.m.</td>
<td>Mary Marrs (541) 471-6515</td>
</tr>
<tr>
<td>Willamette Siuslaw NFs</td>
<td>December 2</td>
<td>Eugene, Oregon Eugene Water and Electric Board</td>
<td>6:30 to 8:30 p.m.</td>
<td>Sue Olson (541) 465-6539 or Julie Cox (541) 465-6524</td>
</tr>
<tr>
<td>Location</td>
<td>Date</td>
<td>Event Details</td>
<td>Time</td>
<td>Contact Details</td>
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<tr>
<td>Malheur NF</td>
<td>December 6</td>
<td>John Day, Oregon Forest Service Office</td>
<td>5:00 to 8:00 p.m.</td>
<td>Sharon Sweeney (541) 575-3144</td>
</tr>
<tr>
<td>Siuslaw NF</td>
<td>December 6</td>
<td>Florence, Oregon Florence Events Center</td>
<td>6:30 to 8:30 p.m.</td>
<td>Joni Quarnstrom (541) 750-7075</td>
</tr>
<tr>
<td>Winema NF</td>
<td>December 6</td>
<td>Klamath Falls, Oregon Supervisor’s Office</td>
<td>6:30 to 7:30 p.m.</td>
<td>Frank Erickson (541) 883-6715</td>
</tr>
<tr>
<td>Winema NF</td>
<td>December 6</td>
<td>Klamath Falls, Oregon Supervisor’s Office</td>
<td>7:30 to 8:30 p.m.</td>
<td>Frank Erickson (541) 883-6715</td>
</tr>
<tr>
<td>Fremont NF</td>
<td>December 7</td>
<td>Lakeview, Oregon Fremont NF/Lakeview Bureau</td>
<td>6:30 to 8:30 p.m.</td>
<td>Lisa Swinney (541) 947-6261</td>
</tr>
<tr>
<td>Ochoco NF</td>
<td>December 7</td>
<td>Prineville, Oregon Supervisor’s Office</td>
<td>7:00 to 9:00 p.m.</td>
<td>Bill Rice (541) 416-6647</td>
</tr>
<tr>
<td>Wenatchee Okanogan NFs</td>
<td>December 7</td>
<td>Wenatchee, Washington Supervisor’s Office</td>
<td>2:00 to 4:00 p.m.</td>
<td>Paul Hart (509) 662-4314</td>
</tr>
<tr>
<td>Wenatchee Okanogan NFs</td>
<td>December 7</td>
<td>Wenatchee, Washington Supervisor’s Office</td>
<td>4:00 to 6:00 p.m.</td>
<td>Paul Hart (509) 662-4314</td>
</tr>
<tr>
<td>Wenatchee Okanogan NFs</td>
<td>December 7</td>
<td>Wenatchee, Washington Supervisor’s Office</td>
<td>6:30 to 8:30 p.m.</td>
<td>Paul Hart (509) 662-4314</td>
</tr>
<tr>
<td>Willamette Siuslaw NFs</td>
<td>December 7</td>
<td>Salem, Oregon Salem Bureau of Land Management Office</td>
<td>6:30 to 8:30 p.m.</td>
<td>Sue Olson (541) 465-6539 or Julie Cox (541) 465-6524</td>
</tr>
<tr>
<td>Location</td>
<td>Date</td>
<td>Time</td>
<td>Location Details</td>
<td>Contact Person</td>
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</tr>
</tbody>
</table>
| Colville NF                   | December 8 | 6:00 to 9:00 p.m. | Spokane, Washington  
Spokane City Hall  
808 West Spokane  
Falls Boulevard          | Cynthia Reichelt  
(509) 684-7187    |                       |
| Mount Hood NF                 | December 8 | 1:00 to 3:00 p.m. | Sandy, Oregon  
Mount Hood NF  
Headquarters  
16400 Champion Way | Glen Sachet  
(503) 668-1791    |                       |
| Colville NF                   | December 9 | 6:00 to 9:00 p.m. | Colville, Washington  
Supervisor’s Office  
765 South Main Street | Ron DeHart  
(425) 744-3573    |                       |
| Wallowa Whitman NFs           | December 9 | 5:00 to 8:00 p.m. | Enterprise, Oregon  
Clover Leaf Hall | John Denne  
(541) 523-1246    |                       |
| Wenatchee Okanogan NFs        | December 9 | 2:00 to 4:00 p.m. | Okanogan, Washington  
Cedar’s Motor Inn | Paul Hart  
(509) 662-4314    |                       |
| Wenatchee Okanogan NFs        | December 9 | 4:00 to 6:00 p.m. | Okanogan, Washington  
Cedar’s Motor Inn | Paul Hart  
(509) 662-4314    |                       |
| Wenatchee Okanogan NFs        | December 9 | 6:30 to 8:30 p.m. | Okanogan, Washington  
Cedar’s Motor Inn | Paul Hart  
(509) 662-4314    |                       |
| Malheur NF                    | December 13| 5:00 to 8:00 p.m. | Burns, Oregon  
Senior Center             | Sharon Sweeney  
(541) 575-3144    |                       |
| Umatilla NF                   | December 13| 7:00 to 9:00 p.m. | Pendleton, Oregon  
Supervisor’s Office  
2517 Southwest Hailey Avenue | Earle Rother  
(541) 278-3734    |                       |
| Willamette Siuslaw NFs        | December 13| 6:30 to 8:30 p.m. | Corvallis, Oregon  
Supervisor’s Office | Sue Olson  
(541) 465-6539  
or Julie Cox  
(541) 465-6524    |                       |
| Umpqua NF                     | December 14| 3:30 to 7:30 p.m. | Roseburg, Oregon  
Douglas County Library | Cheryl Walters  
(541) 957-3259    |                       |
| Wenatchee Okanogan NFs        | December 14| 2:00 to 4:00 p.m. | Yakima, Washington  
Cavanaugh’s Gateway  
9 North 9th Street | Paul Hart  
(509) 662-4314    |                       |
<table>
<thead>
<tr>
<th>Wenatchee Okanogan NFs</th>
<th>December 14</th>
<th>Yakima, Washington Cavanaugh s Gateway 9 North 9th Street</th>
<th>4:00 to 6:00 p.m.</th>
<th>Paul Hart (509) 662-4314</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wenatchee Okanogan NFs</td>
<td>December 14</td>
<td>Yakima, Washington Cavanaugh s Gateway 9 North 9th Street</td>
<td>6:30 to 8:30 p.m.</td>
<td>Paul Hart (509) 662-4314</td>
</tr>
<tr>
<td>Mount Baker Snoqualmie NFs</td>
<td>December 15</td>
<td>Sedro-Woolley, Washington Mount Baker Ranger District 2105 Highway 20</td>
<td>3:30 to 5:30 p.m.</td>
<td>Ron DeHart (425) 744-3573</td>
</tr>
<tr>
<td>Mount Baker Snoqualmie NFs</td>
<td>December 15</td>
<td>Sedro-Woolley, Washington Mount Baker Ranger District 2105 Highway 20</td>
<td>6:30 to 8:30 p.m.</td>
<td>Ron DeHart (425) 744-3573</td>
</tr>
<tr>
<td>Umpqua NF</td>
<td>December 15</td>
<td>Cottage Grove, Oregon Cottage Grove Ranger District</td>
<td>7:00 to 8:30 p.m.</td>
<td>Cheryl Walters (541) 957-3259</td>
</tr>
<tr>
<td>Wallowa Whitman NFs</td>
<td>December 15</td>
<td>Baker City, Oregon Baker Ranger District</td>
<td>5:00 to 8:00 p.m.</td>
<td>John Denne (541) 523-1246</td>
</tr>
<tr>
<td>Deschutes NF</td>
<td>December 16</td>
<td>Bend, Oregon Bend National Guard Armory</td>
<td>6:00 to 9:00 p.m.</td>
<td>Terri Gates (541) 383-5561</td>
</tr>
<tr>
<td>Mount Baker Snoqualmie NFs</td>
<td>December 16</td>
<td>Moutlake Terrace, Washington Supervisor s Office 21905 64th Avenue</td>
<td>3:30 to 5:30 p.m.</td>
<td>Ron DeHart (425) 744-3573</td>
</tr>
<tr>
<td>Mount Baker Snoqualmie NFs</td>
<td>December 16</td>
<td>Moutlake Terrace, Washington Supervisor s Office 21905 64th Avenue</td>
<td>6:30 to 8:30 p.m.</td>
<td>Ron DeHart (425) 744-3573</td>
</tr>
<tr>
<td>Olympic Gifford Pinchot NFs</td>
<td>December 16</td>
<td>Olympia, Washington Supervisor s Office 1835 Black Lake Boulevard</td>
<td>7:00 to 9:00 p.m.</td>
<td>Ken Eldredge (360) 956-2323</td>
</tr>
<tr>
<td>Rogue Siskiyou NFs</td>
<td>December 16</td>
<td>Medford, Oregon Rogue Regency Inn2345 Crater Lake Highway</td>
<td>6:00 to 9:00 p.m.</td>
<td>Mary Marrs (541) 471-6515</td>
</tr>
<tr>
<td>Wenatchee Okanogan NFs</td>
<td>December 16</td>
<td>Ellensburg, Washington Hal Holmes Center</td>
<td>2:00 to 4:00 p.m.</td>
<td>Paul Hart (509) 662-4314</td>
</tr>
<tr>
<td>Administrative Unit</td>
<td>Date (1999)</td>
<td>Meeting Location</td>
<td>Meeting Time</td>
<td>Contact Person</td>
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</tr>
<tr>
<td>Regional Office</td>
<td>November 30</td>
<td>Atlanta, Georgia Georgia International Convention Center 1902 Sullivan Road</td>
<td>6:30 to 9:30 p.m.</td>
<td>Bob Wilhelm (404) 347-5401</td>
</tr>
<tr>
<td>NFs in Alabama</td>
<td>December 7</td>
<td>Andalusia, Alabama</td>
<td>5:00 to 7:00 p.m.</td>
<td>Rick Morgan (334) 832-4470</td>
</tr>
<tr>
<td>NFs in Alabama</td>
<td>December 7</td>
<td>Brent, Alabama</td>
<td>5:00 to 7:00 p.m.</td>
<td>Rick Morgan (334) 832-4470</td>
</tr>
<tr>
<td>NFs in Alabama</td>
<td>December 7</td>
<td>Heflin, Alabama</td>
<td>5:00 to 7:00 p.m.</td>
<td>Rick Morgan (334) 832-4470</td>
</tr>
<tr>
<td>NFs in Alabama</td>
<td>December 7</td>
<td>Talladega, Alabama</td>
<td>5:00 to 7:00 p.m.</td>
<td>Rick Morgan (334) 832-4470</td>
</tr>
<tr>
<td>NFs in Alabama</td>
<td>December 7</td>
<td>Tuskegee, Alabama</td>
<td>5:00 to 7:00 p.m.</td>
<td>Rick Morgan (334) 832-4470</td>
</tr>
<tr>
<td>NFs in Alabama</td>
<td>December 7</td>
<td>Double Springs, Alabama</td>
<td>5:00 to 7:00 p.m.</td>
<td>Rick Morgan (334) 832-4470</td>
</tr>
<tr>
<td>NFs in Florida</td>
<td>December 8</td>
<td>Gainesville, Florida Sheraton Hotel 2900 Southwest 13 Street</td>
<td>6:00 to 8:00 p.m.</td>
<td>Richard Sheller (904) 942-9300</td>
</tr>
<tr>
<td>Caribbean NF</td>
<td>December 8</td>
<td>Caribbean National Forest, Catalina Service Center</td>
<td>5:00 to 8:00 p.m.</td>
<td>Ricardo Garcia (787) 888-1810</td>
</tr>
<tr>
<td>Cherokee NF</td>
<td>December 9</td>
<td>Cleveland, Tennessee Cleveland Community College</td>
<td>1:00 to 3:00 p.m.</td>
<td>Keith Sandifer (423) 576-9700</td>
</tr>
<tr>
<td>Cherokee NF</td>
<td>December 9</td>
<td>Cleveland, Tennessee Cleveland Community College</td>
<td>7:00 to 9:00 p.m.</td>
<td>Keith Sandifer (423) 576-9700</td>
</tr>
<tr>
<td>Location</td>
<td>Date</td>
<td>Time</td>
<td>Contact Information</td>
<td></td>
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</tr>
<tr>
<td>Chattahoochee Oconee NFs</td>
<td>December 13</td>
<td>6:00 to 8:00 p.m.</td>
<td>John Petrick (770) 536-0541</td>
<td></td>
</tr>
<tr>
<td>Ouachita NF</td>
<td>December 13</td>
<td>6:30 to 8:00 p.m.</td>
<td>Steve Cannell (501) 321-5202</td>
<td></td>
</tr>
<tr>
<td>Daniel Boone NF</td>
<td>December 13</td>
<td>4:00 to 5:30 p.m.</td>
<td>Kevin Lawrence (606) 745-3100</td>
<td></td>
</tr>
<tr>
<td>Daniel Boone NF</td>
<td>December 13</td>
<td>7:00 to 8:30 p.m.</td>
<td>Kevin Lawrence (606) 745-3100</td>
<td></td>
</tr>
<tr>
<td>George Washington Jefferson NFs</td>
<td>December 14</td>
<td>6:30 to 8:00 p.m.</td>
<td>Ken Landgraf (540) 265-5100</td>
<td></td>
</tr>
<tr>
<td>NFs in North Carolina</td>
<td>December 14</td>
<td>6:00 to 8:00 p.m.</td>
<td>Larry Hayden (704) 257-4200</td>
<td></td>
</tr>
<tr>
<td>Ozark Saint Francis NFs</td>
<td>December 14</td>
<td>6:00 to 8:00 p.m.</td>
<td>Deryl Jevons (501) 968-2354</td>
<td></td>
</tr>
<tr>
<td>Francis Marion Sumter NFs</td>
<td>December 14</td>
<td>6:00 to 8:00 p.m.</td>
<td>Robin Cooper (803) 561-4000</td>
<td></td>
</tr>
<tr>
<td>Ouachita NF</td>
<td>December 16</td>
<td>6:30 to 8:00 p.m.</td>
<td>Steve Cannell (501) 321-5202</td>
<td></td>
</tr>
<tr>
<td>NFs in Texas</td>
<td>December 16</td>
<td>7:00 to 8:30 p.m.</td>
<td>Betty Miner (409) 639-8501</td>
<td></td>
</tr>
<tr>
<td>NFs in Mississippi</td>
<td>December 16</td>
<td>3:00 to 4:30 p.m.</td>
<td>Jeff Long (601) 965-4931 ext. 149</td>
<td></td>
</tr>
<tr>
<td>NFs in Mississippi</td>
<td>December 16</td>
<td>5:30 to 7:00 p.m.</td>
<td>Jeff Long (601) 965-4931 ext. 149</td>
<td></td>
</tr>
<tr>
<td>Ozark Saint Francis NFs</td>
<td>December 16</td>
<td>6:00 to 8:00 p.m.</td>
<td>Deryl Jevons (501) 968-2354</td>
<td></td>
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</table>
## Eastern Region (Region 9)

<table>
<thead>
<tr>
<th>Administrative Unit</th>
<th>Date (1999)</th>
<th>Meeting Location</th>
<th>Meeting Time</th>
<th>Contact Person</th>
</tr>
</thead>
<tbody>
<tr>
<td>Regional Office</td>
<td>November 16</td>
<td>Milwaukee, Wisconsin University of Wisconsin</td>
<td>5:30 to 9:00 p.m.</td>
<td>Tom Malecek (603) 536-1869</td>
</tr>
<tr>
<td>Chippewa Superior NFs</td>
<td>November 22</td>
<td>Grand Rapids, Minnesota</td>
<td>1:00 to 4:00 p.m.</td>
<td>Denise Dexter (218) 626-4300</td>
</tr>
<tr>
<td>Chippewa Superior NFs</td>
<td>November 22</td>
<td>Bloomington, Minnesota</td>
<td>6:00 to 9:00 p.m.</td>
<td>Denise Dexter (218) 626-4300</td>
</tr>
<tr>
<td>Wayne NF</td>
<td>December 2</td>
<td>Athens, Ohio University Inn</td>
<td>7:00 to 9:00 p.m.</td>
<td>Bob Gianniny (740) 534-6500</td>
</tr>
<tr>
<td>Mark Twain NF</td>
<td>December 3</td>
<td>Rolla, Minnesota University of Minnesota - Rolla</td>
<td>7:00 to 8:30 p.m.</td>
<td>Laura Watts (573) 341-7471</td>
</tr>
<tr>
<td>Monongahela NF</td>
<td>December 4</td>
<td>Seneca Rocks, West Virginia Seneca Rocks Visitor Center</td>
<td>10:30 a.m. to 1:30 p.m.</td>
<td>Richard Cook (304) 636-1800</td>
</tr>
<tr>
<td>Mark Twain NF</td>
<td>December 4</td>
<td>Rolla, Minnesota University of Minnesota - Rolla</td>
<td>12:00 to 1:30 p.m.</td>
<td>Laura Watts (573) 341-7471</td>
</tr>
<tr>
<td>Midewin Tallgrass Prairie NG</td>
<td>December 6</td>
<td>Wilminton, Illinois Midewin Administrative Site</td>
<td>5:00 to 7:00 p.m.</td>
<td>Marta Witt (815) 423-6370</td>
</tr>
<tr>
<td>Chequamegon Nicolet NFs</td>
<td>December 6</td>
<td>Crandon, Wisconsin Crandon High School</td>
<td>6:00 to 9:00 p.m.</td>
<td>Mike Miller (715) 362-1343</td>
</tr>
<tr>
<td>Chequamegon Nicolet NFs</td>
<td>December 7</td>
<td>Park Falls, Wisconsin Park Falls Library</td>
<td>6:00 to 9:00 p.m.</td>
<td>Mike Miller (715) 362-1343</td>
</tr>
<tr>
<td>Allegheny NF</td>
<td>December 7</td>
<td>Warren, Pennsylvania Warren Public Library</td>
<td>7:00 to 9:00 p.m.</td>
<td>Gary Kell (814) 723-5150</td>
</tr>
<tr>
<td>Hoosier NF</td>
<td>December 9</td>
<td>Martinsville, Indiana</td>
<td>6:00 to 8:00 p.m.</td>
<td>Regis Terney (812) 275-5987</td>
</tr>
<tr>
<td>Hoosier NF</td>
<td>December 9</td>
<td>Troy, Indiana</td>
<td>6:00 to 8:00 p.m.</td>
<td>Regis Terney (812) 275-5987</td>
</tr>
<tr>
<td>Ottawa NF</td>
<td>December 13</td>
<td>Ewen, Michigan</td>
<td>5:00 to 7:00 p.m.</td>
<td>Bob Brenner (906) 932-1330</td>
</tr>
<tr>
<td>Administrative Unit</td>
<td>Date (1999)</td>
<td>Meeting Location</td>
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<td>Contact Person</td>
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</tr>
<tr>
<td>White Mountain NF</td>
<td>December 15</td>
<td>Concord, New Hampshire Holiday Inn Motel</td>
<td>6:30 to 8:30 p.m.</td>
<td>Wayne Millen (603) 466-2713</td>
</tr>
<tr>
<td>Green Mountain Finger Lakes NFs</td>
<td>December 15</td>
<td>Rutland, Vermont Howe Center</td>
<td>6:30 to 9:00 p.m.</td>
<td>Rob Clark (802) 362-2307</td>
</tr>
<tr>
<td>White Mountain NF</td>
<td>December 15</td>
<td>Gorham, New Hampshire Town and Country Motel Inn</td>
<td>6:30 to 8:30 p.m.</td>
<td>Wayne Millen (802) 466-2713</td>
</tr>
<tr>
<td>Hiawatha NF</td>
<td>December 16</td>
<td>Manistique, Michigan Manistique High School</td>
<td>4:00 to 8:00 p.m.</td>
<td>Dave Maercklein (906) 789-3301</td>
</tr>
<tr>
<td>Huron Manistee NFs</td>
<td>December 16</td>
<td>Cadillac, Michigan Bill Oliver Best Western Motel</td>
<td>6:00 to 9:00 p.m.</td>
<td>Jim Dimaio (231) 775-2421</td>
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**Alaska Region (Region 10)**

<table>
<thead>
<tr>
<th>Administrative Unit</th>
<th>Date (1999)</th>
<th>Meeting Location</th>
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<th>Contact Person</th>
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</thead>
<tbody>
<tr>
<td>Tongass NF</td>
<td>December 1</td>
<td>Thorne Bay, Alaska Bay Chalet</td>
<td>6:30 to 8:30 p.m.</td>
<td>(907) 828-3304 or John Sherrod (907) 747-4329</td>
</tr>
<tr>
<td>Tongass NF</td>
<td>December 1</td>
<td>Petersburg, Alaska City Council Chambers</td>
<td>6:30 to 8:30 p.m.</td>
<td>(907) 772-5900 or John Sherrod (907) 747-4329</td>
</tr>
<tr>
<td>Tongass NF</td>
<td>December 2</td>
<td>Kake, Alaska Kake Community Hall</td>
<td>4:00 to 7:00 p.m.</td>
<td>(907) 772-5949 or John Sherrod (907) 747-4329</td>
</tr>
<tr>
<td>Tongass NF</td>
<td>December 2</td>
<td>Sitka, Alaska Harrigan Centennial Building</td>
<td>6:00 to 8:00 p.m.</td>
<td>(907) 747-4218 or John Sherrod (907) 747-4329</td>
</tr>
<tr>
<td>National Forest</td>
<td>Date</td>
<td>Location &amp; Contact Information</td>
<td>Time</td>
<td>Contact Information</td>
</tr>
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</tr>
<tr>
<td>Tongass NF</td>
<td>December 2</td>
<td>Wrangell, Alaska Wranger Ranger District</td>
<td>4:00 to 8:00 p.m.</td>
<td>(907) 874-7556 or John Sherrod (907) 747-4329</td>
</tr>
<tr>
<td>Tongass NF</td>
<td>December 2</td>
<td>Ketchikan, Alaska SHEAVC</td>
<td>7:00 to 9:00 p.m.</td>
<td>(907) 228-4114 or John Sherrod (907) 747-4329</td>
</tr>
<tr>
<td>Chugach NF</td>
<td>December 2</td>
<td>Anchorage, Alaska University Conference Center 3700 Sharon Gagon Lane</td>
<td>6:00 to 8:00 p.m.</td>
<td>Chuck Fry (907) 271-2508</td>
</tr>
<tr>
<td>Chugach NF</td>
<td>December 2</td>
<td>Cordova, Alaska Cordova Ranger District</td>
<td>6:00 to 8:00 p.m.</td>
<td>Chuck Fry (907) 424-7661</td>
</tr>
<tr>
<td>Chugach NF</td>
<td>December 6</td>
<td>Girdwood, Alaska Glacier Ranger District</td>
<td>6:00 to 8:00 p.m.</td>
<td>Chuck Fry (907) 783-3242</td>
</tr>
<tr>
<td>Tongass NF</td>
<td>December 7</td>
<td>Hoonah, Alaska Hoonah Ranger District</td>
<td>4:00 to 6:00 p.m.</td>
<td>(907) 945-3631 or John Sherrod (907) 747-4329</td>
</tr>
<tr>
<td>Chugach NF</td>
<td>December 7</td>
<td>Seward, Alaska Seward Ranger District</td>
<td>6:00 to 8:00 p.m.</td>
<td>Chuck Fry (907) 224-3374</td>
</tr>
<tr>
<td>Tongass NF</td>
<td>December 9</td>
<td>Craig, Alaska City Council Chanbers</td>
<td>7:00 to 9:00 p.m.</td>
<td>(907) 826-1641 or John Sherrod (907) 747-4329</td>
</tr>
<tr>
<td>Tongass NF</td>
<td>December 9</td>
<td>Yakutat, Alaska Yakutat District Office</td>
<td>1:00 to 3:00 p.m.</td>
<td>(907) 784-3359 or John Sherrod (907) 747-4329</td>
</tr>
</tbody>
</table>
COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List, Additions and Deletions

AGENCY: Committee for Purchase From People Who Are Blind or Severely Disabled

ACTION: Additions to and Deletions from the Procurement List

SUMMARY: This action adds to the Procurement List a commodity and services to be furnished by nonprofit agencies employing persons who are blind or have other severe disabilities, and deletes from the Procurement List commodities and a service previously furnished by such agencies.


ADDRESSES: Committee for Purchase From People Who Are Blind or Severely Disabled, Crystal Gateway 3, Suite 310, 1215 Jefferson Davis Highway, Arlington, Virginia 22202–4302.

FOR FURTHER INFORMATION CONTACT: Beverly Milkman (703) 603–7740.

SUPPLEMENTARY INFORMATION: On September 24, and October 22, 1999, the Committee for Purchase From People Who Are Blind or Severely Disabled published notices (64 F.R. 51736, 57031 and 57032) of proposed additions to and deletions from the Procurement List:

Additions

After consideration of the material presented to it concerning capability of qualified nonprofit agencies to provide the commodity and services to be furnished by nonprofit agencies employing persons who are blind or have other severe disabilities, and deletes from the Procurement List commodities and a service previously furnished by such agencies.

2. The action will not have a severe economic impact on current contractors for the commodity and services. 3. The action will result in authorizing small entities to furnish the commodity and services to the Government.

4. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O’Day Act (41 U.S.C. 46–48c) in connection with the commodity and services proposed for addition to the Procurement List.

Accordingly, the following commodity and services are hereby added to the Procurement List:

<table>
<thead>
<tr>
<th>Commodity</th>
<th>Services</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Line, Multi-Loop</td>
<td>Grounds Maintenance</td>
<td>Southern Maryland District Courthouse, 6500 Cherrywood Lane, Greenbelt, Maryland</td>
</tr>
<tr>
<td>Grounds Maintenance</td>
<td>Janitorial/grounds</td>
<td>Evo DeConcini Federal Courthouse, 405 West Congress Street, Tucson, Arizona</td>
</tr>
<tr>
<td>Marker, Tube Type, Broad Tip</td>
<td>Meal Kits</td>
<td>(100% of the requirement of the USPFO for Louisiana, New Orleans, Louisiana)</td>
</tr>
<tr>
<td>Meal Kits</td>
<td></td>
<td>(100% of the requirement of the Oklahoma Air National Guard)</td>
</tr>
<tr>
<td>1670–01–062–6310</td>
<td>8970–01–E59–0240C</td>
<td></td>
</tr>
<tr>
<td>1670–01–062–6310</td>
<td>8970–01–E59–0241C</td>
<td></td>
</tr>
<tr>
<td>1670–01–062–6310</td>
<td>8970–01–E59–0242C</td>
<td></td>
</tr>
</tbody>
</table>

Deletions

I certify that the following action will not have a significant impact on a substantial number of small entities.

1. The action will not result in any additional reporting, recordkeeping or other compliance requirements for small entities.

3. The action will not have a severe economic impact on future contractors for the commodity and services.

4. The action may result in authorizing small entities to furnish the commodity and services to the Government.

Accordingly, the following commodity and services are hereby deleted from the Procurement List:

<table>
<thead>
<tr>
<th>Commodities</th>
<th>Services</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Marker, Tube Type, Broad Tip</td>
<td>Meal Kits</td>
<td>(100% of the requirement of the Oklahoma Air National Guard)</td>
</tr>
<tr>
<td>7520–01–424–4880</td>
<td>8970–01–E59–0240C</td>
<td></td>
</tr>
<tr>
<td>7520–01–424–4849</td>
<td>8970–01–E59–0241C</td>
<td></td>
</tr>
</tbody>
</table>
The following commodities have been proposed for deletion from the Procurement List:

<table>
<thead>
<tr>
<th>Commodity</th>
<th>UNS Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>Filter, Air Conditioning</td>
<td>4130-00-870-0696</td>
</tr>
<tr>
<td>4130-00-720-4143</td>
<td></td>
</tr>
<tr>
<td>4130-00-542-4482</td>
<td></td>
</tr>
<tr>
<td>4130-00-756-0978</td>
<td></td>
</tr>
<tr>
<td>4130-00-541-3220</td>
<td></td>
</tr>
<tr>
<td>4130-00-203-3318</td>
<td></td>
</tr>
<tr>
<td>4130-00-959-4734</td>
<td></td>
</tr>
<tr>
<td>4130-00-274-7800</td>
<td></td>
</tr>
<tr>
<td>4130-00-249-0966</td>
<td></td>
</tr>
<tr>
<td>4130-00-756-1840</td>
<td></td>
</tr>
<tr>
<td>4130-00-203-3321</td>
<td></td>
</tr>
<tr>
<td>Pen Set, Desk</td>
<td></td>
</tr>
<tr>
<td>7520-00-106-9840</td>
<td></td>
</tr>
</tbody>
</table>

Beverly L. Milkman,
Executive Director.

[FR Doc. 99-31408 Filed 12-2-99; 8:45 am]
BILLING CODE 6353-01-P

DEPARTMENT OF COMMERCE
Economics and Statistics Administration

2000 Census Advisory Committee

AGENCY: Economics and Statistics Administration, Department of Commerce.

ACTION: Request for nominations of member organizations to serve on the 2000 Census Advisory Committee.

SUMMARY: Pursuant to the Federal Advisory Committee Act (Pub. L. 92–463, as amended by Pub. L. 94–409, Pub. L. 96–523, Pub. L. 97–375, and Pub. L. 105–153), the U.S. Census Bureau invites and requests nominations of organizations for appointment by the Secretary of Commerce to the 2000 Census Advisory Committee (hereinafter referred to as the “Advisory Committee”). Nominations received in response to this notice for appointment to the Advisory Committee will be considered in addition to nominations already received. The Advisory Committee reports to the Secretary of Commerce. The notice’s SUPPLEMENTARY INFORMATION section provides information about the objectives and duties of the Advisory Committee and membership criteria.

DATES: Please submit nominations on or before December 20, 1999.

ADDRESSES: Please submit nominations to Nampeo R. McKenney, Senior Research and Technical Advisor, Department of Commerce, Bureau of the Census, Room 3631, Federal Building 3, Washington, DC 20233, telephone 301–457–2070. Nominations may also be submitted via FAX to 301–457–2642 or by e-mail to Nampeo.R.Mckenney@ccmail.census.gov.

FOR FURTHER INFORMATION CONTACT: Nampeo R. McKenney, Senior Research and Technical Advisor, at the above address, telephone number, or via e-mail.

SUPPLEMENTARY INFORMATION: The Advisory Committee was established in accordance with the Federal Advisory Committee Act (5 U.S.C. Appendix 2) in 1991. The following provides information about the scope of the Advisory Committee, its membership, and the nomination process.

Objectives and Duties

1. The Advisory Committee considers the goals of the decennial census and user needs for information provided by that census, and provides a perspective from the standpoint of the outside user community about how the conduct and implementation of the 2000 decennial census realizes those goals and satisfies those needs.

2. The Advisory Committee functions solely as an advisory body under the Federal Advisory Committee Act and reports to the Secretary of Commerce through the Under Secretary for Economic Affairs.

Membership

1. The Advisory Committee consists of a Chair, Vice Chair, and a designated representative from each member organization. The Advisory Committee is composed of up to forty (40) member organizations. Representatives are heads of member organizations with a substantial interest in the census. The Advisory Committee is representative of private sector users; minority groups; professional associations; state, local, and tribal governments; and other organizations. In addition, sixteen (16) ex-officio members serve in a nonvoting capacity. Ex-officio members are representatives of the Postmaster General, the Chairperson and Ranking Member of the Congressional Census Oversight and Appropriations Committees and Subcommittees, and a representative from the Census Advisory Committees on the Race and Ethnic Populations.

2. Advisory Committee member organizations are selected in accordance with applicable Department of Commerce guidelines and in compliance with Federal Advisory Committee Act regulations. The Advisory Committee will have representation that displays a balanced viewpoint and perspective, considering such factors as geography, minority representation, business, academia, and...
The Advisory Committee membership will have relevant background/experience to significantly assist and/or contribute to the issues, responsibilities, and tasks associated with Advisory Committee membership, including providing advice on complex policy and technical issues.

4. Prospective organizations should reflect a distinct and representative constituency whose input would further the goals and objectives of the 2000 Census Advisory Committee.

5. Nominations of organizations may come from individuals or organizations. A summary of the organization’s qualifications and the experience that qualifies the organization for membership should be included in the nomination letter. Nominated organizations should be able to actively participate in good faith in the tasks of the Advisory Committee. Besides participation in the Advisory Committee meetings, active participation of the organization’s representative will include review of materials, participation in conference calls and working groups, and observation trips.

6. The Department of Commerce is committed to equal opportunity in the workplace and seeks diverse committee membership.

Appendix A—2000 Census Advisory Committee; Member Organizations and Representatives (as of November 13, 1999)

Chair
Robert J. Shapiro,
Under Secretary for Economic Affairs,
Economics and Statistics Administration.
[FR Doc. 99–31411 Filed 12–2–99; 8:45 am]
BILLING CODE 3510–70–M

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[Docket 62–99]

Foreign-Trade Zone 174—Tucson, AZ; Application for Subzone, Imation Enterprises Corporation, Tucson, AZ

An application has been submitted to the Foreign-Trade Zones Board (the Board) by the City of Tucson, grantee of FTZ 174, requesting special-purpose subzone status for the manufacturing facilities (data storage products) of Imation Enterprises Corporation (Imation), located in Tucson, Arizona. The application was submitted pursuant
to the provisions of the Foreign-Trade Zones Act, as amended (19 U.S.C. 81a–81u), and the regulations of the Board (15 CFR part 400). It was formally filed on November 24, 1999.

The Imation plant (73 acres) is located at 8500 S. Rita Road, Tucson, Arizona. The Imation facilities are used for the manufacturing, testing, packaging and warehousing of magnetic data storage tapes (HTS 8523.13, duty free). Components and materials sourced from abroad (representing 48–52% of all parts consumed in manufacturing) include: carbon black, iron oxides, polypropylene, polystyrene and polycarbonate resin, acrylic polymers, articles of plastic and paper, and stainless steel tape guides (HTS 2803, 2821, 3902, 3903, 3907, 3920, 3923, 3926, 4807, 4811, 4819, 4821, 4823, 7320 and 7326.90 duty range from duty free to 10.2%). The application also indicates that the company may in the future import under FTZ procedures other materials used in the production of data storage products. FTZ procedures would exempt Imation from Customs duty payments on the foreign components used in export production. Some 50 percent of the plant’s shipments are exported. On its domestic sales, Imation would be able to choose the duty rates during Customs entry procedures that apply to finished data storage products (duty free) for the foreign inputs noted above. Also, Imation has submitted applications for subzone status at three additional locations, and products shipped to facilities with subzone status could be further processed while remaining in zone status. The request indicates that the savings from FTZ procedures would help improve the plant’s international competitiveness.

In accordance with the Board’s regulations, a member of the FTZ staff has been appointed examiner to investigate the application and report to the Board.

Public comment on the application is invited from interested parties. Submissions (original and 3 copies) shall be addressed to the Board’s Executive Secretary at the address below. The closing period for their receipt is February 1, 2000. Rebuttal comments in response to material submitted during the foregoing period may be submitted during the subsequent 15-day period (to February 16, 2000).

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

U.S. Department of Commerce, Export Assistance Center, 166 West Alameda, Tucson, AZ 85726

Office of the Executive Secretary, Foreign-Trade Zones Board, Room 4008, U.S. Department of Commerce, 14th and Pennsylvania Avenue, N.W., Washington, D.C. 20230.

Dated: November 24, 1999.

Dennis Puccinelli,
Acting Executive Secretary.

[FR Doc. 99–31419 Filed 12–2–99; 8:45 am] BILLY CODE 3510-DS-P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[Docket 63–99]

Foreign-Trade Zone 205—Port Hueneme, California; Application for Subzone, Imation Enterprises Corporation, Camarillo, CA

An application has been submitted to the Foreign-Trade Zones Board (the Board) by the Oxnard Harbor District, grantee of FTZ 205, requesting special-purpose subzone status for the manufacturing facilities (data storage products) of Imation Enterprises Corporation (Imation), located in Camarillo, California. The application was submitted pursuant to the provisions of the Foreign-Trade Zones Act, as amended (19 U.S.C. 81a–81u), and the regulations of the Board (15 CFR part 400). It was formally filed on November 24, 1999.

The Imation plant (49.01 acres) is located at 350 South Lewis Road in Camarillo, California. The Imation facilities are used for the manufacturing, testing, packaging and warehousing of magnetic data storage tapes and unrecorded media (HTS 8523.12 and 8523.13, duty free). Components and materials sourced from abroad (representing some 85% of all parts consumed in manufacturing) include: carbon black, iron oxides, polypropylene, polystyrene and polycarbonate resin, acrylic polymers, articles of plastic and paper, helical springs, and stainless steel tape guides (HTS 2803, 2821, 3902, 3903, 3907, 3920, 3926, 4811, 4819, 7320 and 7326.90 duty range from duty free to 9.5%). The application also indicates that the company may in the future import under FTZ procedures other materials used in the production of data storage products.

FTZ procedures would exempt Imation from Customs duty payments on the foreign components used in export production. Some 50 percent of the plant’s shipments are exported. On its domestic sales, Imation would be able to choose the duty rates during Customs entry procedures that apply to finished data storage products (duty free) for the foreign inputs noted above.

Dated: November 24, 1999.

Dennis Puccinelli,
Acting Executive Secretary.

[FR Doc. 99–31420 Filed 12–2–99; 8:45 am] BILLY CODE 3510-DS-P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[Docket No. 59–99]

Foreign-Trade Zone 26—Atlanta, Georgia Area Application for Expansion

An application has been submitted to the Foreign-Trade Zones (FTZ) Board (the Board), by the Georgia Foreign-Trade Zone, Inc., grantee of Foreign-Trade Zone 26, requesting authority to expand its zone to include an additional site in Canton (Cherokee County), Georgia, adjacent to the Atlanta Customs port of entry. The application was submitted pursuant to the provisions of the Foreign-Trade Zones Act, as amended (19 U.S.C. 81a–81u), and the
regulations of the Board (15 CFR Part 400). It was formally filed on November 23, 1999.

FTZ 26 was approved on January 17, 1977 (Board Order 115, 42 FR 4186, 1/24/77); reorganized on April 18, 1988 (Board Order 381, 53 FR 15254, 4/28/88); and, expanded on April 29, 1996 (Board Order 820, 61 FR 21156, 5/9/96) and March 19, 1999 (Board Order 1033, 64 FR 16421, 4/5/99). The general-purpose zone project currently consists of the following sites:

Site 1 (275 acres)—adjacent to the Hartsfield Atlanta International Airport (HAIA) in Clayton and Fulton Counties, Georgia, including jet fuel storage and distribution facilities at HAIA; and,

Site 2 (2,472 acres)—Peachtree City Development Authority’s Peachtree City Industrial Park, Highway 74 South, Peachtree City.

The applicant is now requesting authority to expand the general-purpose zone to include an additional site in Canton (Cherokee County), Georgia: Proposed Site 3 (85 acres)—Canton-Cherokee County Business and Industrial Park, Brown Industrial Boulevard, Canton, some 45 miles north of downtown Atlanta. Proposed Site 3 would be the first site in the northern Atlanta metropolitan area. No specific manufacturing requests are being made at this time. Such requests would be made to the Board on a case-by-case basis.

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

Public comment on the application is invited from interested parties. Submissions (original and 3 copies) shall be addressed to the Board’s Executive Secretary at the address below. The closing period for their receipt is February 1, 2000. Rebuttal comments in response to material submitted during the foregoing period may be submitted during the subsequent 15-day period (to February 16, 2000). A copy of the application and the accompanying exhibits will be available for public inspection at each of the following locations:

U.S. Department of Commerce, Export Assistance Center, 285 Peachtree Center Avenue, NE, Suite 200, Atlanta, GA 30303–1229

Office of the Executive Secretary, Foreign-Trade Zones Board, Room 4008, U.S. Department of Commerce, 14th & Pennsylvania Avenue, NW, Washington, DC 20230.

Dated: November 24, 1999.

Dennis Puccinelli,
Acting Executive Secretary.
[FR Doc. 99–31416 Filed 12–2–99; 8:45 am] BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[Docket No. 61–99]

Foreign-Trade Zone 103—Grand Forks, North Dakota Application for Subzone Imation Enterprises Corporation Wahpeton, North Dakota

An application has been submitted to the Foreign-Trade Zones Board (the Board) by the Grand Forks Regional Airport Authority, grantees of FTZ 103, requesting special-purpose subzone status for the manufacturing facilities (data storage products) of Imation Enterprises Corporation (Imation), located in the Wahpeton, North Dakota area. The application was submitted pursuant to the provisions of the Foreign-Trade Zones Act, as amended (19 U.S.C. 81a–81u), and the regulations of the Board (15 CFR part 400). It was formally filed on November 24, 1999. Imation Enterprises Corporation has two sites with 510 employees in the Wahpeton, North Dakota area. Site 1 (95 acres) is located at 2100 15th Street North, Wahpeton, North Dakota; Site 2 (17 acres) is located at 1205 North Tower Road, Route 2, Fergus Falls, Minnesota. The Imation facilities are used for the manufacturing, testing, packaging and warehousing of magnetic floppy diskettes, cartridges, cassettes, cassette parts, and CD–RW (HTS 3923, 3926, 8523.20 and 8523.90, duty free). Components and materials sourced from abroad (representing some 95% of all parts consumed in manufacturing) include: carbon black, iron oxides, polypropylene, polystyrene and polycarbonate resins, acrylic polymers, silicones, articles of plastic and paper, helical springs, pigments, stainless steel tape guides, and amino resins (HTS 2803, 2821, 3212, 3902–3910, 3923, 2926, 4807, 4811, 4819, 4821, 4823, 7326.90 and 8523 duty rate ranges from duty free to 10.2%). The application also indicates that the company may in the future import under FTZ procedures other materials used in the production of data storage products. FTZ procedures would exempt Imation from Customs duty payments on the foreign components used in export production. Some 50 percent of the plant’s shipments are exported. On its domestic sales, Imation would be able to choose the duty rates during

Customs entry procedures that apply to finished data storage products (duty free) for the foreign inputs noted above. Also, Imation has submitted applications for subzone status at three additional locations, and products shipped to facilities with subzone status could be further processed while remaining in zone status. The request indicates that the savings from FTZ procedures would help improve the plant’s international competitiveness.

In accordance with the Board’s regulations, a member of the FTZ staff has been appointed examiner to investigate the application and report to the Board.

Public comment on the application is invited from interested parties. Submissions (original and 3 copies) shall be addressed to the Board’s Executive Secretary at the address below. The closing period for their receipt is February 1, 2000. Rebuttal comments in response to material submitted during the foregoing period may be submitted during the subsequent 15-day period (to February 16, 2000). A copy of the application and the accompanying exhibits will be available for public inspection at each of the following locations:

U.S. Customs Service, Hector International Airport, 1801 23rd Avenue, N., Room 105, Fargo, ND 58102

Office of the Executive Secretary, Foreign-Trade Zones Board, Room 4008, U.S. Department of Commerce, 14th and Pennsylvania Avenue, N.W., Washington, D.C. 20230.

Dated: November 24, 1999.

Dennis Puccinelli,
Acting Executive Secretary.
[FR Doc. 99–31418 Filed 12–2–99; 8:45 am] BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[Docket 60–99]

Foreign-Trade Zone 106—Oklahoma City, OK; Application for Subzone Imation Enterprises Corporation, Weatherford, OK

An application has been submitted to the Foreign-Trade Zones Board (the Board) by the Port Authority of the Greater Oklahoma City Area, grantees of FTZ 106, requesting special-purpose subzone status for the manufacturing facilities (data storage products) of Imation Enterprises Corporation (Imation), located in the Weatherford, Oklahoma area. The application was
submitted pursuant to the provisions of the Foreign-Trade Zones Act, as amended (19 U.S.C. 81a–81u), and the regulations of the Board (15 CFR part 400). It was formally filed on November 24, 1999.

Imation Enterprises Corporation has four sites with 320 employees in Custer County, Oklahoma. Site 1 (155 acres) is located at 2000 East Frontage Road in Weatherford, Oklahoma; Site 2 (3 acres) is located at 1300 Lera Drive in Weatherford, Oklahoma and 3501 East Main Street, Weatherford, Oklahoma; Site 3 (2.39 acres) is located at 308 Wilson Road, Weatherford, Oklahoma; and Site 4 (3.27 acres) is located at 7815 Gemini Boulevard, Oklahoma City, Oklahoma. The Imation facilities are used for the manufacturing, testing, packaging and warehousing of 1.44 MB standard and Superdisk™ high capacity magnetic floppy diskettes, media for magnetic floppy diskettes and Superdisk™ 3.5™ internal and external drives (HTS 8523.20 and 8471.70, duty free). Components and materials sourced from abroad (representing 88% of all parts consumed in manufacturing) include: carbon black, iron oxides, polypropylene, polystyrene and polycarbonate resin, acrylic polymers, articles of plastic and paper, helical springs, stainless steel tape guides, electronic conductors and power supplies for data processing, floppy magnetic disk drive units, and electric conductors (HTS 2803, 2821, 3902, 3903, 3907, 3923, 2926, 4807, 4811, 4819, 4821, 4823, 7326.90, 8471 and 8544 duty rate ranges from duty free to 10.2%). The application also indicates that the company may in the future import under FTZ procedures other materials used in the production of data storage products.

FTZ procedures would exempt Imation from Customs duty payments on the foreign components used in export production. Some 50 percent of the plant’s shipments are exported. On its domestic sales, Imation would be able to choose the duty rates during Customs entry procedures that apply to finished data storage products (duty free) for the foreign inputs noted above. Also, Imation has submitted applications for subzone status at three additional locations, and products shipped to facilities with subzone status could be further processed while remaining in zone status. The request indicates that the savings from FTZ procedures would help improve the plant’s international competitiveness.

In accordance with the Board’s regulations, a member of the FTZ staff has been appointed examiner to investigate the application and report to the Board.

Public comment on the application is invited from interested parties. Submissions (original and 3 copies) shall be addressed to the Board’s Executive Secretary at the address below. The closing period for their receipt is February 1, 2000. Rebuttal comments in response to material submitted during the foregoing period may be submitted during the subsequent 15-day period (to February 16, 2000).

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

U.S. Department of Commerce, Export Assistance Center, 301 Northwest 63rd Street, Suite 330, Oklahoma City, OK 73116

Office of the Executive Secretary, Foreign-Trade Zones Board, Room 4008, U.S. Department of Commerce, 14th and Pennsylvania Avenue, N.W., Washington, D.C. 20230.

Dated: November 24, 1999.

Dennis Puccinelli,
Acting Executive Secretary.

[FR Doc. 99–31417 Filed 12–2–99; 8:45 am]

BILLING CODE 3510–05–P

DEPARTMENT OF COMMERCE

International Trade Administration

Initiation of Antidumping and Countervailing Duty Administrative Reviews

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

ACTION: Notice of initiation of antidumping and countervailing duty administrative reviews.

SUMMARY: The Department of Commerce has received requests to conduct administrative reviews of various antidumping and countervailing duty orders and findings with October anniversary dates. In accordance with the Department’s regulations, we are initiating those administrative reviews.

EFFECTIVE DATE: December 3, 1999.


SUPPLEMENTARY INFORMATION:

Background

The Department has received timely requests, in accordance with 19 C.F.R. 351.213(b) (1997), for administrative reviews of various antidumping and countervailing duty orders and findings with October anniversary dates.

Initiation of Reviews

In accordance with section 19 C.F.R. 351.221(c)(1)(ii), we are initiating administrative reviews of the following antidumping and countervailing duty orders and findings. We intend to issue the final results of these reviews not later than October 31, 2000.

<table>
<thead>
<tr>
<th>Antidumping duty proceedings</th>
<th>Period to be reviewed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Koyo Seiko Co., Ltd.</td>
<td></td>
</tr>
<tr>
<td>NSK, Ltd.</td>
<td></td>
</tr>
<tr>
<td>Koyo Seiko Co., Ltd.</td>
<td></td>
</tr>
<tr>
<td>NSK, Ltd.</td>
<td></td>
</tr>
<tr>
<td>NTN Corporation</td>
<td></td>
</tr>
<tr>
<td>MALAYSIA: Extruded Rubber Thread; A–557–805</td>
<td>10/1–9/30/99</td>
</tr>
<tr>
<td>Filati Lastex Sdn. Bhd.</td>
<td></td>
</tr>
<tr>
<td>Filmax Sdn. Bhd.</td>
<td></td>
</tr>
<tr>
<td>Heveafil Sdn. Bhd.</td>
<td></td>
</tr>
<tr>
<td>Rubberflex Sdn. Bhd.</td>
<td></td>
</tr>
<tr>
<td>Zhejiang Waxin Group Co., Ltd. (aka Hangzhou Spring Washer Plant)</td>
<td></td>
</tr>
</tbody>
</table>

*If one of the above named companies does not qualify for a separate rate, all other exporters of helical spring lock washers from the People's Republic of China who have not qualified for a separate rate are deemed to be covered by this review as part of the single PRC entity of which the named exporters are a part.

<table>
<thead>
<tr>
<th>Countervailing duty proceedings</th>
<th>Period to be reviewed</th>
</tr>
</thead>
<tbody>
<tr>
<td>SWEDEN: Certain Carbon Steel Products; G–401–401</td>
<td>1/1–12/31/98</td>
</tr>
<tr>
<td>SSAB Svenskt Stal AB Suspension Agreements: None</td>
<td></td>
</tr>
</tbody>
</table>

During any administrative review covering all or part of a period falling between the first and second or third and fourth anniversary of the publication of an antidumping duty order under section 351.211 or a determination under section 351.218(d)
(sunset review), the Secretary, if requested by a domestic interested party within 30 days of the date of publication of the notice of initiation of the review, will determine whether antidumping duties have been absorbed by an exporter or producer subject to the review if the subject merchandise is sold in the United States through an importer that is affiliated with such exporter or producer. The request must include the name(s) of the exporter or producer for which the inquiry is requested.

For transition orders defined in section 751(c)(6) of the Act, the Secretary will apply paragraph (j)(1) of the Department’s Regulations to any administrative review initiated in 1998 (19 C.F.R. 351.213(j) [1–2]).

Interested parties must submit applications for disclosure under administrative protective orders in accordance with 19 C.F.R. 351.305.

These initiatives and this notice are in accordance with section 751(a) of the Tariff Act of 1930, as amended (19 U.S.C. 1675(a)), and 19 CFR 351.221(c)(1)(i).


Holly A. Kuga,
Acting Deputy Assistant Secretary for Group II, AD/CVD Enforcement.

[FR Doc. 99–31415 Filed 12–2–99; 8:45 am]

BILLING CODE 3510–DS–M

DEPARTMENT OF COMMERCE

International Trade Administration

Extension of Time Limit for Final Results of Five-Year Reviews

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

ACTION: Notice of extension of time limit for final results of five-year (“sunset”) Reviews.

SUMMARY: The Department of Commerce (“the Department”) is extending the time limit for the final results of seven expedited sunset reviews initiated on August 2, 1999 (64 FR 41915) covering various antidumping duty orders as well as a suspended countervailing duty investigation. Based on adequate responses from domestic interested parties and adequate responses from respondent interested parties, the Department is conducting expedited sunset reviews to determine whether revocation of the antidumping duty orders and suspended countervailing duty investigation would be likely to lead to continuation or recurrence of dumping or a countervailable subsidy.

As a result of these extensions, the Department intends to issue its final results not later than February 28, 2000.

EFFECTIVE DATE: December 3, 1999.

FOR FURTHER INFORMATION CONTACT: Scott E. Smith or Melissa G. Skinner, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, N.W., Washington, D.C. 20230; telephone: (202) 482–6397, or (202) 482–1560 respectively.

Extension of Final Results

In accordance with section 751(c)(5)(C)(v) of the Tariff Act of 1930, as amended (“the Act”), the Department may treat a review as extraordinarily complicated if it is a review of a transition order (i.e., an order in effect on January 1, 1995; see section 751(c)(6)(C) of the Act). The Department has determined that the sunset reviews of the following antidumping duty orders and suspended countervailing duty investigation are extraordinarily complicated:

A–588–815 Grey Portland Cement and Cement Clinker from Japan
C–307–804 Grey Portland Cement and Cement Clinker from Venezuela
A–588–817 Flat Panel Displays (Electroluminescent) from Japan
A–570–808 Chrome-Plated Lug Nuts from the People’s Republic of China
A–583–810 Chrome-Plated Lug Nuts from Taiwan
A–557–805 Extruded Rubber Thread from Malaysia
A–823–802 Uranium from the Ukraine

Therefore, the Department is extending the time limit for completion of the final results of these reviews until not later than February 28, 2000, in accordance with section 751(c)(5)(B) of the Act.


Richard W. Moreland,
Acting Assistant Secretary for Import Administration.

[FR Doc. 99–31427 Filed 12–2–99; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

Final Results of Expedited Sunset Reviews: Certain Carbon Steel Butt-Weld Pipe Fittings From Brazil, Taiwan, Japan, Thailand, and The People’s Republic of China

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

ACTION: Notice of final results of expedited sunset reviews: Certain carbon steel butt-weld pipe fittings from Brazil, Taiwan, Japan, Thailand, and The People’s Republic of China.

SUMMARY: On May 3, 1999, the Department of Commerce (“the Department”) initiated sunset reviews of the antidumping duty orders on certain carbon steel butt-weld pipe fittings (“pipe fittings”) from Brazil, Taiwan, Japan, Thailand, and The People’s Republic of China (“China”) (64 FR 23506) pursuant to section 751(c) of the Tariff Act of 1930, as amended (“the Act”). On the basis of a notice of intent to participate and an adequate response filed on behalf of a domestic interested party and inadequate response (in these cases no response) from respondent interested parties in each of these reviews, the Department decided to conduct expedited reviews. As a result of these reviews, the Department finds that revocation of the antidumping duty orders would be likely to lead to the continuation or recurrence of dumping at the levels indicated in the Final Results of Reviews section of this notice.

FOR FURTHER INFORMATION CONTACT: Mark D. Young or Melissa G. Skinner, Office of Policy for Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, N.W., Washington, D.C. 20230; telephone: (202) 482–3207 or (202) 482–1560, respectively.

EFFECTIVE DATE: December 3, 1999.

Statute and Regulations

These reviews were conducted pursuant to sections 751(c) and 752 of the Act. The Department’s procedures for conducting sunset reviews are set forth in Procedures for Conducting Five-year (“Sunset”) Reviews of Antidumping and Countervailing Duty Orders, 63 FR 13516 (March 20, 1998) (“Sunset Regulations”), and 19 CFR Part 351 (1999) in general. Guidance on methodological or analytical issues

Scope
The products covered by these reviews are pipe fittings from Brazil, Taiwan, Japan, Thailand, and China. Pipe fittings from Brazil, Taiwan, and Japan are defined as carbon steel butt-weld pipe fittings, other than couplings, under 14 inches in diameter, whether finished or unfinished form, that have been formed in the shape of elbows, tees, reducer, caps, etc., and, if forged, have been advanced after forging. These advancements may include any one or more of the following: coining, heat treatment, shot blasting, grinding, die stamping or painting. Such merchandise was classifiable under Tariff Schedules of the United States Annotated (“TSUSA”) item number 610.8800. These imports are currently classifiable under the Harmonized Tariff Schedule of the United States (“HTSUS”) item number 7307.93.30.

Pipe fittings from Thailand and China are defined as carbon steel butt-weld pipe fittings, having an inside diameter of less than 14 inches, imported in either finished or unfinished form. These formed or forged pipe fittings are used to join section in piping systems where conditions require permanent welded connections, as distinguished from fittings based on other fastening methods (e.g., threaded grooved, or bolted fittings). These imports are currently classifiable under the HTSUS item number 7307.93.30. The TSUSA and HTSUS subheadings are provided for convenience and United States Customs purposes. The written description remains dispositive as to the scope of the product coverage for each of the orders.

These reviews cover imports from all manufacturers and exporters of pipe fittings from Brazil, Taiwan, Japan, Thailand, and China.

History of the Orders
Brazil
The Department published its final affirmative determination of sales at LTFV with respect to imports of pipe fittings from Brazil on December 29, 1996 (51 FR 46692). In this determination, the Department published weighted-average dumping margins for two companies and an “all others” rate. These margins were later affirmed when the Department published its antidumping duty order on pipe fittings from Brazil on February 10, 1987. The Department has not conducted an administrative review of this order since its imposition. On at least five occasions, the Department published notices of intent to revoke the order, pursuant to 19 CFR 353.25(d)(4), on the grounds that four consecutive anniversary months had passed without a request for administrative review. On each occasion, an interested party under 19 CFR 353.2(k)(5) objected to our intent to revoke this antidumping duty order. Based on the objection, pursuant to 19 CFR 353.25(d)(1)(i), the order remains in effect for all manufacturers and exporters of the subject merchandise from Brazil.

Japan
On October 24, 1986, the Department issued its final affirmative determination of sales at LTFV regarding pipe fittings from Taiwan (51 FR 37772). The Department published its antidumping duty order on December 17, 1986. Since the order was issued, the Department has conducted two administrative reviews with respect to pipe fittings from Taiwan.

In both reviews, the Department established four company-specific dumping margins and an “all others” rate. The order remains in effect for all manufacturers and exporters of the subject merchandise from Taiwan.

Thailand
On May 18, 1992, the Department issued its final affirmative determination of sales at LTFV with respect to imports of pipe fittings from Thailand (57 FR 21065). In this determination, the Department published weighted-average dumping margins for three companies as well as an “all others” rate. One of these companies’ margin was found to be de minimis. These margins were later affirmed when the Department published its antidumping duty order on pipe fittings from Thailand on July 6, 1992. Since the order was issued, the Department has conducted one administrative review with respect to pipe fittings from Thailand. In that review, the Department calculated one company-specific margin. The order remains in effect for all Thai manufacturers and exporters of the

Notes:
1. See Antidumping Duty Order; Certain Carbon Steel Butt-Weld Pipe Fittings from Japan, 52 FR 4167 (February 10, 1987).
2. See Notices of Determination Not to Revoke Antidumping Order, 58 FR 17380 (April 2, 1993); 59 FR 40006 (August 5, 1994); 60 FR 27720 (May 25, 1995); 61 FR 14291 (April 1, 1996); 62 FR 23218 (April 29, 1997).
4. See Notice of Final Determination of Sales at Less Than Fair Value; Certain Carbon Steel Butt-Weld Pipe Fittings from Thailand, 60 FR 10552 (February 27, 1995).
5. See Certain Carbon Steel Butt-Weld Pipe Fittings from Thailand; Final Results of Administrative Review, 62 FR 40797 (July 30, 1997).
6. See Antidumping Duty Order; Certain Carbon Steel Butt-Weld Pipe Fittings from Japan, 52 FR 4167 (February 10, 1987).
7. See Antidumping Duty Order; Certain Carbon Steel Butt-Weld Pipe Fittings from Taiwan, 51 FR 45152 (December 17, 1986).
8. See Notices of Determination Not to Revoke Antidumping Order, 57 FR 3994 (February 3, 1992); 59 FR 40006 (August 5, 1994); 60 FR 27720 (May 25, 1995); 61 FR 6973 (February 23, 1996); 62 FR 10552 (March 7, 1997).
9. See Antidumping Duty Order; Certain Carbon Steel Butt-Weld Pipe Fittings from Taiwan, 51 FR 45152 (December 17, 1986).
10. See Certain Carbon Steel Butt-Weld Pipe Fittings from Taiwan; Final Results of Administrative Review, 56 FR 20187 (May 2, 1991); Certain Carbon Steel Butt-Weld Pipe Fittings from Taiwan; Final Results of Administrative Review, 60 FR 49585 (September 26, 1995).
subject merchandise other than AST which was excluded from the order.

China

The Department published its final affirmative determination of sales at LTFV with respect to imports of pipe fittings from China on May 18, 1992 (57 FR 21058). In this determination, the Department published weighted-average dumping margins for six companies as well as an “all others” rate. These margins were subsequently amended when the Department published its antidumping duty order on pipe fittings from China on July 6, 1992. The Department has not conducted an administrative review of this order since its imposition. In 1994 the Department determined that China’s antidumping duty order was being circumvented by parties that were shipping the subject merchandise to Thailand for finishing. In that determination, the Department found that Chinese pipe fittings were being finished in Thailand by a Thai manufacturer and being sold to the United States as products of Thailand. The order remains in effect for all manufacturers and exporters of the subject merchandise from China.

Background

On May 3, 1999, the Department initiated sunset reviews of the antidumping duty orders on pipe fittings from Brazil, Taiwan, Japan, Thailand, and China (64 FR 23596), pursuant to section 751(c) of the Act. We received Notices of Intent To Participate, in each of the five sunset reviews, on behalf of Trinity Fitting and Weldbend Corporation (``Weldbend’’), Mills Iron Works, Inc. (``Mills’’), and Forgings of America, Inc. (``TFFG’’), Mills Flange Group, Inc. (``TFA’’), and Mills (collectively “domestic interested parties’’), by May 18, 1999, within the 30-day deadline specified in section 351.218(d)(3)(i). The Department determined to conduct expedited, 120-day, reviews of these orders.

In accordance with section 751(c)(5)(C)(v) of the Act, the Department may treat a review as extraordinarily complicated if it is a review of a transition order (i.e., an order in effect on January 1, 1995). The reviews at issue concern transition orders within the meaning of section 751(c)(6)(C)(ii) of the Act. Therefore, the Department determined that the sunset reviews of the antidumping duty orders on pipe fittings from Brazil, Taiwan, Japan, Thailand, and China are extraordinarily complicated and extended the time limit for completion of the final results of these reviews until not later than November 29, 1999, in accordance with section 751(c)(5)(B) of the Act.

Determination

In accordance with section 751(c)(1) of the Act, the Department conducted these reviews to determine whether revocation of the antidumping duty orders would be likely to lead to continuation or recurrence of dumping. Section 752(c) of the Act provides that, in making these determinations, the Department shall consider the weighted-average dumping margins determined in the investigation and subsequent reviews and the volume of imports of the subject merchandise for the period before and the period after the issuance of the antidumping duty order, and it shall provide to the International Trade Commission (“the Commission”) the magnitude of the margins of dumping likely to prevail if the order were revoked.

The Department’s determinations concerning continuation or recurrence of dumping and the magnitude of the margins are addressed below. In addition, parties’ comments with respect to continuation or recurrence of dumping and the magnitude of the margins are addressed within the respective sections below.

Continuation or Recurrence of Dumping

Drawing on the guidance provided in the legislative history accompanying the Uruguay Round Agreements Act (“URAA”), specifically the Statement of Administrative Action (“SAA”), H.R. Rep. No. 103–331, vol. 1 (1994), the House Report, H.R. Rep. No. 103–826, pt.1 (1994), and the Senate Report, S. Rep. No. 103–412 (1994), the Department issued its Sunset Policy Bulletin providing guidance on methodological and analytical issues, including the bases for likelihood determinations. In its Sunset Policy Bulletin, the Department indicated that determinations of likelihood will be made on an order-wide basis (see section II.A.2). In addition, the Department indicated that normally it will determine that revocation of an antidumping duty order is likely to lead to continuation or recurrence of dumping where (a) dumping continued at any level above de minimis after the issuance of the order, (b) imports of the subject merchandise ceased after the issuance of the order, or (c) dumping was eliminated after the issuance of the order and import volumes for the subject merchandise declined significantly (see section II.A.3). In addition to considering the guidance on likelihood cited above, section 751(c)(4)(B) of the Act provides that the Department shall determine that revocation of the order would be likely to lead to continuation or recurrence of dumping where a respondent interested party waives its participation in the sunset review. In these instant reviews, the Department did not receive a substantive response from any respondent interested party. Pursuant to section 351.218(d)(2)(iii) of the Sunset Regulations, this constitutes a waiver of participation.

In their substantive response, the domestic interested parties argue that the substantial decline (or cessation, with respect to Brazil) in the volume of imports of pipe fittings from the subject countries following the issuance of the orders demonstrates the inability of the producers from subject countries to sell in the United States at any significant volume without dumping. The domestic interested parties argue further that revocation of these antidumping duty orders would likely lead to a continuation or recurrence of dumping by Brazilian, Taiwanese, Japanese, Thai,
and Chinese producers/manufacturers. They support this argument with evidence showing that, since the imposition of the orders, respondents have generally reduced their shipments to the United States. Therefore, they assert, were the antidumping duty orders revoked, it is likely that Brazilian, Taiwanese, Japanese, Thai, and Chinese producers would need to dump in order to sell their pipe fittings in any significant quantities in the United States.

Brazil

With respect to subject merchandise from Brazil, the domestic interested parties maintain that, in the years preceding the order, Brazil was a major foreign supplier of the subject merchandise to the U.S. market. Following the issuance of the order, they assert, Brazilian imports of the subject merchandise dropped sharply, and since 1992 have ceased completely. Furthermore, the domestic interested parties comment, deposit rates for Brazilian pipe fitting manufacturers continue to exist at 52.25 percent. In conclusion, they assert, cessation of imports and high dumping margins demonstrate that Brazilian manufacturers cannot maintain a presence in the U.S. market without dumping at levels above de minimis.14

Taiwan

The domestic interested parties assert that all four Taiwanese respondents have had dumping margins well above de minimis levels since the issuance of the order. In addition, they note that in the years preceding the order Taiwan was a leading exporter of the subject merchandise to the U.S. market. They argue that, following the issuance of the order, imports from Taiwan dropped to a level far below their pre-order level and have never been more than 55 percent of their pre-order level. The domestic interested parties conclude that Taiwanese importers need to dump pipe fittings in the U.S. market in order to sell at pre-order volumes. To corroborate this conclusion, the domestic interested parties note that the dumping margins for two Taiwanese manufacturers are extraordinarily high and they have never availed themselves of the administrative review process to demonstrate that their dumping has abated.15

Japan:

The domestic interested parties argue that the imposition of the antidumping duty order had a dramatic effect on subject import volumes from Japan. They indicate that in the years following the order, imports of the subject merchandise from Japan dropped by nearly 95 percent. Moreover, they assert, import volumes of the subject pipe fittings from Japan have remained low, relative to the pre-order levels and the dumping margins for Japanese manufacturers remain very high, ranging from 30.83 to 65.81 percent. In sum, the domestic interested parties argue, the dramatic decline in import volumes following the imposition of the order in conjunction with the fact that Japanese manufacturers never availed themselves of the administrative review process to demonstrate that dumping has ceased or abated provides clear evidence that the Japanese producers are incapable of selling at fair value in the U.S. market.16

Thailand

With respect to imports of the subject merchandise from Thailand, the domestic interested parties assert that imports declined significantly after the imposition of the order and have remained at relatively low levels ever since. In fact, the domestic interested parties argue that by the time the order was published imports were only 68.3 percent of their pre-order levels. Therefore, despite the fact that one major manufacturer was originally exempt from the order, they contend that it is evident that Thai manufacturers need to dump pipe fittings in the U.S. market in order to sell at pre-order levels. To corroborate this conclusion the domestic interested parties argue that the only Thai supplier to have de minimis margins in the original investigation was forced to resort to dumping at a margin of 38 percent three years later in order to sell in the U.S. market.17

China

With respect to subject merchandise from China, the domestic interested parties maintain that, in the year the order was imposed, imports from China fell from approximately 30 million pounds the year before to 113,000 pounds. They argue further that, in the years following the imposition of the order, average import volumes of the subject merchandise were more than 90.5 percent lower than in the years proceeding the issuance of the order. Therefore, the domestic interested parties argue that the near cessation of imports from China demonstrates that Chinese manufacturers need to dump pipe fittings in the U.S. market in order to sell at pre-order volumes. To support this conclusion the domestic interested parties assert that dumping margins from Chinese manufacturers are extraordinarily high, ranging from 35.06 to 182.90 percent. Yet, they contend, Chinese manufacturers never availed themselves of the administrative review process to demonstrate that their dumping has ceased or abated. They add that the Department’s affirmative anti-circumvention determination18 shows that when Chinese manufacturers are confronted with the discipline of an order they resort to illegitimate means to participate in the U.S. market.19

General Discussion

As discussed in section II.A.3 of the Sunset Policy Bulletin, the SAA at 890, and the House Report at 63–64, if companies continue dumping with the discipline of an order in place or imports ceased after the issuance of the order, the Department may reasonably infer that dumping would continue or recur if the discipline were removed. As pointed out above, dumping margins at levels above de minimis continue to exist for shipments of the subject merchandise from Brazil, Taiwan, Japan, Thailand, and China. With respect to Brazil, imports have ceased completely.

Consistent with section 752(c) of the Act, the Department also considers the volume of imports before and after issuance of the order. As outlined in each respective section above, the domestic interested parties argue that a significant decline in the volume of imports of the subject merchandise from Taiwan, Japan, Thailand, and China (and a cessation of imports with regard to Brazil) since the imposition of the orders provides further evidence that dumping would continue if the orders were revoked. In their substantive responses, the domestic interested parties provided statistics demonstrating the decline in import volumes of pipe fittings from Brazil,

14 See June 1, 1999, Substantive Response of the Domestic Interested Parties regarding pipe fittings from Brazil at 7.
15 See June 1, 1999, Substantive Response of the Domestic Interested Parties regarding pipe fittings from Taiwan at 7.
16 See June 1, 1999, Substantive Response of the Domestic Interested Parties regarding pipe fittings from Japan at 7.
17 See June 1, 1999, Substantive Response of the Domestic Interested Parties regarding pipe fittings from Thailand at 7.
19 See June 1, 1999, Substantive Response of the Domestic Interested Parties regarding pipe fittings from China at 7.
Taiwan, Japan, Thailand, and China. The Department agrees with the domestic interested parties’ arguments that imports of the subject merchandise fell sharply and ceased in Brazil’s case after the orders were imposed and never regained pre-order volumes.

As noted above, in conducting its sunset reviews, the Department considered the weighted-average dumping margins and volume of imports in determining whether revocation of these antidumping duty orders would lead to the continuation or recurrence of dumping. Based on this analysis, the Department finds that the existence of dumping margins at levels above de minimis and a reduction (or cessation) in export volumes after the issuance of the order is highly probative of the likelihood of continuation or recurrence of dumping. A deposit rate above de minimis continues in effect for exports of the subject merchandise by all known Brazilian, Taiwanese, Japanese, Thai,20 and Chinese manufacturers/exporters. Therefore, given that dumping has continued over the life of the orders, import volumes have declined significantly or ceased after the imposition of the order, respondent parties have waived participation, and absent argument and evidence to the contrary, the Department determines that dumping is likely to continue or recur if the orders were revoked.

Magnitude of the Margin

In the Sunset Policy Bulletin, the Department stated that normally it will provide to the Commission the margin that was determined in the final determination in the original investigation. Further, for companies not specifically investigated or for companies that did not begin shipping until after the order was issued, the Department normally will provide a margin based on the “all others” rate from the investigation. (See section II.B.1 of the Sunset Policy Bulletin.) Exceptions to this policy include the use of a more recently calculated margin, where appropriate, and consideration of duty-absorption determinations. (See sections II.B.2 and 3 of the Sunset Policy Bulletin.) To date, the Department has not issued any duty-absorption findings in any of these five cases.

In their substantive response, the domestic interested parties recommended that, consistent with the Sunset Policy Bulletin, the Department provide to the Commission the company-specific margins from the original investigations. Moreover, regarding companies not reviewed in the original investigations, the domestic interested parties suggested that the Department report the “all others” rates included in the original investigations.

The Department agrees with the domestic interested parties. The Department finds that the margins calculated in the original investigations are probative of the behavior of Brazilian, Taiwanese, Japanese, Thai, and Chinese manufacturers/exporters if the orders were revoked as they are the only margins which reflect their actions absent the discipline of the order.

In the Sunset Policy Bulletin we indicated that, consistent with the SAA at 889–90 and the House Report at 63, declining imports accompanied by the continued existence of dumping margins, or the cessation of imports after the order, provides a strong indication that dumping would be likely to continue, because such evidence indicates that the particular exporter needs to dump to sell at pre-order volumes. Based on our review of the information submitted by the interested parties, data from our original investigations, and subsequent administrative reviews, we determine that Taiwanese, Japanese, Thai, and Chinese pipe fitting manufacturers have continued to dump with the discipline of the order in place. In contrast, Brazilian pipe fitting manufacturers have ceased exporting the subject merchandise completely. This implies that these pipe-fitting manufacturers could not sell the subject merchandise in the United States at pre-order volumes without resorting to dumping.

Therefore, the Department will report to the Commission the company-specific and all others rates from the original investigations as contained in the Final Results of Reviews section of this notice.

Final Results of Reviews

As a result of these reviews, the Department finds that revocation of the antidumping duty orders would likely lead to continuation or recurrence of dumping at the margins listed below:

<table>
<thead>
<tr>
<th>Manufacturer/exporter</th>
<th>Margin (percent)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brazil:</td>
<td></td>
</tr>
<tr>
<td>All Manufacturers/Producers/exporters</td>
<td>52.25</td>
</tr>
<tr>
<td>Taiwan:</td>
<td></td>
</tr>
<tr>
<td>Rigid</td>
<td>6.84</td>
</tr>
<tr>
<td>C.M.</td>
<td>8.57</td>
</tr>
<tr>
<td>Gei Bay</td>
<td>87.30</td>
</tr>
<tr>
<td>Chup Hsin</td>
<td>87.30</td>
</tr>
<tr>
<td>All Others</td>
<td>49.46</td>
</tr>
<tr>
<td>Japan:</td>
<td></td>
</tr>
<tr>
<td>Awaji Sangyo, K.K.</td>
<td>30.83</td>
</tr>
<tr>
<td>Nippon Benkan Kogyo, Ltd. Co</td>
<td>65.81</td>
</tr>
<tr>
<td>All Others</td>
<td>62.79</td>
</tr>
<tr>
<td>Thailand:</td>
<td></td>
</tr>
<tr>
<td>Thai Benkan Company</td>
<td>50.84</td>
</tr>
<tr>
<td>TTU Industrial Corp., Ltd.</td>
<td>10.68</td>
</tr>
<tr>
<td>Awaji Sangyo Co., Ltd.</td>
<td>38.41</td>
</tr>
<tr>
<td>All Others</td>
<td>39.10</td>
</tr>
<tr>
<td>China:</td>
<td></td>
</tr>
<tr>
<td>China North Industries Corporation</td>
<td>154.72</td>
</tr>
<tr>
<td>Jilin Provincial Machinty &amp; Equipment Import &amp; Export Corp.</td>
<td>75.23</td>
</tr>
<tr>
<td>Liaoning Machinery &amp; Equipment Import Export Corp.</td>
<td>134.79</td>
</tr>
<tr>
<td>Liaoning Metals &amp; Minerals Import &amp; Export Corp.</td>
<td>103.70</td>
</tr>
<tr>
<td>Shenyang Billiongold Pipe Fittings Co. Ltd.</td>
<td>110.39</td>
</tr>
<tr>
<td>Shandong Metals &amp; Minerals Import &amp; Export Corp.</td>
<td>35.06</td>
</tr>
<tr>
<td>Shenyang Machinery &amp; Equipment Import &amp; Export Corp; Liaoning Metals; Shenzhen Machinery Industry Corp.; and All Others</td>
<td>182.90</td>
</tr>
</tbody>
</table>

20 As noted above, AST was excluded from this order. Although a dumping margin was later found, an order was not imposed against AST as a result of the Commission’s negative injury determination.

This notice serves as the only reminder to parties subject to administrative protective order (“APO”) of their responsibility concerning the disposition of proprietary information disclosed under APO in accordance with 19 CFR 351.305 of the Department’s regulations. Timely notification of return/destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and the terms of an APO is a sanctionable violation.

This five-year (“sunset”) review and notice are in accordance with sections 751(c), 752, and 777(i)(1) of the Act.


Richard W. Moreland,
Acting Assistant Secretary for Import Administration.

[FR Doc. 99–31426 Filed 12–2–99; 8:45 am]

BILLING CODE 3510–DS–P
DEPARTMENT OF COMMERCE
International Trade Administration

Final Results of Expedited Sunset Review: Circular Welded Carbon Steel Pipes and Tubes from Thailand

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

ACTION: Notice of final results of expedited sunset review: Circular Welded Carbon Steel Pipes and Tubes from Thailand.

SUMMARY: On May 3, 1999, the Department of Commerce ("the Department") initiated a sunset review of the antidumping duty order on circular welded carbon steel pipes and tubes from Thailand (64 FR 23596) pursuant to section 751(c) of the Act, as amended. The Department finds that revocation of the antidumping duty order would be likely to lead to continuation or recurrence of dumping of the merchandise subject to this order. This review was conducted pursuant to sections 751(c) and 752 of the Act. The Department's procedures for the conduct of sunset reviews are set forth in Procedures for Conducting Five-year ("Sunset") Reviews of Antidumping and Countervailing Duty Orders, 63 FR 13516 (March 20, 1998) ("Sunset Regulations").

Background

On May 3, 1999, the Department initiated a sunset review of the antidumping duty order on circular welded carbon steel pipes and tubes from Thailand (64 FR 23596) pursuant to section 751(c) of the Act. The Department received a notice of intent to participate on behalf of Allied Tube and Conduit Corp., Sawhill Tubular Products, Maverick Tube Corporation, Sharon Tube Company, Western Tube and Conduit, and Wheatland Tube Company (collectively "domestic interested parties") on May 18, 1999, within the deadline specified in section 351.218(d)(1)(i) of the Sunset Statute and Regulations

Statute and Regulations

This review was conducted pursuant to sections 751(c) and 752 of the Act. The Department's procedures for the conduct of sunset reviews are set forth in Procedures for Conducting Five-year ("Sunset") Reviews of Antidumping and Countervailing Duty Orders: Policy Bulletin, 63 FR 18871 (April 16, 1998) ("Sunset Policy Bulletin").

Scope

The merchandise subject to this antidumping duty order is certain circular welded carbon steel pipes and tubes, commonly referred to in the industry as "standard pipe" or "structural tubing," with walls not thinner than 0.065 inches, and 0.375 inches or more, but not over 16 inches in outside diameter. The subject merchandise was classifiable under items 610.3231, 610.3234, 610.3241, 610.3242, 610.3243, and 610.3252, 610.3254, 610.3256, 610.3258, 610.4925 of the Tariff Schedules of the United States Annotated ("TSUSA"); currently, it is classifiable under item numbers 7306.30.1000, 7306.30.5025, 7306.30.5032, and 7306.30.5040, 7306.30.5055, 7306.30.5805 and 7306.30.5090 of the Harmonized Tariff Schedule of the United States ("HTSUS"). Although the TSUSA and HTSUS item numbers are provided for convenience and customs purposes, the written description remains dispositive.

In addition to the two companies subject to the original investigation, the Department, has reviewed imports from producers/exporters Thai Hong Steel Pipe Import Export Co., Ltd. ("Thai Hong"), Thai Union Steel Co., Ltd. ("Thai Union"), Siam Steel Pipe Import Export Co., Ltd. ("Siam Steel Pipe"), and Pacific Pipe Company ("Pacific Pipe") over the life of this order. To date, the Department has not issued a duty-absorption determination in this case.

FOR FURTHER INFORMATION CONTACT:
Kathryn B. McCormick or Melissa G. Skinner, Office of Policy for Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW, Washington, DC 20230; telephone: (202) 482-1698 or (202) 482-1560, respectively.

EFFECTIVE DATE: December 3, 1999.

In the original investigation, covering the period September 1, 1985, through August 31, 1986 (51 FR 3384, January 27, 1986), the Department determined a margin of 15.69 percent for Saha Thai Steel Pipe Co. ("Saha Thai"), 15.60 percent for Thai Steel Pipe Industry Co. ("Thai Steel"), and 15.67 percent for "all others."

There have been seven administrative reviews for the subject antidumping duty order. A summary of these reviews follows:

<table>
<thead>
<tr>
<th>Period of review (&quot;POR&quot;)</th>
<th>Citation</th>
</tr>
</thead>
</table>

VerDate 29-OCT-99 12:20 Dec 02, 1999 Jkt 190000 PO 00000 Frm 00031 Fmt 4703 Sfmt 4703 E:\FR\Fm\A03DE3.051 pfrm02 PsN: 03DEN1
Regulations. The domestic interested parties claimed interested-party status under 19 U.S.C. 1677(9)(C) as U.S. producers of circular welded carbon steel pipes and tubes. We received a complete substantive response from the domestic interested parties on June 2, 1999, within the 30-day deadline specified in the Sunset Regulations under section 351.218(d)(3)(i). We did not receive a substantive response from any respondent interested party to this proceeding. As a result, pursuant to 19 CFR 351.218(e)(1)(iii)(C), the Department determined to conduct an expedited, 120-day review of this order.

In accordance with section 751(c)(5)(C)(v) of the Act, the Department may treat a review as extraordinarily complicated if it is a review of a transition order (i.e., an order in effect on January 1, 1995). On September 27, 1999, the Department determined that the sunset review of the antidumping duty order on circular welded carbon steel pipes and tubes from Thailand is extraordinarily complicated, and extended the time limit for completion of the final results of this review until not later than November 29, 1999, in accordance with section 751(c)(5)(B) of the Act.¹

Determinations

In accordance with section 751(c)(1) of the Act, the Department conducted this review to determine whether revocation of the antidumping order would be likely to lead to continuation or recurrence of dumping. Section 752(c) of the Act provides that, in making this determination, the Department shall consider the weighted-average dumping margins determined in the investigation and subsequent reviews and the volume of imports of the subject merchandise for the period before and the period after the issuance of the antidumping duty order, and shall provide to the International Trade Commission ("the Commission") the magnitude of the margin of dumping likely to prevail if the order is revoked.

The Department’s determinations concerning continuation or recurrence of dumping and the magnitude of the margin are discussed below. Additionally, the domestic interested parties’ comments with respect to continuation or recurrence of dumping and the magnitude of the margin are addressed within the respective sections below.

¹ See Extension of Time Limit for Final Results of Five-Year Reviews, 64 FR 48579 (September 7, 1999).

Continuation or Recurrence of Dumping

Drawing on the guidance provided in the legislative history accompanying the Uruguay Round Agreements Act ("URAA"), specifically the Statement of Administrative Action ("the SAA"), H.R. Doc. No. 103–316, vol. 1 (1994), the House Report, H.R. Rep. No. 103–826, pt. 1 (1994), and the Senate Report, S. Rep. No. 103–412 (1994), the Department issued its Sunset Policy Bulletin providing guidance on methodological and analytical issues, including the bases for liability determinations. In its Sunset Policy Bulletin, the Department indicated that determinations of likelihood will be made on an order-wide basis (see section II.A.2). In addition, the Department indicated that normally it will determine that revocation of an antidumping order is likely to lead to continuation or recurrence of dumping where (a) dumping continued at any level above de minimis after the issuance of the order, (b) imports of the subject merchandise ceased after the issuance of the order, or (c) dumping was eliminated after the issuance of the order and import volumes for the subject merchandise declined significantly (see section II.A.3).

In addition to considering the guidance on likelihood cited above, section 751(c)(4)(B) of the Act provides that the Department shall determine that revocation of an order is likely to lead to continuation or recurrence of dumping where an interested party waives its participation in the sunset review. In the instant review, the Department did not receive a response from any respondent interested party. Pursuant to section 351.218(d)(2)(iii) of the Sunset Regulations, this constitutes a waiver of participation.

In their substantive response, the domestic interested parties argue that revocation of the subject order would result in the continuation of sales at less-than-fair value by margins equivalent to or greater than those found in the original investigation and subsequent reviews (see June 2, 1999, Substantive Response of the domestic interested parties at 3). With respect to whether dumping continued at any level above de minimis after the issuance of the order, the domestic interested parties assert that increases in dumping margins have followed increases in imports. For example, a spike in imports between 1994 and 1996 peaked in the 1987/88 review. Imports also declined from 1996 to 1998 after margin increases in the 1995/96 review.

Based on this analysis, the Department finds that the existence of dumping margins after the issuance of the order is highly probative of the likelihood of continuation or recurrence of dumping. Given that dumping has continued at levels above de minimis after the issuance of the order, import volumes for subject merchandise declined significantly after dumping margins were increased, respondent interested parties have waived their right to participate in this review before the Department, and absent argument and evidence to the contrary, the Department determines that dumping is likely to continue if the order were revoked.

Magnitude of the Margin

In the Sunset Policy Bulletin, the Department stated that it will normally provide to the Commission the margin that was determined in the final determination in the original investigation. Further, for companies not specifically investigated or for companies that did not begin shipping
Steel’s margin increase from the original investigation was insignificant.

Therefore, without a correlation between increases in imports and dumping margins, the Department finds the original rates most probative of the behavior of Thai producers/exporters of circular welded carbon steel pipes and tubes if the order were revoked. Because Siam Steel Pipe, Thai Hong and Thai Union were not specifically investigated until after the order was issued, consistent with the Policy Bulletin (see section II.B.1), the Department will provide a margin based on the all others rate from the investigation for these companies. Thus, the Department will report to the Commission the company-specific and all others rates as contained in the Final Results of Review section of this notice.

**Final Results of Review**

As a result of this review, the Department finds that revocation of the antidumping duty order would likely lead to continuation or recurrence of dumping at the margins listed below:

<table>
<thead>
<tr>
<th>Producer/Exporter</th>
<th>Margin percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Saha Thai Steel Pipe Co. .......</td>
<td>15.69</td>
</tr>
<tr>
<td>Thai Steel Pipe Industry Co. .....</td>
<td>15.60</td>
</tr>
<tr>
<td>All others ........................</td>
<td>15.67</td>
</tr>
</tbody>
</table>

This notice serves as the only reminder to parties subject to administrative protective order (“APO”) of their responsibilities concerning the disposition of proprietary information disclosed under APO in accordance with 19 CFR 351.305 of the Department’s regulations. Timely notification of return/destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and the terms of an APO is a sanctionable violation.

This five-year (“sunset”) review and notice are in accordance with sections 751(c), 752, and 777(f)(1)(J) of the Act.


Richard W. Moreland,
Acting Assistant Secretary for Import Administration.

[FR Doc. 99–31425 Filed 12–2–99; 8:45 am]

**BILLING CODE 3510–01–P**

**DEPARTMENT OF COMMERCE**

**International Trade Administration**


**Final Results of Expedited Sunset Reviews: Certain Circular Welded Non-Alloy Steel Pipe From Brazil, the Republic of Korea, Mexico, Taiwan, and Venezuela**

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

**ACTION:** Notice of final results of expedited sunset reviews: Certain circular-welded non-alloy steel pipe from Brazil, the Republic of Korea, Mexico, Taiwan, and Venezuela.

**SUMMARY:** On May 3, 1999, the Department of Commerce (“the Department”) initiated sunset reviews of the antidumping duty orders on certain circular-welded non-alloy steel pipe from Brazil, the Republic of Korea (“Korea”), Mexico, Taiwan, and Venezuela pursuant to section 751(c) of the Tariff Act of 1930, as amended (“the Act”). On the basis of a notice of intent to participate and an adequate response filed on behalf of a domestic interested party and inadequate responses from respondent interested parties in each of these reviews, the Department conducted expedited sunset reviews. As a result of these reviews, the Department finds that revocation of the antidumping duty orders would likely lead to continuation or recurrence of dumping at the levels indicated in the Final Result of Reviews section of this notice.

**FOR FURTHER INFORMATION CONTACT:** Martha V. Douthit or Melissa G. Skinner, Office of Policy for Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW, Washington, DC 20230; telephone (202) 482–5050 or (202) 482–1560, respectively.

**EFFECTIVE DATE:** December 3, 1999.

**Statute and Regulations**

These reviews were conducted pursuant to sections 751(c) and 752 of the Act. The Department’s procedures for the conduct of sunset reviews are set forth in Procedures for Conducting Five-Year (“Sunset”) Reviews of Antidumping and Countervailing Duty Orders, 63 FR 13516 (March 20, 1998) (“Sunset Regulations”), and 19 CFR Part 351 (1999) in general. Guidance on methodological or analytical issues relevant to the Department’s conduct of sunset reviews is set forth in the

Scope
The merchandise subject to these antidumping duty orders is circular welded non-alloy steel pipe and tube from Brazil, Korea, Mexico, and Venezuela. The product consists of circular cross-section, not more than 406.4mm (16 inches) in outside diameter, regardless of wall thickness, surface finish (black, galvanized, or painted), or end finish (plain end, beveled end, threaded, or threaded and coupled). These pipes and tubes are generally known as standard pipes and tubes and are intended for the low-pressure conveyance of water, steam, natural gas, air and other liquids and gases in plumbing and heating systems, air-conditioning units, automatic sprinkler systems, and other related uses. Standard pipe may also be used for light load-bearing applications, such as for fence tubing, and as structural pipe tubing used for framing and as support members for reconstruction or load-bearing purposes in the construction, shipbuilding, trucking, farm equipment, and other related industries. Unfinished conduit pipe is also included in this order. All carbon steel pipes and tubes within the physical description outlined above are included within the scope of this investigation, except line pipe, oil country tubular goods, boiler tubing, mechanical tubing, pipe and tube hollows for redrives, finished scaffolding, and finished conduit. Standard pipe that is dual or triple certified/stenciled that enters the U.S. as line pipe of a kind used for oil and gas pipelines is also not included in this investigation. Imports of the products covered by this order are currently classifiable under the following Harmonized Tariff Schedule (HTS) subheadings: 7306.30.10, 7306.30.20, 7306.30.25, 7306.30.30, 7306.30.32, 7306.30.35, 7306.30.40, 7306.30.45, 7306.30.50, 7306.30.55, 7306.30.50.85, 7306.30.50.90. Although the HTS subheadings are provided for convenience and customs purposes, our written description of the scope of these proceedings is dispositive.

Scope Clarification: Brazil, Korea, Mexico, and Venezuela
On March 21, 1996, in a final scope ruling, the Department determined that:
(i) Pipe certified to the API 5L line pipe specification, and (ii) pipe certified to both the API 5L line pipe specifications and the less-stringent ASTM A–53 standard pipe specifications which fall within the physical parameters outlined in the scope of the orders and enter as line pipe of a kind used for oil and gas pipelines are outside the scope of the antidumping duty orders on certain welded carbon steel non-alloy pipe from Brazil, Korea, Mexico and Venezuela, irrespective of end use.1 Mexico—On December 31, 1995, Tubacero International Corporation requested clarification to determine whether circular welded carbon steel piping, 16 inches in outside diameter with 3/8 inch wall thickness, for use in extremely heavy load bearing applications, is within the scope of the order. On April 25, 1996, the Department determined that circular welded carbon steel piping, 16 inches in outside diameter with 3/8 inch wall thickness, for use in extremely heavy load bearing applications is within the scope of the order (see Notice of Scope Rulings, 61 FR 18381 (April 25, 1996)).

Mexico—Pending Scope Clarification
Cierra Pipe, Incorporated submitted a request for a scope clarification of the subject merchandise to determine whether line pipe “shorts”, or “old line pipe” which has rushed and pitted after sitting in storage, constitute line pipe of a kind used for oil and gas pipelines or is pipe and tubing covered by the order (see 63 FR 59544 (November 4, 1998)).

Mexico—Pending Anti-Circumvention Inquiry
The domestic interested parties requested a circumcision inquiry to determine whether imports of: (i) Pipe certified to the American Petroleum Institute (API) 5L line pipe specifications (API) 5L, and (ii) pipe certified to both the API 5L line pipe specifications and the less stringent American Society for Testing and Materials ("ASTM") A–53 standard pipe specifications (dual certified pipe), falling within the physical dimensions outlined in the scope of the order, are circumventing the antidumping duty order (see 63 FR 41545 (August 4, 1998)).

History of the Orders
On September 17, 1992, the Department issued final determinations of sales at less than fair value ("LTFV") on imports of certain circular welded non-alloy steel pipe from Brazil, Korea, Mexico, Taiwan, and Venezuela (57 FR 42940, 42942, 42953, 42961, and 42962, respectively). On November 2, 1992, the Department published the Notice of Antidumping Orders on Certain Circular Welded Non-Alloy Steel Pipe from Brazil, the Republic of Korea, Mexico, and Venezuela, and Amendment to Final Determination of Sales at Less Than Fair Value: Circular Welded Non-Alloy Steel Pipe From the Republic of Korea, 57 FR 49453 (November 2, 1992). The order on Korea was subsequently amended (see Notice of Final Court Decision and Amended Final Determination, 60 FR 55833 (November 3, 1995)).

In the investigations, the Department estimated weighted-average dumping margins that ranged from 4.91 percent to 103.38 percent ad valorem. There have been no administrative reviews of the orders on circular welded non-alloy steel pipe from Brazil, Taiwan, and Venezuela. The Department conducted two administrative reviews of the order covering Korea and two administrative reviews of the order covering from Mexico.2 The Department has not found duty absorption for any country subject to these antidumping duty orders.

The antidumping duty orders remain in effect for all producers and exporters of the subject merchandise from Brazil, Korea, Mexico, Taiwan, and Venezuela.

Background
On May 3, 1999, the Department initiated sunset reviews of the antidumping duty orders on certain circular welded non-alloy steel pipe from Brazil, Korea, Mexico, Taiwan, and Venezuela pursuant to section 751(c) of the Act. On May 18, 1999, within the deadline specified in section 351.218(d)(1)(i) of the Sunset Regulation, we received notices of intent to participate from Allied Tube and Conduit Corporation, Sawhill Tubular Division—Armco, Inc., Century Tube, IPSCO Tubular Inc., LTV Steel Tubular Products, Maverick Tube Corporation, Sharon Tube Company, Western Tube and Conduit, and Wheatland Tube Co. (collectively “the

1 See Final Negative Scope Determination of Scope Inquiry on Certain Welded Non-Alloy Steel Pipe and Tube from Brazil, the Republic of Korea, Mexico, and Venezuela, 61 FR 11608 (March 21, 1996).

domestic interested parties’). Each of these parties claimed status as domestic interested parties on the basis that they are domestic producers of the products subject to these orders. In its substantive responses, the domestic interested parties assert that all parties except IPSCO, LTV Tubular, and Maverick participated in the original investigation and subsequent administrative reviews of the subject orders. With respect to related party status, the domestic interested parties state that they are not related to any foreign producers or foreign exporters, and are not importers of the subject merchandise, or related to importers of the subject merchandise.

Within the deadline specified in the Sunset Regulations under section 351.218(d)(3)(i), on June 2, 1999, the Department received complete substantive responses from the domestic interested parties. In addition, we received a complete substantive response from, Tuberia Nacional, S.A. de C.V. (“TUNA”) a Mexican producer/exporter of circular welded non-alloy steel pipe in the sunset review of the order on Mexico. TUNA stated it was not a participant in the original investigation, however, it participated in the 1994–1995 administrative review, and the 1997–1998 administrative review currently being conducted by the Department. On June 2, 1999, the Korea Iron and Steel Association (“KOSA”) and its individual members SeAH Steel Corporation, Ltd., Sinho Steel Company, Hyundai Pipe Company, and Korea Iron and Steel Company, waived their right to participate in the Department’s sunset review of circular welded non-alloy steel pipe from Korea. On June 2, 1999, C.A. Conduven (“Conduven”) waived its right to participate in the Department’s sunset review of circular welded non-alloy steel pipe from Venezuela.

On June 22, 1999, we informed the International Trade Commission (“Commission”) that on the basis of inadequate responses from respondent interested parties, we were conducting expedited sunset reviews of these orders consistent with 19 CFR 351.218(e)(1)(iii)(C)(2). (See Letter to Lynn Featherstone, Director, Office of Investigations from Jeffrey A. May, Director, Office of Policy.)

In accordance with section 751(c)(5)(C)(v) of the Act, the Department may treat a review as extraordinarily complicated if it is a review of a transition order (i.e., an order in effect on January 1, 1995). Therefore, on September 7, 1999, the Department determined that the sunset reviews of the antidumping duty orders on circular-welded non-alloy steel pipe from Brazil, Korea, Mexico, Taiwan, and Venezuela are extraordinarily complicated and extended the time limit for completion of the final results of these reviews until not later than November 29, 1999, in accordance with section 751(c)(5)(B) of the Act.

### Determination

In accordance with section 751(c)(1) of the Act, the Department conducted these reviews to determine whether revocation of the antidumping duty orders would be likely to lead to continuation or recurrence of dumping. Section 752(c) of the Act provides that, in making this determination, the Department shall consider the weighted-average dumping margins determined in the investigation and subsequent reviews and import volume of the subject merchandise for the period before the issuance of the antidumping duty orders and the period after the issuance of the antidumping duty orders. Pursuant to section 752(c)(3) of the Act, the Department shall provide to the Commission the magnitude of the margin likely to prevail if the orders are revoked.

The Department’s determinations concerning continuation or recurrence of dumping, and magnitude of the margin are discussed below. In addition, the parties’ comments with respect to the continuation or recurrence of dumping, and the magnitude of the margin are addressed in the respective sections below.

### Continuation or Recurrence of Dumping

Drawing on the guidance provided in the legislative history accompanying the Uruguay Round Agreements Act (“URAA”), specifically the Statement of Administrative Action (“the SAA”), H.R. Doc. No. 103–316, vol. 1 (1994), the House Report, H.R. Rep. No. 103–826, pt. 1 (1994), and the Senate Report, S. Rep. No. 103–412 (1994), the Department issued its Sunset Policy Bulletin providing guidance on methodology and analytical issues, including the basis for likelihood determinations. In its Sunset Policy Bulletin, the Department indicates that determinations of likelihood will be made on an order-wide basis (see section II.A.2). In addition, the Department indicated that normally it will determine that revocation of an antidumping duty order is likely to lead to continuation or recurrence of dumping where: (a) Dumping continued at any level above de minimis after the issuance of the order, (b) imports of the subject merchandise ceased after the issuance of the order, or (c) dumping was eliminated after the issuance of the order and import volumes for the subject merchandise declined significantly (see section II.A.3).

In addition to considering the guidance on likelihood cited above, section 751(c)(4)(B) of the Act provides that the Department shall determine that revocation of an order is likely to lead to continuation or recurrence of dumping where a respondent interested party waives its participation in the sunset review. In the instant reviews, the Department either did not receive a response, or did receive a waiver, from producers and exporters of circular welded non-alloy steel pipe from Brazil, Korea, Taiwan, and Venezuela. Pursuant to section 351.218(d)(2)(ii) or section 351.218(d)(2)(ii), as applicable, of the Sunset Regulations, this constitutes a waiver of participation.

In their substantive responses, the domestic interested parties assert that revocation of the antidumping duty orders on the subject merchandise from Brazil, Korea, Mexico, Taiwan, and Venezuela, would be likely to lead to continuation of dumping at margins equivalent to or greater than the margins above found in the original investigations. The domestic interested parties support their argument by stating that after the issuance of the antidumping duty orders, dumping margins above de minimis levels continued to exist. In addition, import volumes declined significantly, and in some instances, no shipments were reported. The domestic interested parties provided the Department the following import statistics:

- **Brazil**—In 1991 (the year prior to the imposition of the antidumping duty order), shipment of Brazilian circular-welded non-alloy steel pipe to the United States totaled 54,000 tons. After the issuance of the order imports declined dramatically. By 1998, no imports were reported.
- **Korea**—Imports declined from 321,000 in 1991, to 174,000 in 1998.
- **Mexico**—Imports declined from 48,000 tons in 1991, to 13,500 tons in 1998.
- **Taiwan**—Imports were over 38,000 tons in 1991, and in 1998, almost ceased as the volume declined dramatically to 60 tons.
- **Venezuela**—Imports accounted for over 16,000 tons in 1991. In 1998, imports dropped significantly to 3,300 tons, down nearly 80 percent compared to 1991 import volume.
The domestic interested parties, citing to the Department’s Sunset Policy Bulletin, state that existence of dumping margins after the order, or the cessation of imports after the order, is highly probative of the likelihood of continuation or recurrence of dumping. Therefore, they argue that the continued existence of dumping margins coupled with the significant decrease in imports, strongly indicates the likelihood of continuation or recurrence of dumping should the antidumping duty orders be revoked.

In its substantive response, TUNA, the only respondent in the sunset review of the antidumping duty order of circular welded non-alloy steel pipe from Mexico, argues that revocation of the antidumping duty order would not result in continuation or recurrence of dumping. TUNA basis its assertion on the decline of dumping margins and increase in import volumes. TUNA argues that the Department, in the original investigation, assigned Hylsa S.A. de C.V. (“Hylsa”) (the only respondent reviewed in the investigation) a 32.62 percent dumping margin, and established an “all others” duty deposit rate of 32.62 percent. After the investigation, Hylsa’s rate of 32.62 percent declined to a single digit level. Although TUNA was not a participant in the original investigation, in the 1994–1995 administrative review, the Department assigned TUNA a 1.77 percent dumping margin. TUNA argues that 1.77 percent (its current duty deposit rate) is considered de minimis under the World Trade Organization (“WTO”) Agreement on Implementation of Article VI of the General Agreement on Tariffs and Trade 1994 (“Antidumping Agreement”). Therefore, TUNA argues that the order should be revoked (see TUNA’s Substantive Response at 4). In addition, TUNA argues that import volume and value of the subject merchandise from Mexico has increased significantly in recent years. From 1993, the year after the imposition of the order, to 1998, imports from Mexico more than tripled, from approximately $2.5 million to approximately $7.8 million in 1998 (see TUNA’s Substantive Response at 10). In Attachment 3 and Attachment 5 of its substantive response, TUNA provides its volume and value of exports to the U.S., and its estimate of the percentage of exports to the U.S. TUNA concludes that Mexican producers and exporters of the subject merchandise can ship to the U.S. without dumping should the antidumping duty order be revoked because dumping margins declined after the issuance of the order and imports increased or remained steady.

Finally, TUNA argues that good cause exists to consider other factors. TUNA argues that because the URAA presumes revocation unless there is evidence that dumping will continue, a reasoned decision will often require consideration of factors other than the dumping margin. TUNA argues that in most cases it will be impossible for the Department to render a reasoned determination without considering all relevant information.

TUNA argues that in this case, the original dumping margin was determined when domestic demand was at or near the bottom of a business cycle of several years’ duration. Since that time, demand has increased steadily and is expected to continue to increase. TUNA notes that in 1996, the ITC issued a negative injury determination regarding imports of circular welded non-alloy pipe from Romania and South Africa. TUNA asserts that the domestic industry has clearly benefitted from increases in construction activity and that the strong domestic demand has enabled TUNA to achieve increasing volumes of exports. In this situation, TUNA asserts that dumping is unlikely to continue or recur.

Section II.A.3. of the Sunset Policy Bulletin, the SAA at 890, and the House Report at 63–64 provide that the existence of dumping margins after the order, or cessation of imports after the order, is highly probative of the likelihood of continuation or recurrence of dumping. If companies continue to dump with the discipline of an order in place, it is reasonable to assume that dumping would continue if the discipline were removed. Further, as noted above, in determining whether revocation of an order is likely to lead to continuation or recurrence of dumping, the Department considers the margins determined in the investigation and subsequent administrative reviews and volume of imports.

With respect to dumping margins in the antidumping duty orders on circular welded non-alloy steel pipe from Brazil, Korea, Mexico, Taiwan, and Venezuela, we agree with the domestic interested parties that margins above de minimis levels continued to exist. We disagree with TUNA’s assertion that its margin of 1.77 percent should be considered de minimis for purposes of this sunset review. Both the statute and regulation clearly provide that in reviews of orders, the Department will assert that any weighted average dumping margin that is less than 0.5 percent ad valorem (section 752 (c)(4)(B) of the Act and 19 CFR 351.106 (C)(1)). The 2.0 percent de minimis level in Article 5.8 of the Antidumping Agreement applies only to investigations, not reviews (see SAA at 844–45).

With respect to import volumes of the subject merchandise, our analysis of import statistics covering total imports and company-specific imports demonstrate that import volumes and values have fluctuated over the life of these orders and have not reached pre-order volumes for any of the subject countries. Although TUNA’s imports increased after the issuance of the order, its reported post-order import volumes were nonetheless insignificant compared to its pre-order volumes. Therefore, given that dumping margins above de minimis levels were found to exist and continue in effect with respect to each of these orders, and respondent interested parties waived their right to participate in these (other than Mexico) reviews before the Department, the Department determines that dumping is likely to continue or recur if the orders were revoked.

**Magnitude of the Margin**

In the Sunset Policy Bulletin, the Department stated that, consistent with the SAA and House Report, the Department normally will provide to the Commission a margin from the investigation because that is the only calculated rate that reflects the behavior or exporters without the discipline of an order in place. Further, for companies not specifically investigated or for companies that did not begin shipping until after the order was issued, we normally will provide a margin based on the “all others” rate from the investigation. (See section II.B.1 of the Sunset Policy Bulletin.) Exceptions to this policy include the use of a more recently calculated margin, where appropriate, and consideration of duty-absorption determinations. (See sections II.B.2 and 3 of the Sunset Policy Bulletin.)

In its substantive responses, the domestic interested parties argue that the Department should report to the Commission the dumping margins determined in the original investigations because these rates best reflect the behavior of producers and exporters of circular welded non-alloy steel pipe from Brazil, Korea, Mexico, Taiwan, and Venezuela absent the antidumping duty orders.

With respect to the Mexican case, TUNA reasserts that the dumping margins that are likely to prevail were the order revoked are de minimis. Additionally, citing to the SAA (at 890-
TUNA notes that in certain instances, it may be more appropriate to provide the Commission a more recently calculated margin. TUNA argues that it is not appropriate to report the margins from the original investigation where, as in this case, dumping margins decreased and import volume remained steady or increased. TUNA argues that the weighted-average dumping margins for Hylsa (the only respondent in the investigation), declined to single digit levels, from 32.62 percent in the investigation to 2.99 percent in 1994–1995, and to 7.39 percent in 1995–1996. Further, TUNA notes that it was subject to the all others rate until the 1994–1995 administrative review, when the Department assigned TUNA a 1.77 percent dumping margin (its only individual margin) (see 62 FR 37014, July 10, 1997).

In addition, TUNA argues that dumping margins assigned in the original investigation are inappropriate as indicators of the rates that would be found upon revocation in light of changes in the methodology used to calculate antidumping duty margins introduced by the Uruguay Round. TUNA asserts that the use of margins that would not be obtained under current law would be unfair and contrary to the Antidumping Agreement.

With respect to duty absorption, TUNA notes although the Department has not made any duty absorption findings, in the 1997–1998 administrative review, the petitioners requested a duty absorption investigation. As discussed above, we disagree with TUNA’s assertion that a dumping margin of 1.77 percent is de minimis. Further, we note that the current deposit rates for Hylsa (7.39 percent) and all others Mexican producers/exporters (32.63 percent) are not de minimis.

With respect to TUNA’s argument concerning the magnitude of the margin likely to prevail, we disagree. In the Sunset Policy Bulletin we indicated that, consistent with the SAA at 889–90 and the House Report at 63, we may determine, in cases where declining or no dumping margins are accompanied by steady or increasing imports, that a more recently calculated rate reflects that companies do not have to dump to maintain market share in the United States and, therefore, that dumping is less likely to continue or recur if the order were revoked. Further, we noted that, in determining whether a more recently calculated margin is probative of an exporter’s behavior absent the discipline of an order, we will normally consider the company’s relative market share, with such information to be provided by the parties. It is clear, therefore, that in determining whether a more recently calculated margin is probative of the behavior of exporters, the order were to be revoked, the Department considers company-specific exports and company-specific margins. In its substantive response, TUNA provided the volume and value of its exports to the United States for 1990 (the year prior to the issuance of the order) and for years 1994 through 1998. Additionally, for the years 1994 through 1998, TUNA reported its exports as a percentage of total consumption imports of subject merchandise from Mexico. This information shows the post-order exports from TUNA continue to be significantly below TUNA’s pre-order exports. Additionally, although as TUNA argues, its exports in 1998 are greater than its exports in 1994, TUNA’s exports over this five-year period have greatly fluctuated. Therefore, we are not persuaded that the use of a more recently calculated rate is appropriate in this case. Additionally, we find there is no basis to reject margins calculated in an investigation because of subsequent changes in methodology. Such changes do not invalidate margins calculated under prior methodology.

The Department agrees with the domestic interested parties concerning the margins likely to prevail if these orders were revoked. Absent argument and evidence to the contrary, and consistent with the Sunset Policy Bulletin, we determine that the margins calculated in the Department’s original investigation are probative of the behavior of Brazilian, Korean, Taiwanese, and Venezuelan producers and exporters of circular welded non-alloy steel pipe without the discipline of the orders in place. Further, based on the above analysis, we find that the margins calculated in the original investigation covering Mexico are probative of the behavior of Mexican producers and exporters of circular welded non-alloy steel pipe without the discipline of the order. Therefore, we will report to the Commission the margins indicated in the Final Results of the Reviews section of this notice.

Final Results of Reviews

As a result of these reviews, the Department finds that revocation of the antidumping duty orders would be likely to lead to continuation or recurrence of dumping at the margins listed below:

<table>
<thead>
<tr>
<th>Manufacturers/exporters</th>
<th>Margin (percent)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brazil</td>
<td></td>
</tr>
<tr>
<td>Persico Pizzamiglio S.A.</td>
<td>103.38</td>
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<tr>
<td>All Others ...............</td>
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<tr>
<td>Korea</td>
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<td>Hyundai Steel Pipe Co., Ltd</td>
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<td>Korea Steel Pipe Co., Ltd</td>
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<td>Masan Steel Tube Works Co., Ltd</td>
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<td>All Others ...............</td>
<td>52.51</td>
</tr>
</tbody>
</table>

These notices serves as the only reminder to parties subject to administrative protective order (“APO”) of their responsibility concerning the disposition of proprietary information disclosed under APO in accordance with 19 CFR 351.305 of the Department’s regulation. Timely notification of return/destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and the terms of an APO is sanctionable violation.

These five-year (“sunset”) reviews and notice are published in accordance with sections 751(c), 752 and 777(i)(1) of the Act.


Richard W. Moreland,
Acting Assistant Secretary for Import Administration.

[FR Doc. 99–31428 Filed 12–2–99; 8:45 am]
BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

International Trade Administration

Final Results of Expedited Sunset Review: Electrolytic Manganese Dioxide From Japan

AGENCY: Import Administration, International Trade Administration, Department of Commerce.
ACTION: Notice of final results of expedited sunset review: Electrolytic manganese dioxide from Japan.

SUMMARY: On May 3, 1999, the Department of Commerce ("the Department") initiated a sunset review of the antidumping duty order on electrolytic manganese dioxide from Japan (64 FR 23596) pursuant to section 751(c) of the Tariff Act of 1930, as amended ("the Act"). On January 6, 1992, the Department ruled that high-grade chemical manganese dioxide (CMD-U) is within the scope of the order. This merchandise is currently classifiable under the Harmonized Tariff Schedule ("HTS") item number 2820.10.0000. The HTS item number is provided for convenience and customs purposes. The written description remains dispositive.

History of the Order

The Department, in its final determination of sales at less than fair value ("LTFV"), published two company-specific weighted-average dumping margins as well as an "all others" rate (54 FR 8778, March 2, 1989). The antidumping duty order on EMD from Japan was published in the Federal Register on April 17, 1989 (54 FR 15244). Since that time, the Department has conducted three administrative reviews. This sunset review covers imports from all known Japanese producers/exporters. To date, the Department has issued no duty-absorption findings in this case.

Background

On May 3, 1999, the Department initiated a sunset review of the antidumping duty order on EMD from Japan (64 FR 23596), pursuant to section 751(c) of the Act. The Department received a notice of intent to participate on behalf of Chemetals, Inc. ("Cochemetsals"), and Kerr-McGee Chemical LLC ("KMC") (collectively, "domestic industry") on May 18, 1999, within the deadline specified in section 351.218(d)(1)(i) of the Sunset Regulations. We received a complete substantive response from Chemetals and KMC on June 2, 1999, within the 30-day deadline specified in the Sunset Regulations in section 351.218(d)(3)(i).

Scope

The merchandise subject to this antidumping duty order is electrolytic manganese dioxide ("EMD"). EMD is manganese dioxide (MnO₂) that has been refined in an electrolysis process. The subject merchandise is an intermediate product used in the production of dry-cell batteries. EMD is sold in all forms, powder, chip, or plate, and two grades, alkaline and zinc chloride. EMD in all three forms and both grades is included in the scope of the order.

There has been one scope clarification with regard to EMD from Japan. On June 2, 1999, the Department ruled that high-grade chemical manganese dioxide (CMD-U) is within the scope of the order. This merchandise is currently classifiable under the Harmonized Tariff Schedule ("HTS") item number 2820.10.0000. The HTS item number is provided for convenience and customs purposes. The written description remains dispositive.

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Both Chemetals and Kerr-McGee claimed interested-party status pursuant to section 771(9)(C) of the Act as U.S. producers of a like product. In addition, both Chemetals and KMC stated that they participated in the original investigation and every segment of the proceeding since the original investigation. We did not receive any response from respondent interested parties to this proceeding. As a result, pursuant to section 351.218(e)(1)(ii)(C) of the Sunset Regulations, the Department determined to conduct an expedited, 120-day, review of this order.

In accordance with section 751(c)(5)(C)(v) of the Act, the Department may treat a review as extraordinarily complicated if it is a review of a transition order (i.e., an order in effect on January 1, 1995). On September 7, 1999, the Department determined that the sunset review of the antidumping duty order on EMD from Japan is extraordinarily complicated and extended the time limit for completion of the final results of this review until not later than November 29, 1999, in accordance with section 751(c)(5)(B) of the Act.

Determination

In accordance with section 751(c)(1) of the Act, the Department conducted this review to determine whether revocation of the antidumping duty order would be likely to lead to continuation or recurrence of dumping and the magnitude of the margin of dumping likely to prevail if the order is revoked. The Department’s determinations concerning continuation or recurrence of dumping and the magnitude of the margin are discussed below. In addition, interested parties’ comments with respect to continuation or recurrence of dumping and the magnitude of the margin are addressed within the respective sections below.

Continuation or Recurrence of Dumping

Bulletin providing guidance on methodological and analytical issues, including the bases for likelihood determinations. In its Sunset Policy Bulletin, the Department indicated that determinations of likelihood will be made on an order-wide basis (see section II.A.2). In addition, the Department indicated that normally it will determine that revocation of an antidumping duty order is likely to lead to continuation or recurrence of dumping where: (a) Dumping continued at any level above de minimis after the issuance of the order, (b) imports of the subject merchandise ceased after the issuance of the order, or (c) dumping was eliminated after the issuance of the order and import volumes for the subject merchandise declined significantly (see section II.A.3 of the Sunset Policy Bulletin).

In addition to considering the guidance on likelihood cited above, section 751(c)(4)(B) of the Act provides that the Department shall determine that revocation of an order is likely to lead to continuation or recurrence of dumping where a respondent interested party waives its participation in the sunset review. In the instant review, the Department did not receive a response from any respondent interested party. Pursuant to section 351.218(d)(2)(iii) of the Sunset Regulations, this constitutes a waiver of participation.

In their substantive response, the domestic interested parties argue that revocation of the order on EMD from Japan would be likely to lead to continuation or recurrence of dumping due to the fact that dumping margins above de minimis have been calculated after the issuance of the order and import volumes declined sharply following the imposition of the order.

The domestic interested parties assert that, in administrative reviews conducted after the imposition of the order, the Department calculated margins well above de minimis for Tosoh Corporation (see June 2, 1999, substantive response of the domestic interested parties at 7). They also argue that imports of EMD from Japan fell from approximately 19,000 short tons in 1988, the year before the order was imposed, to approximately 143 short tons in 1989, the year in which the order was imposed. Moreover, the domestic interested parties assert that, since the order was imposed, imports of Japanese EMD have remained at relatively negligible levels (less than one percent of their pre-order volume (see id. at 8)). Therefore, they conclude that the sharp decline in import volumes accompanied by the continued existence of dumping margins above de minimis after the imposition of the order provides a strong indication that dumping would continue or recur if the order is revoked.

The Department agrees, based on an examination of the final results of administrative reviews, that dumping margins above de minimis levels have continued throughout the life of the order. As discussed in section II.A.3 of the Sunset Policy Bulletin, the SAA at 890, and the House Report at 63–64, if companies continue dumping with the discipline of an order in place, the Department may reasonably infer that dumping would continue if the discipline were removed.

With respect to import levels, the Department agrees that imports of the subject merchandise decreased in 1990, the year following the imposition of the order. However, since that time, imports of EMD from Japan have fluctuated greatly, showing no overall trend.4 As explained above, the Department finds that the continued dumping margins after the issuance of the order is highly probative of the likelihood of continuation or recurrence of dumping. A deposit rate above a de minimis level remains in effect for exports of the subject merchandise for at least one known Japanese producer/exporter. Given that dumping has continued over the life of the order and respondent interested parties waived their right to participate in this review before the Department, and absent argument and evidence to the contrary, the Department determines that dumping is likely to continue or recur if the order is revoked.

Magnitude of the Margin

In the Sunset Policy Bulletin, the Department stated that normally it will provide to the Commission the margin that was determined in the final determination in the original investigation. Further, for companies not specifically investigated or for companies that did not begin shipping until after the order was issued, normally the Department will provide a margin based on the “all others” rate from the investigation. (See section II.B.1 of the Sunset Policy Bulletin.) Exceptions to this policy include the use of a more recently calculated margin, where appropriate, and consideration of duty-absorption determinations. (See sections II.B.2 and 3 of the Sunset Policy Bulletin.) To date, the Department has not made any duty-absorption findings in this case.

In their substantive response, the domestic interested parties suggest that the Department adhere to its normal policy and select the margins from the original investigation for Mitsui Mining and Smelting (“Mitsui”) and the “all others” rate. However, they recommend that the Department forward to the Commission the more recently calculated margin from the second administrative review of 77.43 percent for Tosoh Corporation (“Tosoh”). The domestic interested parties point out that Tosoh participated in the first administrative review (1990–91) and received a rate of 20.43 percent, lower than the 71.91 percent margin determined for Tosoh in the original LTFV investigation and antidumping duty order. They argue that Tosoh seemed content with its margin of 20.43 percent and, thus, sought to “lock in” that rate and thereby avoid a possibly higher margin by refusing to participate in the second (1991–92) and third (1992–93) administrative reviews (see June 2, 1999, substantive response of the domestic interested parties at 10).

Therefore, the domestic interested parties argue that the Department should conclude that the dumping margin of 77.43 percent determined in the 1991–92 and 1992–93 reviews most accurately reflects Tosoh’s likely dumping margin should revocation occur.

We agree with the domestic interested parties that we should forward to the Commission the rates for the original investigation for Mitsui and “all others.” As for the margin for Tosoh, the Department disagrees with the domestic interested parties. As noted in the Sunset Regulations and Sunset Policy Bulletin, the Department may provide to the Commission a more recently calculated margin for a particular company where dumping margins increased after the issuance of the order or if that particular company increased dumping to maintain or increase market share. Such circumstances are not present in this case. As noted above, domestic interested parties argued that import volumes actually declined over the life of the order and the domestic interested parties did not provide any argument or evidence that Tosoh was attempting to increase or maintain market share.

Therefore, consistent with the Sunset Policy Bulletin, the Department determines that the margins calculated in the original investigation are appropriate for Japanese producers/exporters of EMD if the order were revoked as they are the only rates

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which reflect the behavior of these producers and exporters without the discipline of the order in place. As such, the Department will report to the Commission the company-specific and “all others” rates from the original investigation as contained in the Final Results of Review section of this notice.

Final Results of Review

As a result of this review, the Department finds that revocation of the antidumping duty order would likely lead to continuation or recurrence of dumping at the margins listed below:

<table>
<thead>
<tr>
<th>Manufacturer/exporter</th>
<th>Margin (percent)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mitsui Mining and Smelting</td>
<td>77.73</td>
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<tr>
<td>(“Mitsui”)</td>
<td></td>
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<tr>
<td>Tosoh Corporation (“Tosoh”)</td>
<td>71.91</td>
</tr>
<tr>
<td>All Others</td>
<td>73.30</td>
</tr>
</tbody>
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This notice serves as the only reminder to parties subject to an administrative protective order ("APO") of their responsibility concerning the disposition of proprietary information disclosed under APO in accordance with 19 CFR 351.305 of the Department’s regulations. Timely notification of return/destruction of APO materials or conversion to judicial sanctionable violation.

Failure to comply with the regulations and the terms of an APO is a failure to comply with the regulations and the terms of an APO is a sanctionable violation.

EFFECTIVE DATE: December 3, 1999.

Statute and Regulations

This review was conducted pursuant to sections 751(c) and 752 of the Act. The Department’s procedures for the conduct of sunset reviews are set forth in Procedures for Conducting Five-year ("Sunset") Reviews of Antidumping and Countervailing Duty Orders, 63 FR 13516 (March 20, 1998) ("Sunset Regulations") and 19 CFR Part 351 (1999) in general. Guidance on methodological or analytical issues relevant to the Department’s conduct of sunset reviews is set forth in the Department’s Policy Bulletin 98:3—Policies Regarding the Conduct of Five-year ("Sunset") Reviews of Antidumping and Countervailing Duty Orders; Policy Bulletin, 63 FR 18871 (April 16, 1998) ("Sunset Policy Bulletin").

Scope

The merchandise subject to this antidumping duty order is electrolytic manganese dioxide ("EMD"). EMD is manganese dioxide (MnO₂) that has been refined in an electrolysis process. The subject merchandise is an intermediate product used in the production of dry-cell batteries. EMD is sold in three physical forms, powder, chip, or plate, and two grades, alkaline and zinc chloride. EMD in all three forms and both grades is included in the scope of the order.

This merchandise is currently classified under the Harmonized Tariff Schedule ("HTS") under number 2820.10.0000. The HTS item number is provided for convenience and customs purposes. The written description remains dispositive.

History of the Order

The Department, in its final determination of sales at less than fair value ("LTFV"), published one company-specific weighted-average dumping margin as well as an "all others" rate (54 FR 8771, March 2, 1989). The antidumping duty order on EMD from Greece was published in the Federal Register on April 17, 1989 (54 FR 15243). On November 16, 1989, after the deadline for submitting comments in this sunset review, the Department published the final results of the only administrative review conducted of this order (64 FR 62169). This sunset review covers imports from all known Greek producers/exporters. To date, the Department has issued no duty absorption findings in this case.

Background

On May 3, 1999, the Department initiated a sunset review of the antidumping duty order on EMD from Greece (64 FR 23596), pursuant to section 751(c) of the Act. The Department received a notice of intent to participate on behalf of Chemetals, Inc. ("Chemetals") and Kerr-McGee Chemical LLC ("KMC") on May 18, 1999, within the deadline specified in section 351.218(d)(1)(i) of the Sunset Regulations. We also received a notice of intent to participate from The Eveready Battery Company ("Eveready") on May 14, 1999. We received complete substantive responses from Chemetals, KMC, and Eveready on June 2, 1999, within the 30-day deadline specified in the Sunset Regulations in section 351.218(d)(3)(i). Both Chemetals and KMC claimed interested-party status pursuant to section 771(9)(A) and 771(9)(C) of the Act as U.S. producers of a like product. Eveready claimed interested-party status pursuant to sections 771(9)(A) and 771(9)(C) as a U.S. importer of the subject merchandise and a producer of a domestic like product. In addition, Chemetals, KMC, and Eveready each stated that they had participated in the original investigation and every segment of the proceeding since the original investigation. On June 7, 1999, we received rebuttal comments from Chemetals, KMC, and Eveready. In its rebuttal comments, Eveready asserted that the joint response of Chemetals and KMC was inadequate and incomplete and should be disregarded along with any rebuttal comments filed by Chemetals and KMC.

On June 9, 1999, Eveready requested that the 500-page rebuttal comments of Chemetals and KMC, which proffered...
lengthy factual and legal analysis never before seen by Eveready or the Department, be stricken from the record. On June 11, 1999, Chemetals and KMC responded that Eveready’s June 9 submission should be stricken from the record but, if maintained, it nevertheless did not provide a basis for striking the rebuttal comments.

On June 22, 1999, we notified the International Trade Commission (“the Commission”) that we did not receive an adequate response (in this case, no response) to our notice of initiation from any respondent interested parties to this proceeding (see Letter to Mr. Lynn Featherstone from Jeffrey A. May, June 22, 1999). As a result, pursuant to section 351.218(e)(1)(ii)(C) of the Sunset Regulations, the Department determined to conduct an expedited, 120-day, review of this order.

In accordance with section 751(c)(5)(C)(v) of the Act, the Department may treat a review as extraordinarily complicated if it is a review of a transition order (i.e., an order in effect on January 1, 1995). On September 7, 1999, the Department determined that the sunset review of the antidumping duty order on EMD from Greece is extraordinarily complicated and extended the time limit for completion of the final results of this review until not later than November 29, 1999, in accordance with section 751(c)(5)(B) of the Act.\(^1\)

### Adequacy

As noted above, on June 22, 1999, we notified the Commission that we determined to conduct an expedited review of this order on the basis that we had not received an adequate response (in this case, no response) to our notice of initiation from any respondent interested party. On July 12, 1999, within the deadline provided in section 351.309(e)(ii) of the Sunset Regulations. Eveready argued that the Department erred when it stated that it had received “no response” from respondent interested parties because Eveready filed its substantive response not only as a producer in the United States of a domestic like product (under section 771(9)(C) of the Act) but also as a United States importer of the subject merchandise (under section 771(9)(A) of the Act). Further, Eveready argued that its response should be considered adequate despite the fact that it did not provide the additional information required by subparagraphs (A) through (E) of section 351.218(d)(3)(iii) of the Sunset Regulations to be submitted by respondent interested parties. Eveready supports this argument by asserting that these subparagraphs are not applicable to Eveready because they are intended for foreign exporters of the subject merchandise (the second type of respondent interested party under the regulations). However, Eveready adds that it nonetheless provided information in its response identifying the dumping margin in effect, as well as the volume and value of Greek exports of EMD by quarter and year from 1983 to the present. Eveready also states that although it is not a foreign exporter of the subject merchandise, the statistics it provided in its response shows that it purchased all of the exports of EMD from Greece in 1998 and 1999. Further, Eveready asserts that it purchased 94 percent of the total imports of EMD from Greece for the past five years. On this basis, Eveready argues that the Department should reverse its erroneous decision and conduct a full sunset review.

We also received comments from Chemetals and KMC on July 12, 1999, concerning the adequacy of response to the notice of initiation and the appropriateness of an expedited review. Chemetals and KMC supported the Department’s determination to conduct an expedited review and referred to their rebuttal comments for specific argument. Specifically, Chemetals and KMC asserted that the Department correctly determined to conduct an expedited review on the basis that: (1) Tosoh Hellas A.I.C. (“Tosoh Greece”), the sole manufacturer in Greece of the subject merchandise, did not respond; (2) Eveready’s response did not provide the information required of a U.S. importer; (3) Eveready, despite its assertion, is not a U.S. importer of the subject merchandise; (4) the Department did not receive complete substantive responses from respondent interested parties accounting on average for more than 50 percent of the total exports of the subject merchandise; and (5) Eveready’s response was non-responsive to the information requested in the Department’s notice of initiation.

On September 14, 1999, Eveready again requested that the Department reconsider its determination to conduct an expedited review. On September 23, 1999, Chemetals and KMC responded, arguing that the time for filing comments had expired and, therefore, Eveready’s submission should be rejected and no action taken.

We agree with Chemetals and KMC that we should conduct an expedited review in this case. Section 351.218(e)(1)(ii)(C) of the Sunset Regulations provides that normally the Department will conduct an expedited review in accordance with section 751(c)(3)(B) of the Act where the Secretary determines that respondent interested parties provided inadequate response to a notice of initiation. Although Eveready argues that certain information requirements are not applicable to Eveready as an importer, the Department’s regulations make no such exception. Furthermore, although it is possible that the Department may have considered Eveready’s information requirement arguments in determining whether Eveready’s substantive response was complete, the fact is that Eveready never attempted to explain this position in its substantive response. By failing to provide the required information in subparagraphs (A) through (E) of section 351.218(d)(3)(iii), or even to explain its rationale for not providing such information, Eveready’s response cannot be considered complete and, hence, cannot be considered adequate.

In their rebuttal comments, as well as in subsequent submissions, Chemetals and KMC argue that Eveready does not qualify as an interested party under section 771(9)(A) of the Act because it is, in fact, not an importer of subject merchandise. Rather, they contend, Eveready is a U.S. purchaser of the imported material. In support of this argument, Chemetals and KMC refer to the July 7, 1998, questionnaire response of Tosoh Greece in the 1997/98 administrative review in which Tosoh Greece stated that Mitsubishi International Corporation is its importer and reseller of EMD in the U.S. market. In its comments on the Department’s adequacy determination, Eveready does not dispute the comments of Chemetals and KMC regarding that Eveready is not a U.S. importer.

As we noted in Final Results of Full Sunset Review: Sugar from the European Community, 64 FR 49464 (September 13, 1999), adequacy determinations are made for the purpose of determining whether there is sufficient participation to warrant a full review. In this case, because we received an incomplete response from the one party claiming respondent interested-party status and we did not receive a response from any other party claiming respondent interested-party status, we continue to determine that we received inadequate respondent interested-party participation to warrant a full review.

### Determination

In accordance with section 751(c)(1) of the Act, the Department conducted
Bulletin methodological and analytical issues, at any level above to continuation or recurrence of antidumping duty order is likely to lead will determine that revocation of an order is likely to prevail if the order is revoked. The Department’s determinations concerning continuation or recurrence of dumping and the magnitude of the margin are discussed below. In addition, interested parties’ comments with respect to continuation or recurrence of dumping and the magnitude of the margin are addressed within the respective sections below.

Continuation or Recurrence of Dumping

Drawing on the guidance provided in the legislative history accompanying the Uruguay Round Agreements Act (“URAA”), specifically the Statement of Administrative Action (“the SAA”), H.R. Doc. No. 103–316, vol. 1 (1994), the House Report, H.R. Rep. No. 103–826, pt. 1 (1994), and the Senate Report, S. Rep. No. 103–412 (1994), the Department issued its Sunset Policy Bulletin providing guidance on methodological and analytical issues, including the bases for likelihood determinations. In its Sunset Policy Bulletin, the Department indicated that determinations of likelihood will be made on an order-wide basis (see section II.A.2). In addition, the Department indicated that normally it will determine that revocation of an antidumping duty order is likely to lead to continuation of dumping where (a) Dumping continued at any level above de minimis after the issuance of the order, (b) imports of the subject merchandise ceased after the issuance of the order, or (c) dumping was eliminated after the issuance of the order and import volumes for the subject merchandise declined significantly (see section II.A.3 of the Sunset Policy Bulletin).

In addition to considering the guidance on likelihood cited above, section 751(c)(4)(B) of the Act provides that the Department shall determine that revocation of an order is likely to lead to continuation of dumping where a respondent interested party waives its participation in the sunset review. In the instant review, the Department did not receive a complete substantive response from respondent interested parties. Pursuant to section 351.218(d)(2)(iii) of the Sunset Regulations, this constitutes a waiver of participation.

In their substantive response, Chemetals and KMC argue that revocation of the order on EMD from Greece would be likely to lead to continuation or recurrence of dumping due to the fact that dumping margins above de minimis remain in place and import volumes declined sharply following the imposition of the order. Specifically, Chemetals and KMC assert that imports of EMD from Greece fell from approximately 97 short tons in 1988, the year before the order was imposed, to zero short tons in 1990, the first full year following the imposition of the order. Moreover, Chemetals and KMC assert that no EMD was imported from Greece from 1997 to 1996. Finally, they argue that, since 1997, imports of Greek EMD have remained at relatively negligible levels (see June 2, 1999, substantive response from Chemetals and KMC at 9). Therefore, Chemetals and KMC conclude that the sharp decline in import volumes following the imposition of the order accompanied by the continued existence of dumping margins above de minimis provides a strong indication that dumping would continue or recur if the order is revoked.

In its substantive response, Eveready argues that the likely effect of revocation of the order would be that dumping would not continue or recur (see June 2, 1999, substantive response of Eveready at 48). Eveready bases its argument on several factors. For one, Eveready argues that market forces have changed dramatically since the order was imposed in 1989 (see id. at 5). Furthermore, Eveready maintains that the technological revolution, including the growth of portable electronics, has caused the demand for batteries, and, hence, EMD, to grow quickly (see id. at 5–6). Eveready argues further that battery manufacturers have had to adjust to these changes and provide this rapidly evolving market with smaller portable power sources that can handle the rigorous demands of the new high-drain technologies. Eveready maintains that the batteries used to power these portable devices are the AA and AAA-size alkaline batteries which last longer and, as a result, require a higher-quality EMD, referred to as “high quality” or “high-drain” EMD, in their production (see id. at 6). Eveready maintains that EMD produced by Chemetals does not qualify, despite nearly two years’ effort. Further, with respect to foreign manufacturers, Eveready states that the only firms that it has either qualified or appear to be able to be qualified are those in Japan, Greece, and Ireland (see id. at 7).

Moreover, Eveready argues that the Greek producers of EMD need not dump their product in the U.S. market because they already have market share and already sell all the EMD they produce (see id. at 7–8). While Eveready agrees that imports of EMD from Greece declined after the issuance of the order and by 1990 ceased altogether, Eveready asserts that the decline in import volumes was due to the fact that Greece did not produce any EMD that was usable in the U.S. market, not due to the imposition of the order (see id. at 24–25).

In their rebuttal, Chemetals and KMC assert that nowhere in Eveready’s submission is specific evidence or good cause shown as to why the revocation of the order would not result in continuation or recurrence of dumping. They argue that there have not been significant changed circumstances since the time of the original investigation. Chemetals and KMC maintain that the growth in AA and AAA battery use does not constitute changed circumstances because this trend has not led to a corresponding increase in the number of AA and AAA batteries produced (see June 7, 1999, rebuttal of Chemetals and KMC, Appendix B, at 13). In sum, Chemetals and KMC rebut Eveready’s statement that revocation of the order would not lead to continuation or recurrence of dumping while also maintaining that changed circumstances have not been demonstrated in this case.

In its rebuttal, Eveready argues that the fact that antidumping duties were paid on shipments of the subject merchandise from Greece does not lead automatically to the conclusion that dumping continued at levels above de minimis following the imposition of the order (see June 7, 1999, rebuttal of Eveready at 6). Moreover, Eveready rebuts the arguments of Chemetals and KMC that the cessation of imports of EMD from Greece following the imposition of the order provides a strong indication that dumping would continue or recur were the order revoked (see id. at 7). Furthermore, Eveready claims that import volumes provided by Chemetals and KMC in their substantive response are misleading because they are reported in short tons, as opposed to metric tons. In addition, Eveready maintains that the claim by Chemetals and KMC that the cessation of imports was due solely to the antidumping duty order overlooks
the changing market place and the shift in battery production (see id. at 7).

With respect to import levels, the Department agrees that imports of the subject merchandise ceased in 1990, the year following the imposition of the order. Imports remained at zero until 1997. Since that time, imports of EMD from Greece have been negligible. The final results of the 1997–98 administrative review were not issued until November 16, 1999; however, the results were consistent with the preliminary results on which interested parties based their arguments. While the final results reflected a zero dumping margin for Tosoh Greece, the analysis was based on minimal exports, as acknowledged by all interested parties. Therefore, the cessation of dumping occurred at the expense of exports of the subject merchandise from Greece.

Based on this analysis, the Department finds that the sharp decline in imports is highly probative of the likelihood of continuation or recurrence of dumping. Given that import volumes ceased for a period of time following the imposition of the order and have since been negligible and respondent interested parties waived their right to participate in this review before the Department, the Department determines that dumping is likely to continue or recur if the order is revoked. Because we are basing our determination on the fact that import volumes sharply declined following the imposition of the order, we have not addressed Eveready’s arguments regarding changed circumstances as a basis for revocation.

Magnitude of the Margin

In the Sunset Policy Bulletin, the Department stated that it will normally provide to the Commerce the margin that was determined in the final determination in the original investigation. Further, for companies not specifically investigated or for companies that did not begin shipping until after the order was issued, the Department normally will provide a margin based on the “all others” rate from the investigation. (See section II.B.1 of the Sunset Policy Bulletin.) Exceptions to this policy include the use of a more recently calculated margin, where appropriate, and consideration of duty absorption determinations. (See sections II.B.2 and 3 of the Sunset Policy Bulletin.) To date, the Department has not made any duty absorption findings in this case.

In their substantive response, Chemetals and KMC suggest that the Department adhere to its normal policy and select the margins from the original investigation. They therefore recommend that the Department forward the rates of 36.72 percent for Tosoh and 36.72 percent for all others from the original investigation (see June 2, 1999, substantive response of Chemetals and KMC at 11).

Eveready asserts that the dumping margin would disappear if the order were revoked (see June 2, 1999, substantive response of Eveready at 48). Eveready cites as support for its argument the preliminary results of the 1997–1998 administrative review conducted by the Department, in which the dumping margin was found to be zero for Tosoh.

In their rebuttal, Chemetals and KMC state that Eveready does not challenge the Department’s normal practice of forwarding margins from the original investigation, but instead contends that a zero margin should apply since, in the currently pending administrative review for 1997–1998, the Department preliminarily determined that sales by Tosoh (Greece) were not made below fair value. However, citing to the sunset review of the order on frozen concentrated orange juice from Brazil, Chemetals and KMC point out that the Department has refused to base its margin recommendation on preliminary results of ongoing administrative reviews. Eveready, in its rebuttal, argues that Chemetals and KMC have not provided any factual evidence regarding why the margins from the original investigation should be forwarded to the Commission. The Department agrees with Chemetals and KMC that we should forward to the Commission the rates from the original investigation for Tosoh and “all others.” The Department notes that although in the 1997–1998 administrative review it calculated a weighted-average dumping margin of zero for Tosoh, this margin was based on minimal exports of the subject merchandise. As acknowledged by Chemetals, KMC, and Eveready, imports of the subject merchandise from Greece fell sharply following the imposition of the order and have not regained their pre-order levels.

Therefore, consistent with the Sunset Policy Bulletin, the Department determines that the margins calculated in the original investigation are probative of the behavior of Greek producers/exporters of EMD if the order were revoked as it is the only rate that reflects the behavior of these producers and exporters without the discipline of the order. As such, the Department will report to the Commission the company-specific and “all others” rates from the original investigation as contained in the Final Results of Review section of this notice.

Final Results of Review

As a result of this review, the Department finds that revocation of the antidumping duty order would likely lead to continuation or recurrence of dumping at the margins listed below:

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This notice serves as the only reminder to parties subject to administrative protective order (“APO”) of their responsibility concerning the disposition of proprietary information disclosed under APO in accordance with 19 CFR 351.305 of the Department’s regulations. Timely notification of return/destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and terms of an APO is a sanctionable violation.

This five-year (“sunset”) review and notice are in accordance with sections 751(c), 752, and 777(i)(1) of the Act.


Richard W. Moreland,
Acting Assistant Secretary for Import Administration.

[FR Doc. 99–31433 Filed 12–2–99; 8:45 am]
BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[570–848]

Notice of Extension of Time Limit for Final Results of the Antidumping Administrative Review and New-Shipper Reviews: Freshwater Crawfish Tail Meat From the People’s Republic of China

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

Therefore, in accordance with these sections, the Department is extending the time limits for the final results to April 9, 2000.

This extension of time limits is in accordance with section 751(a)(3)(A) of the Act, and 19 CFR 351.213(h)(2) of the Department’s regulations.

Dated: November 19, 1999.

Joseph A. Spetrini,
Deputy Assistant Secretary for AD/CVD Enforcement III.

[FR Doc. 99–31414 Filed 12–2–99; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration


Final Results of Expedited Sunset Reviews: Granular Polytetrafluoroethylene Resin From Italy and Japan

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

ACTION: Notice of final results of expedited sunset reviews: Granular polytetrafluoroethylene resin from Italy and Japan.

SUMMARY: On May 3, 1999, the Department of Commerce (“the Department”) initiated sunset reviews of the antidumping duty orders on granular polytetrafluoroethylene resin (“PTFE”) from Italy and Japan (64 FR 23596) pursuant to section 751(c) of the Tariff Act of 1930, as amended (“the Act”). On the basis of notices of intent to participate and adequate substantive comments filed on behalf of domestic interested parties and inadequate response (in these cases, no response) from respondent interested parties, the Department determined to conduct expedited reviews. As a result of these reviews, the Department finds that revocation of the antidumping duty orders would be likely to lead to continuation or recurrence of dumping at the levels indicated in the Final Results of Reviews section of this notice.

FOR FURTHER INFORMATION CONTACT: Darla D. Brown or Melissa G. Skinner, Office of Policy for Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW, Washington, D.C. 20230; telephone: (202) 482–3207 or (202) 482–1560, respectively.

EFFECTIVE DATE: December 3, 1999.

Statute and Regulations


Scope

The merchandise subject to these antidumping duty orders is PTFE from Italy and Japan. The subject merchandise is defined as granular PTFE resin, filled or unfilled. The order explicitly excludes PTFE dispersions in water and PTFE fine powders. Such merchandise is currently classifiable under the Harmonized Tariff Schedule (HTS) item number 3904.61.00. This HTS item number is provided for convenience and customs purposes only. The written description remains dispositive.

There has been one scope ruling with respect to the order on PTFE from Japan in which reprocessed PTFE powder was determined to be outside the scope of the order (57 FR 57420; December 4, 1992). The Department issued a circumvention determination in which it determined that PTFE wet raw polymer exported from Italy to the United States falls within the scope of the order on PTFE from Italy (58 FR 26100; April 30, 1993). These reviews cover imports from all manufacturers and exporters of PTFE from Italy and Japan.

History of the Orders

Italy

The Department published its final affirmative determination of sales at less than fair value (“LTFV”) with respect to imports of PTFE from Italy on July 11, 1988 (53 FR 26196). In this determination, the Department published a weighted-average dumping margin for one company as well as an
Background

On May 3, 1999, the Department initiated sunset reviews of the antidumping duty orders on PTFE from Italy and Japan (64 FR 23596), pursuant to section 751(c) of the Act. For both of the reviews, the Department received a notice of intent to participate on behalf of E.I. DuPont de Nemours & Company (“DuPont”), on May 18, 1999, within the deadline specified in section 351.218(d)(1)(i) of the Sunset Regulations. Pursuant to section 771(9)(C) of the Act, DuPont claimed interested party status as a domestic producer of the subject merchandise. The Department received complete substantive responses from DuPont on May 28, 1999, within the 30-day deadline specified in the Sunset Regulations under section 351.218(d)(3)(i). We did not receive a substantive response from any respondent interested party to these proceedings. As a result, pursuant to 19 CFR 351.218(e)(1)(iii)(C), the Department determined to conduct expedited, 120-day reviews of these orders.

In accordance with section 751(c)(5)(C)(v) of the Act, the Department may treat a review as extraordinarily complicated if it is a review of a transition order (i.e., an order in effect on January 1, 1995). On September 7, 1999, the Department determined that the sunset reviews of the antidumping duty orders on PTFE from Italy and Japan are extraordinarily complicated and extended the time limit for completion of the final results of these reviews until not later than November 29, 1999, in accordance with section 751(c)(5)(B) of the Act. The Department’s determinations concerning continuation or recurrence of dumping and the magnitude of the margins are discussed below. In addition, DuPont’s comments with respect to continuation or recurrence of dumping and the magnitude of the margins are addressed within the respective sections below.

Continuation or Recurrence of Dumping

Drawing on the guidance provided in the legislative history accompanying the Uruguay Round Agreements Act (“URAA”), specifically the Statement of Administrative Action (“the SAA”), H.R. Doc. No. 103–316, vol. 1 (1994), the House Report, H.R. Rep. No. 103–826, pt. 1 (1994), and the Senate Report, S. Rep. No. 103–412 (1994), the Department issued its Sunset Policy Bulletin providing guidance on methodological and analytical issues, including the bases for likelihood determinations. In its Sunset Policy Bulletin, the Department indicated that determinations of likelihood will be made on an order-wide basis (see section II.A.2). In addition, the Department indicated that it normally will determine that revocation of an antidumping duty order is likely to lead to continuation or recurrence of dumping where: (a) Dumping continued at any level above de minimis after the issuance of the order, (b) imports of the subject merchandise ceased after the issuance of the order, or (c) dumping was eliminated after the issuance of the order and import volumes for the subject merchandise declined significantly (see section II.A.3). In addition to considering the guidance on likelihood cited above, section 751(c)(4)(B) of the Act provides that the Department shall conclude that revocation of the order would be likely to lead to continuation or recurrence of dumping where an interested party waives its participation in the sunset review. In these instant reviews, the Department did not receive a substantive response from any respondent interested party. Pursuant to section 351.218(d)(2)(iii) of the of the Sunset Regulations, this constitutes a waiver of participation.

Italy

In its substantive response, DuPont argues that revocation would likely lead to continuation or recurrence of dumping because dumping has continued over the life of the order at levels well above de minimis and that import volumes significantly after the issuance of the order. DuPont points out that, in the most recent

1 See Granular Polytetrafluoroethylene Resin from Italy: Final Results of Antidumping Duty Administrative Review, 55 FR 50834 (December 11, 1990); Granular Polytetrafluoroethylene Resin from Italy: Final Results of Antidumping Duty Administrative Review, 65 FR 38031 (November 15, 1991); Granular Polytetrafluoroethylene Resin from Italy: Final Results of Antidumping Duty Administrative Review, 60 FR 19884 (April 21, 1995); Granular Polytetrafluoroethylene Resin from Italy: Final Results of Antidumping Duty Administrative Review, 60 FR 53737 (October 17, 1995); Granular Polytetrafluoroethylene Resin from Italy: Final Results of Antidumping Duty Administrative Review, 61 FR 25195 (May 20, 1996); Granular Polytetrafluoroethylene Resin from Italy: Final Results of Antidumping Duty Administrative Review, 62 FR 53980 (February 6, 1997); as amended, Granular Polytetrafluoroethylene Resin from Italy: Amended Final Results of Antidumping Duty Administrative Review, 62 FR 23219 (April 29, 1997); Granular Polytetrafluoroethylene Resin from Italy: Final Results of Antidumping Duty Administrative Review, 62 FR 48592 (September 16, 1997); Notice of Final Results of Antidumping Duty Administrative Review: Granular Polytetrafluoroethylene Resin from Italy, 63 FR 49080 (September 14, 1998).

2 See Granular Polytetrafluoroethylene Resin from Japan: Final Results of Antidumping Duty Administrative Review, 58 FR 50143 (September 27, 1993); Granular Polytetrafluoroethylene Resin from Japan: Final Results of Antidumping Duty Administrative Review, 60 FR 13186 (June 27, 1995); Granular Polytetrafluoroethylene Resin from Japan: Final Results of Antidumping Duty Administrative Review, 61 FR 2489 (January 26, 1996).

3 See Extension of Time Limit for Final Results of Five-Year Reviews, 64 FR 48579 (September 7, 1999).
administrative review, the dumping margin for Ausimont S.p.A., an Italian manufacturer/exporter of the subject merchandise, was calculated to be 45.72 percent, a significant increase from the margin of 5.95 percent determined in the preceeding administrative review (see May 28, 1999, substantive response of DuPont at 6). Moreover, DuPont argues that the post-order decline in import volumes provides further strong support for a determination that dumping is likely to continue or recur should the order be revoked. To support its argument DuPont pointed out that imports of PTFE from Italy declined by over 43 percent between 1987, the year preceding the order, and 1990, the second year following the order (see id. at 6–7).

Japan

DuPont makes similar arguments regarding the likely effect of revocation of the Japanese order. Indeed, DuPont again argues that because dumping has continued over the life of the order at levels well above de minimis and import volumes declined significantly after the issuance of the order, the Department should determine that revocation of the order would likely lead to continuation or recurrence of dumping. DuPont points out that dumping margins levels significantly above de minimis have been found in the three administrative reviews conducted by the Department. DuPont also maintains that PTFE imports from Japan decreased by over 78 percent between 1987, the year preceding the issuance of the order, and 1990, the second year following the order (see May 28, 1999, substantive response of DuPont at 5–6).

As discussed in Section II.A.3 of the Sunset Policy Bulletin, the SAA at 890, and the House Report at 63–64, if companies continue to dump with the discipline of an order in place, the Department may reasonably infer that dumping would continue if the discipline were removed. As pointed out above, dumping margins above de minimis continue to exist for shipments of the subject merchandise from Italy and Japan.

Consistent with section 752(c) of the Act, the Department also considers the volume of imports before and after issuance of the order. As demonstrated in each respective section above, DuPont argues that a significant decline in the volume of imports of the subject merchandise from Italy and Japan since the imposition of the orders provides further evidence that dumping would continue if the orders were revoked. Moreover, as mentioned above, in its substantive responses, DuPont provides statistics demonstrating the decline in import volumes of PTFE from Italy and Japan.

Using the Department’s statistics, including IM146 reports, on imports of the subject merchandise from these countries, we agree with the domestic interested parties’ assertions that imports of the subject merchandise declined after the orders were imposed and have not regained pre-order volumes.

As noted above, in conducting its sunset reviews, pursuant to section 752(c) of the Act, the Department considers the weighted-average dumping margins and volume of imports before and after the imposition of the order when determining whether revocation of an antidumping duty order would lead to the continuation or recurrence of dumping. Based on this analysis, the Department finds that the existence of dumping margins above de minimis levels and a reduction in import volumes after the issuance of the orders is highly probative of the likelihood of continuation or recurrence of dumping. A deposit rate above a de minimis level continues in effect for imports of the subject merchandise from at least one Italian and one Japanese manufacturer/exporter. Therefore, given that dumping has continued over the life of the orders, import volumes declined significantly after the imposition of the orders, respondent parties waived participation, and absent argument and evidence to the contrary, the Department determines that dumping is likely to continue if the orders were revoked.

Magnitude of the Margin

In the Sunset Policy Bulletin, the Department stated that it normally will provide to the Commission the margin that was determined in the final determination in the original investigation. Further, for companies not specifically investigated or for companies that did not begin shipping until after the order was issued, the Department normally will provide a margin based on the “all others” rate from the investigation. (See section II.B.1 of the Sunset Policy Bulletin.) Exceptions to this policy include the use of a more recently calculated margin, where appropriate, and consideration of duty absorption determinations. (See sections II.B.2 and 3 of the Sunset Policy Bulletin.) To date, the Department has not issued any duty-absorption findings in either of these cases.

In their substantive responses, DuPont recommends that, consistent with the Sunset Policy Bulletin, Department provide to the Commission the company-specific margins from the original investigations. Moreover, regarding companies not reviewed in the original investigation, DuPont suggested that the Department report the “all others” rates included in the original investigations.

The Department agrees with DuPont. The Department finds that the margins calculated in the original investigation are probative of the behavior of Italian and Japanese producers and/or exporters if the orders were revoked as they are the only margins which reflect their behavior without the discipline of the order in place. Therefore, the Department will report to the Commission the company-specific and “all others” rates from the original investigations as contained in the Final Results of Reviews section of this notice.

Final Results of Reviews

As a result of these reviews, the Department finds that revocation of the antidumping duty orders would likely lead to continuation or recurrence of dumping at the margins listed below:

<table>
<thead>
<tr>
<th>Manufacturer/exporter</th>
<th>Margin (percent)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Montefluos S.P.A./Ausimont</td>
<td>46.46</td>
</tr>
<tr>
<td>U.S.A.</td>
<td>46.46</td>
</tr>
<tr>
<td>All Others</td>
<td>46.46</td>
</tr>
</tbody>
</table>

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Japan</td>
<td></td>
</tr>
<tr>
<td>Daikin Industries, Inc.</td>
<td>103.00</td>
</tr>
<tr>
<td>Asahi Fluoropolymers Co., Ltd.</td>
<td>51.45</td>
</tr>
<tr>
<td>All Others</td>
<td>91.74</td>
</tr>
</tbody>
</table>

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These five-year (“sunset”) reviews and notices are in accordance with sections 751(c), 752, and 777(i)(1) of the Act.

Dated: November 24, 1999.

Joseph A. Spetrini,
Acting Assistant Secretary for Import Administration.
Final Results of Expedited Sunset Review: Light-Walled Rectangular Pipe and Tube From Singapore

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

**ACTION:** Notice of final results of Expedited Sunset Review: Light-walled rectangular pipe and tube from Singapore.

**SUMMARY:** On May 3, 1999, the Department of Commerce (the “Department”) initiated a sunset review of the antidumping order on light-walled rectangular pipe and tube from Singapore (64 FR 23596) pursuant to section 751(c) of the Tariff Act of 1930, as amended (the “Act”). On the basis of a notice of intent to participate and adequate substantive response filed on behalf of domestic interested parties and inadequate response (in this case, no response) from respondent interested parties, the Department determined to conduct an expedited sunset review. As a result of this review, the Department finds that revocation of the antidumping duty order would be likely to lead to continuation or recurrence of dumping at the levels indicated in the Final Result of Review section of this notice.

**FOR FURTHER INFORMATION CONTACT:** Eun W. Cho or Melissa G. Skinner, Office of Policy for Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, D.C. 20230; telephone: (202) 482-1698 or (202) 482-1560, respectively.

**EFFECTIVE DATE:** December 3, 1999.

**Statute and Regulations**


**Scope**

The subject merchandise under consideration is light-walled rectangular pipes and tubes (“rectangular pipes”) from Singapore, which are mechanical pipes and tubes or welded carbon steel pipes and tubes of rectangular (including square) cross-section, having a wall thickness of less than 0.156 inch. Light-walled rectangular pipes and tubes are currently classifiable under item number 7306.60.5000 of the Harmonized Tariff Schedule of the United States (“HTSUS”). The HTSUS item number is provided for convenience and customs purposes only. The written product description of the scope of this order remains dispositive.

**History of the Order**

The antidumping duty order on light-walled rectangular pipes and tubes from Singapore was published in the Federal Register on November 13, 1986 (51 FR 41142). In that order, the Department determined that the weighted-average dumping margins for Steel Tubes of Singapore, Ltd. (“PTE”) as well as for all others are 12.03 percent. The Department has not conducted any administrative review since that time. We note that the Department has not conducted any investigation with respect to duty absorption regarding the exports of the subject merchandise. The order remains in effect for all manufacturers and exporters of the subject merchandise.

**Background**

On May 3, 1999, the Department initiated a sunset review of the antidumping duty order on rectangular pipes from Singapore (64 FR 23596) pursuant to section 751(c) of the Act. The Department received, on May 3, 1999, a Notice of Intent to Participate on behalf of members of The Committee on Pipe and Tube Imports (“CPTI”) within the deadline specified in section 351.218(d)(3)(i) of the Sunset Regulations. In its Notice of Intent to Participate, the CPTI notes that none of its members is related to foreign producers and exporters, nor are any of its members an importer of the subject merchandise within the meaning of 771(9)[B] of the Act. The members of the CPTI claimed interest party status under section 771(9)[C] of the Act as producers and manufacturers of the domestic like product.

We received a complete substantive response from the CPTI on June 2, 1999, within the 30-day deadline specified in the Sunset Regulations under section 351.218(d)(3)(i). In its substantive response, the CPTI noted that it participated in the original investigation. (See June 2, 1999, Substantive Response of the CPTI at 2.)

We did not receive a substantive response from any respondent interested parties to this proceeding. Consequently, pursuant to section 351.218(e)(1)(ii)(C) of the Sunset Regulations, the Department determined to conduct an expedited, 120-day, review of this order.

In accordance with section 751(c)(5)(C)(v) of the Act, the Department may treat a review as extraordinarily complicated if it is a review of a transition order (i.e., an order in effect on January 1, 1995). Therefore, on September 7, 1999, the Department determined that the sunset reviews of the antidumping duty order on rectangular pipes from Singapore are extraordinarily complicated and extended the time limit for completion of the final results of these reviews until not later than November 29, 1999, in accordance with section 751(c)(5)(B) of the Act.

**Determination**

In accordance with section 751(c)(1) of the Act, the Department conducted this review to determine whether revocation of the antidumping order would be likely to lead to continuation or recurrence of dumping. Section 752(c) of the Act provides that, in making this determination, the Department shall consider the weighted-average dumping margins determined in the investigation and subsequent reviews and the volume of imports of the subject merchandise for the period before and the period after the issuance of the antidumping order, and shall provide to the International Trade Commission (“the Commission”) the magnitude of the margin of dumping likely to prevail if the order is revoked.

The Department’s determinations concerning continuation or recurrence of dumping and the magnitude of the margin are discussed below. In addition, the CPTI’s comments with respect to continuation or recurrence of dumping and the magnitude of the margin are...
addressed within the respective sections below.

Continuation or Recurrence of Dumping

Drawing on the guidance provided in the legislative history accompanying the Uruguay Round Agreements Act ("URAA"), specifically the Statement of Administrative Action ("the SAA"), H.R. Doc. No. 103–316, vol. 1 (1994), the House Report, H.R. Rep. No. 103–826, pt.1 (1994), and the Senate Report, S. Rep. No. 103–412 (1994), the Department issued its Sunset Policy Bulletin providing guidance on methodological and analytical issues, including the bases for likelihood determinations. In its Sunset Policy Bulletin, the Department indicated that determinations of likelihood will be made on an order-wide basis (see section II.A.2). In addition, the Department indicated that normally it will determine that revocation of an antidumping order is likely to lead to continuation or recurrence of dumping where: (a) Dumping continued at any level above de minimis after the issuance of the order, (b) imports of the subject merchandise ceased after the issuance of the order, or (c) dumping was eliminated after the issuance of the order and import volumes for the subject merchandise declined significantly (see section II.A.3).

In addition to considering the guidance on likelihood cited above, section 751(c)(4)(B) of the Act provides that the Department shall determine that revocation of an order is likely to lead to continuation or recurrence of dumping where a respondent interested party waives its participation in the sunset review. In the instant review, the Department did not receive a response from any respondent interested party. Pursuant to section 351.218(d)(2)(iii) of the Sunset Regulations, this constitutes a waiver of participation.

In its substantive response, the CPTI argues that revocation of the antidumping order will result in resumption of sales of the subject merchandise at less-than-fair value by margins equivalent to or greater than those found in the original investigation. (See, June 2, 1999 Substantive Response of the CPTI at 2 & 3.) While arguing that a cessation of imports after the issuance of an antidumping order is highly probative of the likelihood of continuation or recurrence of dumping, the CPTI provided data which indicate that imports of the subject merchandise ceased after the issuance of the

antidumping duty order. Based on the aforementioned data, the CPTI asserts that imports of the subject merchandise have ceased since the issuance of the antidumping duty order, and therefore the Department should find that dumping is likely to recur or continue should the order be revoked. Id.

According to U.S. International Trade Commission Trade Data, which integrates tariff and trade data from the Department, the U.S. Treasury, and the U.S. International Trade Commission, soon after the issuance of the antidumping order, the volume of imports of the subject merchandise fell drastically—the average volume of imports of the subject merchandise between 1989 and 1991 is 37 metric tons. This is less than 1.5 percent of 1985 pre-order volume of over 2700 metric ton. Furthermore, the volume of imports of the subject merchandise for the period of seven years, 1992–1998, is zero. As a result, the Department agrees with the CPTI’s claim that, after the issuance of the order, imports of the subject merchandise ceased.

As noted above, the Department normally will determine that the cessation of imports after the issuance of the order is highly probative of the likelihood of continuation or recurrence of dumping.

In conclusion, inasmuch as the respondent interested parties waived their right to participate in this review, the deposit rates continue to exist, and imports of the subject merchandise ceased after the imposition of the order, we find that revocation of the antidumping order would be likely to lead to continuation or recurrence of dumping.

Magnitude of the Margin

In the Sunset Policy Bulletin, the Department stated that it normally will provide to the Commission the margin that was determined in the final determination in the original investigation. Further, for companies not specifically investigated or for companies that did not begin shipping until after the order was issued, the Department normally will provide a margin based on the all-others rate from the investigation. (See section II.B.1 of the Sunset Policy Bulletin.) Exceptions to this policy include the use of a more recently calculated margin, where appropriate, and consideration of duty absorption determinations. (See sections II.B.2 and 3 of the Sunset Policy Bulletin.)

The Department, in its notice of the antidumping duty order on rectangular pipes from Singapore, established both company-specific and all-others weighted-average dumping margins of 12.03 percent for all imports of the subject merchandise from Singapore (51 FR 41142, November 13, 1986). We note that, to date, the Department has not issued any duty absorption findings in this case.

The CTPI urges the Department to determine that the magnitude of the dumping margins that are likely to prevail, if the order is revoked, should be those from the original investigation. (See the CPTI’s June 2, 1999, substantive response.) We agree with the CTPI. Absent argument and evidence to the contrary, we find the margins calculated in the original investigation are probative of the behavior of Singaporean producers/exporters if the order were revoked, as those are the only margins which reflect the behavior of Singaporean producers/exporters absent the discipline of the order. Therefore, we will report to the Commission the company-specific and all-others margins reported in the Final Results of Review section of this notice.

Final Results of Review

Based on the above analysis, the Department finds that revocation of the antidumping order would likely lead to continuation or recurrence of dumping at the margins listed below:

<table>
<thead>
<tr>
<th>Manufacturer/exporter</th>
<th>Margin (percent)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Steel Tubes of Singapore (PTE), Ltd.</td>
<td>12.03</td>
</tr>
<tr>
<td>All others</td>
<td>12.03</td>
</tr>
</tbody>
</table>

This notice serves as the only reminder to parties subject to administrative protective order ("APO") of their responsibility concerning the disposition of proprietary information disclosed under APO in accordance with 19 CFR 351.305 of the Department’s regulations. Timely notification of return/destuction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and the terms of an APO is a sanctionable violation.

This five-year ("sunset") review and notice are in accordance with sections 751(c), 752, and 777(i)(1) of the Act.
DEPARTMENT OF COMMERCE
International Trade Administration

Final Results of Expedited Sunset Review: Light-Walled Welded Rectangular Carbon Steel Tubing From Argentina

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

ACTION: Notice of final results of expedited Sunset Review: Light-walled welded rectangular carbon steel tubing from Argentina.

SUMMARY: On May 3, 1999, the Department of Commerce ("the Department") initiated a sunset review of the antidumping duty order on light-walled welded rectangular carbon steel tubing from Argentina (64 FR 23596) pursuant to section 751(c) of the Tariff Act of 1930, as amended ("the Act"). On the basis of a notice of intent to participate and substantive comments filed on behalf of the domestic interested parties and inadequate response (in this case, no response) from respondent interested parties, the Department determined to conduct an expedited review. As a result of this review, the Department finds that revocation of the antidumping order would be likely to lead to continuation or recurrence of dumping at the levels indicated in the Final Results of Review section of this notice.

FOR FURTHER INFORMATION CONTACT: Kathryn B. McCormick or Melissa G. Skinner, Office of Policy for Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW, Washington, D.C. 20230; telephone: (202) 482–1698 or (202) 482–1560, respectively.

EFFECTIVE DATE: December 3, 1999.

Statute and Regulations

This review was conducted pursuant to sections 751(c) and 752 of the Act. The Department's procedures for the conduct of sunset reviews are set forth in Procedures for Conducting Five-year ("Sunset") Reviews of Antidumping and Countervailing Duty Orders, 63 FR 13516 (March 20, 1998) ("Sunset Regulations") and 19 C.F.R. Part 351 (1998) in general. Guidance on methodological or analytical issues relevant to the Department's conduct of sunset reviews is set forth in the Department's Policy Bulletin 98:3—Policies Regarding the Conduct of Five-year ("Sunset") Reviews of Antidumping and Countervailing Duty Orders; Policy Bulletin, 63 FR 18871 (April 16, 1998) ("Sunset Policy Bulletin").

Scope

The merchandise subject to this antidumping duty order is light-walled welded carbon steel tubing of rectangular (including square) cross-section, having a wall thickness of less than 0.156 inch, from Argentina. The subject merchandise is classifiable under item 7306.60.50.00 of the Harmonized Tariff Schedule of the United States ("HTSUS"). Although the HTSUS item number is provided for convenience and U.S. customs purposes, the written description remains dispositive.

This review covers imports from all producers and exporters of light-walled welded carbon steel tubing from Argentina.

History of the Order

In the original investigation, covering the period January 1, 1988, through June 30, 1988, the Department determined a margin of 56.26 percent for U.S. imports of subject merchandise from Argentina. Since the issuance of the order, the Department has not conducted any administrative reviews.

Background

On May 3, 1999, the Department initiated a sunset review of the antidumping duty order on light-walled welded carbon steel tubing from Argentina (64 FR 23596), pursuant to section 751(c) of the Act. The Department received a notice of intent to participate on behalf of California Steel and Tube, Hannibal Industries Inc., Maruichi American Corporation, Searing Industries, Leavitt Tube, Vest Inc., and Western Tube and Conduit (collectively "domestic interested parties"), within the applicable deadline (May 18, 1999) specified in section 351.218(d)(1)(i)(l) of the Sunset Regulations. The domestic interested parties claimed interested party status under section 771(9)(C) of the Act as U.S. producers of a domestic like product. We received a complete substantive response from the domestic interested parties on June 2, 1998, within the 30-day deadline specified in the Sunset Regulations under section 351.218(d)(3)(i). Many of the domestic interested parties are members of the Committee on Pipe and Tube Imports, the trade association on whose behalf the original petition was filed. We did not receive a substantive response from any respondent interested party to this proceeding. As a result, pursuant to 19 CFR 351.218(e)(1)(i)(i)(C), the Department determined to conduct an expedited, 120-day review of this order.

In accordance with section 751(c)(5)(C)(v) of the Act, the Department may treat a review as extraordinarily complicated if it is a review of a transition order (i.e., an order in effect on January 1, 1995). On September 7, 1999, the Department determined that the sunset review of the antidumping order on light-walled welded rectangular carbon steel tubing from Argentina is extraordinarily complicated and extended the time limit for completion of the final results of this review until not later than November 29, 1999, in accordance with section 751(c)(5)(B) of the Act.

Determination

In accordance with section 751(c)(1) of the Act, the Department conducted this review to determine whether revocation of the antidumping duty order would be likely to lead to continuation or recurrence of dumping. Section 752(c) of the Act provides that, in making this determination, the Department shall consider the weighted-average dumping margins determined in the investigation and subsequent reviews and the volume of imports of the subject merchandise for the period before and after the issuance of the antidumping order, and shall provide to the International Trade Commission ("the Commission") the magnitude of the margin of dumping likely to prevail if the order is revoked.

The Department's determination concerning continuation or recurrence of dumping and the magnitude of the margin are discussed below. Additionally, the domestic interested parties' comments with respect to continuation or recurrence of dumping and the magnitude of the margin are addressed within the respective sections below.

Continuation or Recurrence of Dumping

Drawing on the guidance provided in the legislative history accompanying the

1 See Final Determination of Sales at Less than Fair Value: Light-Walled Welded Rectangular Carbon Steel Tubing from Argentina, 54 FR 13913 (April 6, 1989).

2 See Extension of Time Limit for Final Results of Five-Year Reviews, 64 FR 48579 (September 7, 1999).
Uruguay Round Agreements Act ("URAA"), specifically the Statement of Administrative Action ("the SAA"), H.R. Doc. No. 103–316, vol. 1 (1994), the House Report, H.R. Rep. No. 103–826, pt.1 (1994), and the Senate Report, S. Rep. No. 103–412 (1994), the Department issued its Sunset Policy Bulletin providing guidance on methodological and analytical issues, including the bases for likelihood determinations. In its Sunset Policy Bulletin, the Department indicated that determinations of likelihood will be made on an order-wide basis (see section II.A.2). In addition, the Department indicated that normally it will determine that revocation of an antidumping duty order is likely to lead to continuation or recurrence of dumping where (a) dumping continued at any level above de minimis after the issuance of the order, (b) imports of the subject merchandise ceased after the issuance of the order, or (c) dumping was eliminated after the issuance of the order and import volumes for the subject merchandise declined significantly (see section II.A.3).

In addition to considering the guidance on likelihood cited above, section 751(c)(4)(B) of the Act provides that the Department shall determine that revocation of an order is likely to lead to continuation or recurrence of dumping where a respondent interested party waives its participation in the sunset review. In the instant review, the Department did not receive a response from any respondent interested party. Pursuant to section 351.218(f)(2)(iii) of the Sunset Regulations, this constitutes a waiver of participation.

In their substantive response, the domestic interested parties argue that revocation of the subject order would have the effect of resumption of sales at less than fair value by margins equivalent to or greater than those found in the original investigation and subsequent reviews (see June 2, 1999 Substantive Response of the domestic interested parties at 3). With respect to whether imports of the subject merchandise ceased after the issuance of the order, the domestic interested parties assert that since the issuance of the order, imports of subject tubing from Argentina into the United States have almost disappeared entirely. Id. Because imports of subject merchandise from Argentina into the United States have nearly ceased, the domestic interested parties argue that there is a strong likelihood of continuation of dumping should this order be terminated (see June 2, 1999 Substantive Response of domestic interested parties at page 3). Moreover, the continued dumping at 56.26 percent is highly probable of the likelihood of continuation or recurrence of dumping. Id.

Consistent with section 752(c) of the Act, the Department considered the volume of imports before and after the 1989 issuance of the order. The statistics on imports of the subject merchandise cited by the domestic interested parties and those examined by the Department (U.S. Census Bureau IM146 reports), demonstrate that imports of the subject merchandise have ceased since the issuance of the order. Additionally, the margin of 56.26 percent ad valorem, the estimate from the original investigation, has continued throughout the history of the order.

The Department finds that the cessation of imports after the issuance of the order is highly probative of the likelihood of continuation or recurrence of dumping. Given that imports of subject merchandise have ceased, that an above de minimis deposit rate remains in effect for all imports, that respondent interested parties have waived their right to participate in this review, and absent argument and evidence to the contrary, the Department determines that dumping is likely to continue or recur if the order were revoked.

Magnitude of the Margin

In the Sunset Policy Bulletin, the Department states that it will normally provide to the Commission the margin that was determined in the final determination in the original investigation. Further, for companies not specifically investigated or for companies that did not begin shipping until after the order was issued, the Department normally will provide a margin based on the “all others” rate from the original investigation, (see section II.B.1 of the Sunset Policy Bulletin). Exceptions to this policy include the use of a more recently calculated margin, where appropriate, and consideration of duty absorption determinations (see sections II.B.2 and 3 of the Sunset Policy Bulletin). In their substantive response, the domestic interested parties assert that, because imports of subject merchandise from Argentina into the U.S. ceased after the issuance of the order, the Department should find the magnitude of the margin to be 56.26 percent, the margin from the original investigation (see June 2, 1999 Substantive Response of domestic interested parties at 3).

The Department agrees with the domestic interested parties’ argument concerning the choice of the margin to report to the Commission. Since there have been no administrative reviews of the order, the rate from the original investigation is the only rate available to the Department. Therefore, we determine that the margin determined in the original investigation is probative of the behavior of producers/exporters of subject merchandise from Argentina if the order was revoked.

Final Results of Review

As a result of this review, the Department finds that revocation of the antidumping duty order would likely lead to continuation or recurrence of dumping at the margin listed below:

<table>
<thead>
<tr>
<th>Producer/exporter</th>
<th>Margin (percent)</th>
</tr>
</thead>
<tbody>
<tr>
<td>All Argentinian producers/exporters</td>
<td>56.26</td>
</tr>
</tbody>
</table>

This notice serves as the only reminder to parties subject to administrative protective order ("APO") of their responsibility concerning the disposition of proprietary information disclosed under APO in accordance with 19 CFR 351.305 of the Department’s regulations. Timely notification of return/destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and the terms of an APO is a sanctionable violation.

This five-year ("sunset") review and notice are in accordance with sections 751(c), 752, and 777(i)(1) of the Act.


Richard W. Moreland,
Acting Assistant Secretary for Import Administration.

[FR Doc. 99–31422 Filed 12–2–99; 8:45 am]
BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–583–003]

Final Results of Expedited Sunset Review: Light-Walled Welded Rectangular Carbon Steel Tubing From Taiwan

AGENCY: Import Administration, International Trade Administration, Department of Commerce.
ACTION: Notice of final results of expedited Sunset Review: Light-walled welded rectangular carbon steel tubing from Taiwan.

SUMMARY: On May 3, 1999, the Department of Commerce (“the Department”) initiated a sunset review of the antidumping duty order on light-walled welded rectangular carbon steel tubing from Taiwan (54 FR 22794) pursuant to section 751(c) of the Tariff Act of 1930, as amended (“the Act”). On the basis of a notice of intent to participate and substantive comments filed on behalf of the domestic interested parties and inadequate response (in this case, no response) from respondent interested parties, the Department determined to conduct an expedited review. As a result of this review, the Department finds that revocation of the antidumping duty order would be likely to lead to continuation or recurrence of dumping at the levels indicated in the Final Results of Review section of this notice.

FOR FURTHER INFORMATION CONTACT: Kathryn B. McCormick or Melissa G. Skinner, Office of Policy for Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW, Washington, D.C. 20230; telephone: (202) 482-1698 or (202) 482-1560, respectively.

EFFECTIVE DATE: December 3, 1999.

Statute and Regulations


Scope

The merchandise subject to this antidumping duty order is Taiwanese light-walled welded carbon steel tubing of rectangular (including square) cross-section, having a wall thickness of not less than 0.065 inches, and 0.375 inches or more but not over 4.5 inches in outside diameter. The subject merchandise is classifiable under item number 7306.60.50.00 of the Harmonized Tariff Schedule of the United States (“HTSUS”). Although the HTSUS item number is provided for convenience and customs purposes, the written description remains dispositive.

History of the Order

In the original investigation, covering the period January 1, 1988, through June 30, 1988, the Department determined the following margins for U.S. imports of subject merchandise from Taiwan: 1

<table>
<thead>
<tr>
<th>Producer/exporter</th>
<th>Margin (percent)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ornatube Enterprise</td>
<td>5.51</td>
</tr>
<tr>
<td>Vulcan Industrial Corp.</td>
<td>40.97</td>
</tr>
<tr>
<td>Yieh Hsing Industries, Ltd</td>
<td>40.97</td>
</tr>
<tr>
<td>All Others</td>
<td>29.15</td>
</tr>
</tbody>
</table>

Since the issuance of the order in 1989, the Department has conducted two administrative reviews. In the first review, covering the period November 21, 1988, through February 28, 1990, the Department determined a margin of 0.1975 percent for Ornatube. In the second review, covering the period March 1, 1990, through February 28, 1991, the margin for Ornatube was 18.05 percent. To date, the Department has not issued a duty-absorption determination in this case.

Background

On May 3, 1999, the Department initiated a sunset review of the antidumping duty order on light-walled welded carbon steel tubing from Taiwan (64 FR 23596), pursuant to section 751(c) of the Act. The Department received a notice of intent to participate on behalf of California Steel and Tube, Hannibal Industries Inc., Maruichi American Corporation, Searing Industries, Leavitt Tube, Vest Inc., and Western Tube and Conduit (collectively “domestic interested parties”), within the applicable deadline (May 18, 1999) specified in section 351.218(d)(1)(i) of the Sunset Regulations. The domestic interested parties claimed interested-party status under section 771(9)(C) of the Act as U.S. producers of a domestic like product. We received a complete substantive response from the domestic interested parties on June 2, 1998, within the 30-day deadline specified in the Sunset Regulations under section 351.218(d)(1)(i). Many of the domestic interested parties are members of the Committee on Pipe and Tube Imports.

1 See Final Determination of Sales at Less than Fair Value; Light-Walled Welded Rectangular Carbon Steel Tubing from Taiwan, 54 FR 5532 (February 3, 1989).

Determination

In accordance with section 751(c)(1) of the Act, the Department conducted this review to determine whether revocation of the antidumping duty order would be likely to lead to continuation or recurrence of dumping. Section 752(c) of the Act provides that, in making this determination, the Department shall consider the weighted-average dumping margins determined in the investigation and subsequent reviews and the volume of imports of the subject merchandise for the period before and the period after the issuance of the antidumping duty order, and it shall provide to the International Trade Commission (“the Commission”) the magnitude of the margin of dumping likely to prevail if the order is revoked.

The Department’s determination concerning continuation or recurrence of dumping and the magnitude of the margin are discussed below. Additionally, the domestic interested parties’ comments with respect to continuation or recurrence of dumping and the magnitude of the margin are addressed within the respective sections below.

Continuation or Recurrence of Dumping


2 See Extension of Time Limit for Final Results of Five-Year Reviews, 64 FR 48870 (September 7, 1999).
The Department agrees with the domestic interested parties’ argument that continuing margins and the nearly total cessation of U.S. imports from Taiwan indicate a strong likelihood that Taiwanese importers/producers will continue to export at less than fair value in the absence of the order. We found that, according to the U.S. Census Bureau IM149 reports, imports declined significantly during the period following the order and margins continue to exist at levels above de minimis. If imports cease or decline significantly, it is reasonable to assume that exporters could not sell in the United States without dumping and that, to reenter the U.S. market, they would have to resume dumping.\(^3\) Further, if dumping continues after the issuance of an order, it is reasonable to determine that dumping would continue were the order revoked.

Given that dumping has continued at levels above de minimis after the issuance of the order, import volumes for subject merchandise declined significantly (see section II.A.3). In addition to considering the guidance on likelihood cited above, section 751(c)(4)(B) of the Act provides that the Department shall determine that revocation of an order is likely to lead to continuation or recurrence of dumping where (a) dumping continued at any level above de minimis after the issuance of the order, (b) imports of the subject merchandise ceased after the issuance of the order, or (c) dumping was eliminated after the issuance of the order and import volumes for the subject merchandise declined significantly (see section II.A.3).

In addition to considering the guidance on likelihood cited above, the Department indicated that determinations of likelihood will be made on an order-wide basis (see section II.A.2). In addition, the Department indicated that normally it will determine that revocation of an antidumping duty order is likely to lead to continuation or recurrence of dumping where (a) dumping continued at any level above de minimis after the issuance of the order, (b) imports of the subject merchandise ceased after the issuance of the order, or (c) dumping was eliminated after the issuance of the order and import volumes for the subject merchandise declined significantly (see section II.A.3).

With respect to whether imports of the subject merchandise ceased after the issuance of the order, the domestic interested parties assert that, since the issuance of the order, imports of subject tubing from Taiwan to the United States have almost disappeared entirely. Id. For instance, they contend, whereas in 1988 (the year before the antidumping duty order was issued), there were nearly 16,000 tons of U.S. imports of subject merchandise from Taiwan, in 1998, there were less than 100 tons of subject imports from Taiwan. Id. Thus, the domestic interested parties argue that continuing margins and the nearly total cessation of U.S. imports of the subject merchandise from Taiwan indicate a strong likelihood of continuation of dumping should the Department revoke this order. Id.

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This notice serves as the only reminder to parties subject to administrative protective order (“APO”) of their responsibility concerning the disposition of proprietary information disclosed under APO in accordance with 19 CFR 351.305 of the Department’s regulations. Timely notification of return/destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and the terms of an APO is a sanctionable violation. This five-year (“sunset”) review and notice are in accordance with sections 751(c), 752, and 777(i)(1) of the Act.

Dated: November 27, 1999.

Richard W. Moreland,
Acting Assistant Secretary for Import Administration.

[FR Doc. 99–31424 Filed 12–2–99; 8:45 am]
BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[\(–583–008\)]

Final Results of Expedited Sunset Review: Small Diameter Carbon Steel Pipes and Tubes From Taiwan.

AGENCY: Import Administration, International Trade Administration, Department of Commerce
ACTION: Notice of final results of expedited sunset review: Small diameter carbon steel pipes and tubes from Taiwan.

SUMMARY: On May 3, 1999, the Department of Commerce (the “Department”) initiated a sunset review of the antidumping duty order on small diameter carbon steel pipes and tubes from Taiwan (64 FR 23596) pursuant to section 751(c) of the Tariff Act of 1930, as amended (the “Act”). On the basis of a notice of intent to participate and adequate substantive response filed on behalf of domestic interested parties and inadequate response (in this case, no response) from respondent interested parties, the Department determined to conduct an expedited sunset review. As a result of this review, the Department finds that revocation of the antidumping duty order would be likely to lead to continuation or recurrence of dumping at the levels indicated in the Final Result of Review section of this notice.

FOR FURTHER INFORMATION CONTACT: Eun W. Cho or Melissa G. Skinner, Office of Policy for Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, D.C. 20230; telephone: (202) 482–1698 or (202) 482–1560, respectively.

EFFECTIVE DATE: December 3, 1999.

Statute and Regulations

This review was conducted pursuant to sections 751(c) and 752 of the Act. The Department’s procedures for the conduct of sunset reviews are set forth in Procedures for Conducting Five-year (“Sunset”) Reviews of Antidumping and Countervailing Duty Orders, 63 FR 13516 (March 20, 1998) (“Sunset Regulations”) and in 19 C.F.R. Part 351 (1999) in general. Guidance on methodological or analytical issues relevant to the Department’s conduct of sunset reviews is set forth in the Department’s Policy Bulletin 98:3—Policies Regarding the Conduct of Five-year (“Sunset”) Reviews of Antidumping and Countervailing Duty Orders; Policy Bulletin, 63 FR 18871 (April 16, 1998) (“Sunset Policy Bulletin”).

Scope

The subject merchandise under consideration is welded carbon steel pipes and tubes of circular cross section, from Taiwan (“steel pipes”), with walls not thinner than 0.065 inch and outside diameter 0.375 inch or more but not over 4½ inches. These products are commonly referred to in the industry as standard pipe and are produced to various American Society of Testing Materials specifications, most notably A–53, A–120, or A–135.

Standard pipe is currently classified under Harmonized Tariff Schedule of the United States (“HTSUS”) item numbers 7306.30.5025, 7306.30.5032, 7306.30.5040, and 7306.30.5055. The HTSUS item numbers are provided for convenience and customs purposes only. The written product description of the scope of this order remains dispositive.

History of the Order

The antidumping duty order on small diameter carbon steel pipes and tubes from Taiwan was published in the Federal Register on May 7, 1984 (49 FR 19369). In that order, the Department determined that the weighted-average dumping margins for Kao Hsing Chang, Tai Feng, Yieh Hsing, and all others are 9.7, 43.7, 38.5, and 9.7 percent, respectively. Since that time, the Department has completed several administrative reviews, one revision of a review, and is currently conducting a sixth administrative review, for which the Department has published the preliminary results. We note that the Department has not conducted any investigation with respect to duty absorption regarding the exports of the subject merchandise. The order remains in effect for all manufacturers and exporters of the subject merchandise.

Background

On May 3, 1999, the Department initiated a sunset review of the antidumping duty order on steel pipes from Taiwan (64 FR 23596) pursuant to section 751(c) of the Act. The Department received a joint Notice of Intent to Participate on behalf of Allied Tube and Conduit Corp., Sawhill Tubular Division—Armco, Inc., Century Tube, IPSCO Tubular Inc., LTV Steel Tubular Products, Maverick Tube Corporation, Sharon Tube Company, Western Tube and Conduit, and Wheatland Tube Co. (hereinafter referred to as “domestic interested parties”) on May 18, 1999, within the deadline specified in section 351.218(d)(1)(i) of the Sunset Regulations. In their Notice of Intent to Participate, the domestic interested parties note that they are not related to foreign producers and exporters, nor are they importers of the subject merchandise within the meaning of 771(4)(B) of the Act.

We received a complete substantive response from the domestic interested parties on June 2, 1999, within the 30-day deadline specified in section 351.218(d)(3)(i) of the Sunset Regulations. The domestic interested parties claim interest party status under section 771(9)(C) of the Act as producers or manufacturers of a domestic like product. The domestic interested parties note that while some companies participated in the original investigation and a particular company in previous administrative reviews, others are partaking in the instant review for the first time. We did not receive a substantive response from any respondent interested party to this proceeding. Consequently, pursuant to section 351.218(e)(1)(iii)(C) of the Sunset Regulations, the Department determined to conduct an expedited, 120-day, review of this order.

In accordance with section 751(c)(5)(C)(v) of the Act, the Department may treat a review as extraordinarily complicated if it is a review of a transition order (i.e., order in effect on January 1, 1995). Therefore, on September 7, 1999, the Department determined that the sunset review of the antidumping duty order on steel pipes from Taiwan is extraordinarily complicated and extended the time limit for completion of the final results of this review until not later than
November 29, 1999, in accordance with section 751(c)(3)(B) of the Act.\footnote{See Extension of Time Limit for Final Results of Five-Year Reviews, 64 FR 48579 (September 7, 1999).}

**Determination**

In accordance with section 751(c)(1) of the Act, the Department conducted this review to determine whether revocation of the antidumping order would be likely to lead to continuation or recurrence of dumping. Section 752(c) of the Act provides that, in making this determination, the Department shall consider the weighted-average dumping margins determined in the investigation and subsequent reviews and the volume of imports of the subject merchandise for the period before and the period after the issuance of the antidumping order, and shall provide to the International Trade Commission (“the Commission”) the magnitude of the margin of dumping likely to prevail if the order is revoked.

The Department’s determinations concerning continuation or recurrence of dumping and the magnitude of the margin are discussed below. In addition, the comments of the domestic interested parties, with respect to continuation or recurrence of dumping and the magnitude of the margin, are addressed within the respective sections below.

**Continuation or Recurrence of Dumping**

Drawing on the guidance provided in the legislative history accompanying the Uruguay Round Agreements Act (“URAA”), specifically the Statement of Adiministrative Action (“the SAA”), H.R. Doc. No. 103–316, vol. 1 (1994), the House Report, H.R. Rep. No. 103–826, pt.1 (1994), and the Senate Report, S. Rep. No. 103–412 (1994), the Department issued its Sunset Policy Bulletin providing guidance on methodological and analytical issues, including the bases for likelihood determinations. In its Sunset Policy Bulletin, the Department indicated that determinations of likelihood will be made on an order-wide basis (see section II.A.2). In addition, the Department indicated that normally it will determine that revocation of an antidumping order is likely to lead to continuation or recurrence of dumping where (a) dumping continued at any level above *de minimis* after the issuance of the order, (b) imports of the subject merchandise ceased after the issuance of the order, or (c) dumping was eliminated after the issuance of the order and import volumes for the subject merchandise declined significantly (see section II.A.3).

In addition to considering the guidance on likelihood cited above, section 751(c)(4)(B) of the Act provides that the Department shall determine that revocation of an order is likely to lead to continuation or recurrence of dumping where a respondent interested party waives its participation in the sunset review. In the instant review, the Department did not receive a response from any respondent interested party. Pursuant to section 351.218(d)(2)(iii) of the Sunset Regulations, this constitutes a waiver of participation.

The domestic interested parties argue that the sales of the subject merchandise at less-than-fair value would resume if the antidumping order were revoked. (See June 2, 1999 Substantive Response of the domestic interested parties at 3.) In support of their argument, the domestic interested parties proffer data pertaining to the import volumes and dumping margins of the subject merchandise during the relevant period. Specifically, the domestic interested parties note that the volume of imports of the subject merchandise immediately and dramatically decreased after the discipline of the antidumping order was put into effect. *Id.* Furthermore, the domestic interested parties indicate that, at least for some companies, the dumping margins have continuously existed at levels above *de minimis* since the issuance of the order. *Id.*

Domestic interested parties’ argument concerning the import volumes of the subject merchandise are supported by the data in both U.S. Census Bureau IM146 reports (“IM146”) and U.S. International Trade Commission Interactive Tariff and Trade Data Web (“TTC Data Web”). A year before the issuance of antidumping order, 1983, the import volume of the subject merchandise was 118,510 metric tons. In the year of the order, in 1984, the import volume fell to 3,250 metric tons—a drop of more than 97 percent. From 1985 to 1994, although the volumes of import of the subject merchandise varied widely, the average import volume of the subject merchandise was 9,191 metric tons, which is less than 8 percent of the pre-order volume.

As the Sunset Policy Bulletin notes, the continued existence of dumping margins with the discipline of an order in place is highly indicative of the likelihood that dumping would continue or recur if the discipline is removed. (See the Sunset Policy Bulletin, 63 FR at 18872, the SAA at 890, and the House Report at 63–64.) The Department has issued five final results of administrative reviews with respect to the antidumping order under consideration. Also, the Department currently is conducting an administrative review and has issued its preliminary results.\footnote{See Certain Circular Welded Carbon Steel Pipes and Tubes From Taiwan; Antidumping Duty Order, 49 FR 19369 (May 7, 1984).} Except in one review, in which the Department did not find any dumping by the companies reviewed, the Department found the dumping margins above the *de minimis* level in all other reviews. As a result, we find that, since the issuance of the antidumping duty order, dumping of steel pipes from Taiwan has continued at margins above the *de minimis* level. In conclusion, inasmuch as the respondent interested parties waived their right to participate in this review, import volumes of the subject merchandise have declined significantly after the imposition of the order, and dumping of the subject merchandise continued at margins above *de minimis*, we find that revocation of the antidumping duty order would be likely to lead to continuation or recurrence of dumping.

**Magnitude of the Margin**

In the Sunset Policy Bulletin, the Department stated that it will normally provide to the Commission the margin that was determined in the final determination in the original investigation. Further, for companies not specifically investigated or for companies that did not begin shipping until after the order was issued, the Department normally will provide a margin based on the all-others rate from the investigation. (See section II.B.1 of the Sunset Policy Bulletin.) Exceptions to this policy include the use of a more recently calculated margin, where appropriate, and consideration of duty absorption determinations. (See sections II.B.2 and 3 of the Sunset Policy Bulletin.)

The Department, in its notice of the antidumping duty order on steel pipes from Taiwan, established both company-specific and all-others weighted-average dumping margins (49 FR 19369, May 7, 1984).\footnote{See footnote 1 above.} We note that, to date, the Department has not issued any duty absorption findings in this case.

The domestic interested parties urge the Department to find that the dumping
DEPARTMENT OF COMMERCE
International Trade Administration

[A-549–502]


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

EFFECTIVE DATE: December 3, 1999.

SUMMARY: The Department of Commerce (the Department) is extending the time limit for the preliminary results of the antidumping duty administrative review of the antidumping order on certain welded carbon steel pipes and tubes from Thailand, covering the period March 1, 1998 through February 28, 1999.


SUPPLEMENTARY INFORMATION: Under section 751(a)(3)(A) of the Tariff Act, as amended (the Act), the Department may extend the deadline for completion of an administrative review if it determines that it is not practicable to complete the review within the statutory time limit of 365 days. In the instant case, the Department has determined that it is not practicable to complete the review within the statutory time limit. See Memorandum from Joseph A. Spetrini to Robert S. LaRussa (November 19, 1999).

Therefore, in accordance with section 751(a)(3)(A) of the Act, the Department is extending the time limit for the preliminary results until March 30, 2000.

Dated: November 22, 1999.

Joseph A. Spetrini,
Deputy Assistant Secretary, Enforcement Group III.

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–489–501]

Final Results of Expedited Sunset Review: Certain Welded Carbon Steel Pipes and Tubes From Turkey

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

ACTION: Notice of final results of Expedited Sunset Review: Certain welded carbon steel pipes and tubes from Turkey.

SUMMARY: On May 3, 1999, the Department of Commerce (the Department) initiated a sunset review of the antidumping duty order on certain welded carbon steel pipes and tubes from Turkey (64 FR 23596) pursuant to section 751(c) of the Tariff Act of 1930, as amended ("the Act"). On the basis of a notice of intent to participate and substantive comments filed on behalf of domestic interested parties and inadequate response (in this case, no response) from respondent interested parties, the Department determined to conduct an expedited review. As a result of this review, the Department finds that revocation of the antidumping duty order would be likely to lead to continuation or recurrence of dumping at the levels indicated in the Final Results of Review section of this notice.

FOR FURTHER INFORMATION CONTACT: Kathryn B. McCormick or Melissa G. Skinner, Office of Policy for Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW, Washington, D.C. 20230; telephone: (202) 482–1930 or (202) 482–1560, respectively.

EFFECTIVE DATE: December 3, 1999.

Statute and Regulations

This review was conducted pursuant to sections 751(c) and 752 of the Act. The Department’s procedures for the conduct of sunset reviews are set forth in Procedures for Conducting Five-year (“Sunset”) Reviews of Antidumping and Countervailing Duty Orders, 63 FR 13516 (March 20, 1998) (“Sunset Regulations”), and 19 C.F.R. Part 351(1999) in general. Guidance on methodological or analytical issues relevant to the Department’s conduct of sunset reviews is set forth in the Department’s Policy Bulletin 98:3—Policies Regarding the Conduct of Five-year (“Sunset”) Reviews of Antidumping and Countervailing Duty Orders; Policy Bulletin, 63 FR 18871

Scope

The products covered by this order include circular welded non-alloy steel pipes and tubes, of circular cross-section, with an outside diameter of 0.372 inches or more, but not more than 16 inches in outside diameter, regardless of wall thickness, surface finish (black, galvanized, or painted) or end finish (plain end, beveled end, threaded, or threaded and coupled). These pipes and tubes are generally known as standard pipe, though they may also be called structural or mechanical tubing in certain applications. Standard pipes and tubes are intended for the low-pressure conveyance of water steam, natural gas, air and other liquids and gases in plumbing and heating systems, air-conditioner units, automatic sprinkler systems, and other related uses.

Standard pipe may also be used for light load-bearing and mechanical applications, such as for fence tubing, and for protections of electrical wiring, such as conduit shells.

The scope is not limited to standard pipe or fence tubing or those types or mechanical and structural pipe that are used in standard pipe applications. All carbon-steel pipes and tubes within the physical description outline above are included in the scope of this order, except for line pipe, oil-country tubular goods, boiler tubing, cold-drawn or cold-rolled mechanical tubing, pipe and tube hollows for redrags, finished scaffolding, and finished rigid conduit. The subject merchandise was classifiable under items 610.3231, 610.3234, 610.3241, 610.3242, 610.3243, and 610.3252, 610.3254, 610.3256, 610.3258, 610.4925 of the Tariff Schedules of the United States Annotated ("TSUSA"); currently, it is classifiable under item numbers 7306.30.1000, 7306.30.5025, 7306.30.5032, and 7306.30.5040, 7306.30.5055, 7306.30.5805 and 7306.30.5900 of the Harmonized Tariff Schedule of the United States ("HTSUS"). Although the TSUSA and HTSUS item numbers are provided for convenience and customs purposes, the written description remains dispositive.

History of the Order

In the original investigation, covering the period February 1, 1985, through July 31, 1986 (51 FR 13044, April 7, 1986), the Department determined a margin of 1.26 percent for Borusan Ithlicat ve Dagitim ("Borusan"); 23.12 percent for Mannesmann-Sumerbank Boru Industrisi ("Mannesmann") and Erkboru Profil Sanayi ve Ticaret ("Erkboru"); and 14.17 percent for “all others.” There have been six administrative reviews for the subject antidumping duty order. A summary of these reviews follows:

<table>
<thead>
<tr>
<th>Review</th>
<th>Period of Review (&quot;POR&quot;)</th>
<th>Citation</th>
</tr>
</thead>
<tbody>
<tr>
<td>(1) ...</td>
<td>3 Jan 1986–30 April 1987</td>
<td>53 FR 39632 (October 11, 1988).</td>
</tr>
<tr>
<td>(2) ...</td>
<td>1 May 1987–30 April 1988</td>
<td>57 FR 54046 (November 16, 1992).</td>
</tr>
<tr>
<td>(4) ...</td>
<td>1 May 1993–30 April 1994</td>
<td>62 FR 51629 (October 2, 1997).</td>
</tr>
<tr>
<td>(6) ...</td>
<td>1 May 1996–30 April 1997</td>
<td>61 FR 69067 (December 31, 1996).</td>
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</tbody>
</table>

In addition to the companies subject in the original investigation, the Department has investigated and/or reviewed imports from producers/exporters Borusan Holding A.S., Borusan Gemlik Boru Tesisleri A.S., Borusan Boru Sanayii A.S., Istikal Ticaret A.S., Borusan Ihracat Ithalat ve Dagitim A.S., and Tubebo Pipe and Steel Corporation (collectively, the “Borusan Group”); Yucelboru Ithalat, Ithalat ve Pazarlama A.S. ("Yucel Boru"); and Erbosan Ervias Boru Sanayii ve Ticaret A.S. ("Erbosan"). To date, the Department has not issued a duty absorption determination in this case.

Background

On May 3, 1999, the Department initiated a sunset review of the antidumping duty order on certain welded carbon steel pipes and tubes from Turkey (64 FR 23596), pursuant to section 751(c) of the Act. The Department received a notice of intent to participate on behalf of Allied Tube and Conduit Corp., Sawhill Tubular Division—Amoco, Inc., Century Tube, IPSCO Tubular Inc., LTV Steel Tubular Products, Maverick Tube Corporation, Sharon Tube Company, Western Tube and Conduit, and Wheatland Tube Company (collectively “domestic interested parties”) on May 18, 1999, within the deadline specified in section 351.218(d)(1)(i) of the Sunset Regulations. The domestic interested parties claimed interested party status under 19 U.S.C. 1677(9)(C) as U.S. producers of welded carbon steel pipes and tubes. We received a complete substantive response from the domestic interested parties on June 2, 1999, within the 30-day deadline specified in the Sunset Regulations under section 351.218(d)(3)(i). We did not receive a substantive response from any respondent interested party to this proceeding. As a result, pursuant to 19 CFR 351.218(e)(1)(ii)(C), the Department determined to conduct an expedited, 120-day review of this order.

In accordance with section 751(c)(5)(C)(v) of the Act, the Department may treat a review as extraordinarily complicated if it is a review of a transition order (i.e., an order in effect on January 1, 1995). On September 7, 1999, the Department determined that the sunset review of the antidumping order on welded carbon steel pipes and tubes from Turkey is extraordinarily complicated and, therefore, the Department extended the time limit for completion of the final results of this review until not later than November 29, 1999, in accordance with section 751(c)(5)(B) of the Act.1

Determination

In accordance with section 751(c)(1) of the Act, the Department conducted this review to determine whether revocation of the antidumping order would be likely to lead to continuation or recurrence of dumping. Section 752(c) of the Act provides that, in making this determination, the Department shall consider the weighted-average dumping margins determined in the investigation and subsequent reviews and the volume of imports of the subject merchandise for the period before and the period after the issuance of the antidumping duty order, and

1 See Extension of Time Limit for Final Results of Five-Year Reviews, 64 FR 48579 (September 7, 1999).
shall provide to the International Trade Commission ("the Commission") the magnitude of the margin of dumping likely to prevail if the order is revoked.

The Department’s determinations concerning continuation or recurrence of dumping and the magnitude of the margin are discussed below. Additionally, the domestic interested parties’ comments with respect to continuation or recurrence of dumping and the magnitude of the margin are addressed within the respective sections below.

**Continuation or Recurrence of Dumping**

Drawing on the guidance provided in the legislative history accompanying the Uruguay Round Agreements Act ("URAAs"), specifically the Statement of Administrative Action ("the SAA"), H.R. Doc. No. 103–316, vol. 1 (1994), the House Report, H.R. Rep. No. 103–826, pt. I (1994), and the Senate Report, S. Rep. No. 99–412 (1994), the Department issued its Sunset Policy Bulletin providing guidance on methodological and analytical issues, including the bases for likelihood determinations. In its Sunset Policy Bulletin, the Department indicated that determinations of likelihood will be made on an order-wide basis (see section II.A.2). In addition, the Department indicated that normally it will determine that revocation of an antidumping order is likely to lead to continuation or recurrence of dumping where (a) dumping continued at any level above de minimis after the issuance of the order, (b) imports of the subject merchandise ceased after the issuance of the order, or (c) dumping was eliminated after the issuance of the order and import volumes for the subject merchandise declined significantly (see section II.A.3).

In addition to consideration of the guidance on likelihood cited above, section 751(c)(4)(B) of the Act provides that the Department shall determine that revocation of an order is likely to lead to continuation or recurrence of dumping where a respondent interested party waives its participation in the sunset review. In the instant review, the Department did not receive a response from any respondent interested party. Pursuant to section 351.218(f)(2)(iii) of the Sunset Regulations, this constitutes a waiver of participation.

In their substantive response, the domestic interested parties argue that revocation of the antidumping duty order would likely lead to continuation or recurrence of dumping at the margins listed below:

<table>
<thead>
<tr>
<th>Producer/exporter</th>
<th>Margin (percent)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Borusan Ithicat ve Dagital</td>
<td>1.26</td>
</tr>
<tr>
<td>Ekerboru Profil Sanayi ve Ticaret</td>
<td>23.12</td>
</tr>
<tr>
<td>Mannesmann-Summerbank</td>
<td></td>
</tr>
<tr>
<td>Boru Industri</td>
<td>23.12</td>
</tr>
<tr>
<td>All others</td>
<td>14.74</td>
</tr>
</tbody>
</table>

This notice serves as the only reminder to parties subject to administrative protective order ("APO") of their responsibility concerning the disposition of proprietary information disclosed under APO in accordance with the APO agreement.
with 19 CFR 351.305 of the Department’s regulations. Timely notification of return/destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and the terms of an APO is a sanctionable violation.

This five-year (“sunset”) review and notice are in accordance with sections 751(c), 752, and 777(i)(1) of the Act.

Dated: November 9, 1999.

Richard W. Moreland,
Acting Assistant Secretary for Import Administration.

[FR Doc. 99-31421 Filed 12-2-99; 8:45 am]

BILLING CODE 3510-DS-P

DEPARTMENT OF COMMERCE

International Trade Administration

[ A–533–502 ]

Final Results of Expedited Sunset Review: Certain Welded Carbon Steel Pipes and Tubes From India

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

ACTION: Notice of final results of expedited Sunset Review: Certain welded carbon steel pipes and tubes from India.

SUMMARY: On May 3, 1999, the Department of Commerce (“the Department”) initiated a sunset review of the antidumping duty order on certain welded carbon steel pipes and tubes from India (64 FR 23596) pursuant to section 751(c) of the Tariff Act of 1930, as amended (“the Act”). The products covered by this order include circular welded non-alloy steel pipes and tubes, of circular cross-section, with an outside diameter of 0.372 inches or more, but not more than 16 inches in outside diameter, regardless of wall thickness, surface finish (black, galvanized, or painted) or end finish (plain end, beveled end, threaded, or threaded and coupled). These pipes and tubes are generally known as standard pipe, though they may also be called structural or mechanical tubing in certain applications. Standard pipes and tubes are intended for the low-pressure conveyance of water, steam, natural gas, air and other liquids and gases in plumbing and heating systems, air-conditioner units, automatic sprinkler systems, and other related uses. Standard pipe may also be used for light load-bearing and mechanical applications, such as for fence tubing, and for protections of electrical wiring, such as conduit shells.

The scope is not limited to standard pipe and fence tubing or those types or mechanical and structural pipe that are used in standard pipe applications. All carbon-steel pipes and tubes within the physical description outline above are included in the scope of this order, except for line pipe, oil-country tubular goods, boiler tubing, cold-drawn or cold-rolled mechanical tubing, pipe and tube hollows for redraws, finished scaffolding, and finished rigid conduit. The subject merchandise was classifiable under items 610.3231, 610.3241, 610.3242, 610.3243, 610.3252, 610.3254, 610.3256, 610.3258, and 610.4925 of the Tariff Schedules of the United States Annotated (“TSUSA”); currently, it is classifiable under item numbers 7306.30.1000, 7306.30.5025, 7306.30.5032, 7306.30.5040, 7306.30.5055, 7306.30.5805, and 7306.30.5090 of the Harmonized Tariff Schedule of the United States (“HTSUS”). Although the TSUSA and HTSUS item numbers are provided for convenience and customs purposes, the written description remains dispositive.

History of the Order

In the final determination of the original investigation, covering the period February 1, 1985, through July 31, 1985 (51 FR 9089, March 17, 1986), the Department determined a margin of 7.08 percent for Tata Iron & Steel Co., Ltd. (“TISCO”), and “all others.”

There have been six administrative reviews for the subject antidumping duty order. A summary of these reviews follows:

<table>
<thead>
<tr>
<th>Period of Review (“POR”)</th>
<th>Citation</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 May 1987—30 April 1988</td>
<td>56 FR 64753 (December 12, 1991)</td>
</tr>
<tr>
<td>1 May 1988—30 April 1989</td>
<td>56 FR 64753 (December 12, 1991)</td>
</tr>
<tr>
<td>1 May 1990—30 April 1991</td>
<td>57 FR 54360 (November 18, 1992)</td>
</tr>
<tr>
<td></td>
<td>63 FR 39269 (July 22, 1998) Amended</td>
</tr>
<tr>
<td></td>
<td>63 FR 66120 (December 1, 1998) Amended</td>
</tr>
<tr>
<td></td>
<td>64 FR 23821 (May 4, 1999)</td>
</tr>
</tbody>
</table>

1 Two of the three companies investigated, Zenith Steel Pipes and Industries Ltd. and Gujarat Steel Tubes Ltd., were excluded from the final affirmative determination, since the Department found no sales at less than fair value.
In addition to the companies subject to the original investigation, the Department has investigated and/or reviewed imports from producers/exporters Jindal Pipes Ltd. (“Jindal”), Rajinder Pipes Ltd. (“Rajinder”) and Rajinder Steel Ltd. (collectively “RSL”), and Lloyd’s Metals & Engineers (“Lloyds”).

To date, the Department has not issued a duty-absorption determination in this case.

Background

On May 3, 1999, the Department initiated a sunset review of the antidumping duty order on welded carbon steel pipes and tubes from India (64 FR 23596), pursuant to section 751(c) of the Act. The Department received a notice of intent to participate on behalf of Allied Tube and Conduit Corp., Sawhill Tubular Division—Amoco, Century Tube, IPSCO Tubular Inc., LTV Steel Tubular Products, Maverick Tube Corporation, Sharon Tube Company, Western Tube and Conduit, and Wheatland Tube Company (collectively “domestic interested parties”) on May 18, 1999, within the deadline specified in section 351.218(d)(1)(i) of the Sunset Regulations. The domestic interested parties claimed interested-party status under section 771(9)(C) of the Act as U.S. producers of certain welded carbon steel pipes and tubes. We received a complete substantive response from the domestic interested parties on June 2, 1999, within the 30-day deadline specified in the Sunset Regulations under section 351.218(d)(3)(i). We did not receive a substantive response from any respondent interested party to this proceeding. As a result, pursuant to 19 CFR 351.218(e)(1)(ii)(C), the Department determined to conduct an expedited, 120-day review of this order.

In accordance with section 751(c)(5)(C)(v) of the Act, the Department may treat a review as extraordinarily complicated if it is a review of a transition order (i.e., an order in effect on January 1, 1985). On September 7, 1999, the Department determined that the sunset review of the antidumping duty order on circular welded carbon steel pipes and tubes from India is extraordinarily complicated and extended the time limit for completion of the final results of this review until not later than November 29, 1999, in accordance with section 751(c)(5)(B) of the Act.2

Determination

In accordance with section 751(c)(1) of the Act, the Department conducted this review to determine whether revocation of the antidumping duty order would be likely to lead to continuation or recurrence of dumping. Section 752(c) of the Act provides that, in making this determination, the Department shall consider the weighted-average dumping margins determined in the investigation and subsequent reviews and the volume of imports of the subject merchandise for the period before and the period after the issuance of the antidumping duty order, and it shall provide to the International Trade Commission (“the Commission”) the magnitude of the margin of dumping likely to prevail if the order is revoked. The Department’s determinations concerning continuation or recurrence of dumping and the magnitude of the margin are discussed below.

Additionally, the domestic interested parties’ comments with respect to continuation or recurrence of dumping and the magnitude of the margin are addressed within the respective sections below.

Continuation or Recurrence of Dumping

Drawing on the guidance provided in the legislative history accompanying the Uruguay Round Agreements Act (“URAA”), specifically the Statement of Administrative Action (“the SAA”), H.R. Doc. No. 103–316, vol. 1 (1994), the House Report, H.R. Rep. No. 103–826, pt.1 (1994), and the Senate Report, S. Rep. No. 103–412 (1994), the Department issued its Sunset Policy Bulletin providing guidance on methodological and analytical issues, including the bases for likelihood determinations. In its Sunset Policy Bulletin, the Department indicated that determinations of likelihood will be made on an order-wide basis (see section II.A.2). In addition, the Department indicated that normally it will determine that revocation of an antidumping duty order is likely to lead to continuation or recurrence of dumping where (a) dumping continued at any level above de minimis after the issuance of the order, (b) imports of the subject merchandise ceased after the issuance of the order, or (c) dumping was eliminated after the issuance of the order and import volumes for the subject merchandise declined significantly (see section II.A.3).

In addition to considering the guidance on likelihood cited above, section 751(c)(4)(B) of the Act provides that the Department shall determine that revocation of an order is likely to lead to continuation or recurrence of dumping where a respondent interested party waives its participation in the sunset review. In the instant review, the Department did not receive a response from any respondent interested party. Pursuant to section 351.218(d)(2)(iii) of the Sunset Regulations, this constitutes a waiver of participation.

In their substantive response, the domestic interested parties argue that revocation of the subject order would result in the resumption of sales at less than fair value by margins equivalent to those found in the original investigation (see June 2, 1999, Substantive Response of domestic interested parties at 3). With respect to whether dumping continued at any level above de minimis after the issuance of the order, the domestic interested parties assert that margins have increased since the original investigation. For example, domestic interested parties note the dumping margins for two investigated companies, Tisco and Rajinder, increased to 87.39 percent. Id. id.

With respect to import volumes, the domestic interested parties assert that import volumes for the subject merchandise declined significantly, noting that 1998 imports amounted to 12,000 tons, or nearly a 50-percent drop from the 22,000 tons imported in 1985 (the year prior to the subject order). Id. In their substantive response, the domestic interested parties argue that both the overall decrease in imports from India into the United States and continued presence of even higher dumping margins than those found in the original investigation indicate a strong likelihood of continuation of dumping should the order be terminated.

As discussed in section II.A.3 of the Sunset Policy Bulletin, the SAA at 890, and the House Report at 63–64, if companies continue dumping with the discipline of an order in place, the Department may reasonably infer that dumping would continue if the discipline were removed. Dumping margins above de minimis have existed throughout the life of the order, and continue to exist, for shipments of subject merchandise from all Indian producers/exporters investigated other than those excluded from this order.

Consistent with section 752(c) of the Act, we considered the volume of imports before and after the issuance of the order in 1986. The statistics on imports of the subject merchandise cited by the domestic interested parties and those we examined show that Indian producers/exporters continued to export after the order was issued, although not

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2 See Extension of Time Limit for Final Results of Five-Year Reviews, 64 FR 48579 (September 7, 1999).
at pre-order levels. According to U.S. Census Bureau IM146 reports, in 1985, the year prior to the order, approximately 20 million kilograms of subject merchandise were imported into the United States. Although imports peaked in 1988, average imports declined to approximately 7.5 million kilograms over the next ten years, which is almost 50 percent of pre-order levels.

Based on this analysis, the Department finds that the existence of dumping margins after the issuance of the order is highly probative of the likelihood of continuation or recurrence of dumping. Given that dumping has continued at levels above de minimis after the issuance of the order, average imports of subject merchandise declined after the issuance of the order, respondent interested parties have waived their right to participate in this review before the Department, and absent argument and evidence to the contrary, the Department determines that dumping is likely to continue if the order were revoked.

**Magnitude of the Margin**

In the *Sunset Policy Bulletin*, the Department stated that it will normally provide to the Commission the margin that was determined in the final determination in the original investigation. Further, for companies not specifically investigated or for companies that did not begin shipping until after the order was issued, the Department normally will provide a margin based on the “all others” rate from the investigation (see section II.B.1 of the *Sunset Policy Bulletin*). Exceptions to this policy include the use of a more recently calculated margin, where appropriate, and consideration of duty-absorption determinations (see sections II.B.2 and 3 of the *Sunset Policy Bulletin*).

In their substantive response, the domestic interested parties, based on their argument that dumping is likely to continue should the order be terminated, urge the Department to find that the magnitudes of the margins likely to prevail are identical to the margins found for Indian producers/exporters in the original investigation (see June 2, 1999, Substantive Response of domestic interested parties at 3).

We agreed with the domestic interested parties’ assertion that we should report to the Commission the margins from the original investigation. These margins reflect the behavior of exporters without the discipline of the order in place. Absent argument, or evidence to the contrary, we see no reason to change our usual practice. Therefore, the Department, consistent with the SAA at 890 and the House Report at 64, will report to the Commission the margins from the original investigation as contained in this Final Results of Review section of this notice.

**Final Results of Review**

As a result of this review, the Department finds that revocation of the antidumping duty order would likely lead to continuation or recurrence of dumping at the margin listed below:

<table>
<thead>
<tr>
<th>Producer/exporter</th>
<th>Margin (percent)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tata Iron and Steel Company, Ltd.</td>
<td>7.08</td>
</tr>
<tr>
<td>All others</td>
<td>7.08</td>
</tr>
</tbody>
</table>

This notice serves as the only reminder to parties subject to administrative protective order (“APO”) of their responsibility concerning the disposition of proprietary information disclosed under APO in accordance with 19 C.F.R. 351.305 of the Department’s regulations. Timely notification of return/destruction of APO materials or conversion to judicial proceedings is hereby requested. Failure to comply with the regulations and the terms of an APO is a sanctionable violation.

This five-year (“sunset”) review and notice are in accordance with sections 751(c), 752, and 777I(a)(1) of the Act.


Richard W. Moreland,
Acting Assistant Secretary for Import Administration.

[FR Doc. 99–31423 Filed 12–2–99; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

Closed Meeting of the U.S. Automotive Parts Advisory Committee (APAC)

**AGENCY:** Interagency Trade Administration, Commerce.

**ACTION:** Notice.

**SUMMARY:** The APAC will have a closed meeting on December 16, 1999 at a location to be announced to discuss U.S.-made automotive parts sales in Japanese and other Asian markets.

**DATES:** December 16, 1999.


**SUPPLEMENTARY INFORMATION:** The U.S. Automotive Parts Advisory Committee (the “Committee”) advises U.S. Government officials on matters relating to the implementation of the Fair Trade in Automotive Parts Act of 1998 (Pub. L. 105–261). The Committee: (1) reports to the Secretary of Commerce on barriers to sales of U.S.-made automotive parts and accessories in Japanese and other Asian markets; (2) reviews and considers data collected on sales of U.S.-made auto parts and accessories in Japanese and Asian markets; (3) advises the Secretary of Commerce during consultations with other Governments on issues concerning sales of U.S.-made automotive parts in Japanese and other Asian markets; and (4) assists in establishing priorities for the initiative to increase sales of U.S.-made auto parts and accessories to Japanese markets, and otherwise provides assistance and direction to the Secretary of Commerce in carrying out the intent of that section; and (5) assists the Secretary of Commerce in reporting to Congress by submitting an annual written report to the Secretary on the sale of U.S.-made automotive parts in Japanese and other Asian markets, as well as any other issues with respect to which the Committee provides advice pursuant to its authorizing legislation. At the meeting, committee members will discuss specific trade and sales expansion programs related to automotive parts trade policy between the United States and Japan and other Asian markets.

The Assistant Secretary for Administration, with the concurrence of the General Counsel formally determined on November 29, 1999, pursuant to Section 10(d) of the Federal Advisory Committee Act, as amended, that the December 16 meeting of the Committee and of any subcommittee thereof, dealing with privileged or confidential commercial information may be exempt from the provisions of the Act relating to open meeting and public participation therein because these items are concerned with matters that are within the purview of 5 U.S.C. 552(b) (c)(4) and (9)(B). A copy of the Notice of Determination is available for public inspection and copying in the Department of Commerce Records Inspection Facility, Room 6020, Main Commerce.

Dated: December 1, 1999.

Henry P. Misisco,
Director, Office of Automotive Affairs.

[FR Doc. 99–31493 Filed 12–2–99; 8:45 am]

BILLING CODE 3510–DR–M
That initial eligibility requirements be all persons holding permits on September 16, 1999 are eligible;

Permit transfers during the moratorium be allowed between (1) vessels owned by the permit holder and (2) individuals without transfer of the vessel; and,

Reissuance of permits not renewed (or permanently revoked) will not be reissued by NMFS during the moratorium.

The Council did not select preferred alternatives for: (1) a new Gulf permit for coastal migratory pelagics fisheries; (2) vessel size restriction on permit transfers; (3) the appeals process under moratorium; or (4) vessel reporting requirements.

The Draft Charter Vessel/Headboat Permit Moratorium Amendment will be reviewed by the Ad Hoc Charter Vessel/Headboat AP and by the SSC at their respective meetings, times, and dates. Although other non-emergency issues not on the agendas may come before the AP/SSC for discussion, in accordance with the Magnuson-Stevens Fishery Conservation and Management Act, those issues may not be the subject of formal action during these meetings. Actions of the AP/SSC will be restricted to those issues specifically identified in the agendas and any issues arising after publication of this notice that require emergency action under Section 305(c) of the Magnuson-Stevens Act, provided the public has been notified of the Council’s intent to take action to address the emergency.

Written comments will be accepted on the draft amendment if received by January 3, 2000. A copy of the draft amendment can be obtained by calling 813–228–2815. Copies of the agenda can be obtained by calling 813–228–2815.

Special Accommodations

This meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Anne Alford at the Council (see ADDRESSES) by December 28, 1999.


Bruce C. Morehead,
Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

BILLING CODE 3510–22–F

The applicant is requesting authorization to harass the following species of cetaceans annually, over a five year period: humpback whales (Megaptera novaeangliae), during aerial and vessel studies, including in-water work; and sperm whales (Physeter macrocephalus), fin whales (Balaenoptera physalus), spinner dolphins (Stenella longirostris), spotted dolphins (Stenella attenuata), striped dolphins (Stenella coeruleoalba), short-finned pilot whales (Globicephala macrorhynchus), bottlenose dolphins (Tursiops truncatus), melon-headed whales (Peponocephala electra), rough-toothed dolphins (Steno bredanensis), Blainville's beaked whales (Mesoplodon densirostris), Cuvier's beaked whales (Ziphius cavirostris), false killer whales (Pseudorca crassidens), Risso's dolphins (Grampus griseus), pygmy sperm whales (Kogia spp.), and dwarf sperm whales (Kogia spp.), during aerial surveys. The research will be carried out in waters surrounding all of the major Hawaiian Islands.

In compliance with the National Environmental Policy Act of 1969 (42 U.S.C. 4321 et seq.), an initial determination has been made that the activity proposed is categorically excluded from the requirement to prepare an environmental assessment or environmental impact statement.

Concurrent with the publication of this notice in the Federal Register, NMFS is forwarding copies of this application to the Marine Mammal Commission and its Committee of Scientific Advisors.

Dated: November 26, 1999.

Ann D. Terbush,
Chief, Permits and Documentation Division, Office of Protected Resources, National Marine Fisheries Service.


SUPPLEMENTARY INFORMATION:

I. Background

The Corporation for National and Community Service was established in 1993 to engage Americans of all ages and backgrounds in service to their communities. The Corporation’s national and community service programs provide opportunities for participants to serve full-time and part-time, with or without stipend, as individuals or as part of a team. AmeriCorps*State, National, VISTA, and National Civilian Community Corps programs engage thousands of Americans on a full, or part-time basis, at over 1,000 locations to help communities meet their toughest challenges. Learn and Serve America integrates service into the academic life or experiences of nearly one million youth from kindergarten through higher education in all 50 states. The National Senior Service Corps utilizes the skills, talents and experience of over 500,000 older Americans to help make communities stronger, safer, healthier and smarter.

AmeriCorps*State and AmeriCorps*National programs, which involve over 40,000 Americans each year in results-driven community service, are grant programs managed by: (1) State commissions that select and oversee programs operated by local organizations; (2) national non-profit organizations that act as parent organizations for operating sites across the country; (3) Indian tribes; or (4) U.S. Territories. Learn and Serve America grants provide service-learning opportunities for youth through grants to state education agencies, community-based organizations, and higher education institutions and organizations. The National Senior Service Corps operates through grants to nearly 1,300 local organizations for the Retired and Senior Volunteer (RSVP), Foster Grandparent (FGP) and Senior Companion (SCP) programs to provide service to their communities. For additional information on the national service programs supported by the Corporation, go to http://www.nationalservice.org.

In addition, the Corporation supports the AmeriCorps*VISTA (Volunteers in Service to America) and AmeriCorps*NCCC (National Civilian
Community Corps) programs. More than 6,000 AmeriCorps*VISTA members develop grassroots programs, mobilize resources and build capacity for service across the nation. AmeriCorps*NCCC provides the opportunity for approximately 1,000 individuals between the ages of 18 and 24 to participate each year in ten-month residential programs located mainly on inactive military bases.

See “Glossary of Terms” in Section VI for additional information.

II. Eligibility

Public-sector agencies, non-profit organizations, institutions of higher education, Indian tribes, and for-profit companies are eligible to apply. Pursuant to the Lobbying Disclosure Act of 1995, an organization described in section 501(c)(4) of the Internal Revenue Code of 1986, 26 U.S.C. 501(c)(4), which engages in lobbying, is not eligible to apply. Organizations that operate or intend to operate Corporation-supported programs are eligible.

We will consider proposals from single applicants, applicants in partnership and applicants proposing other approaches to meeting the requirement we consider to be responsive to this Notice.

Organizations may apply to provide training and technical assistance in partnership with organizations seeking other Corporation funds. Based on previous training and technical assistance competitions and our estimate of potential applicants, we expect fewer than ten applications to be submitted in each area.

III. Period of Assistance and Other Conditions

A. Cooperative Agreements

Awards made under this Notice will be in the form of cooperative agreements. Administration of cooperative agreements is controlled by Corporation regulations, 45 CFR Part 2541 (for agreements with state and local government agencies) and 45 CFR Part 2543 (for agreements with institutions of higher education, non-profit organizations and other non-governmental organizations). The awardee must comply with reporting requirements, including submitting quarterly financial reports and quarterly progress reports linking progress on deliverables to expenditures.

B. Use of Materials

To ensure that materials generated for training and technical assistance purposes are available to the public and readily accessible to grantees and sub-grantees, the Corporation retains royalty-free, non-exclusive, and irrevocable licenses to obtain, use, reproduce, publish, or disseminate products, including data produced under the agreement, and to authorize others to do so. The awardee will agree to make products available to the national service field as identified by the Corporation at no cost or at the cost of reproduction. All materials developed for the Corporation will be produced consistent with Corporation editorial and publication guidelines.

C. Time Frame

The Corporation expects that activities assisted under the agreements awarded through this Notice will commence on or about February 2000, following the conclusion of the selection and award process. The Corporation will make awards covering a period not to exceed three years. Applications must include a proposed budget and proposed activities for the entire award period. If the Corporation approves an application and enters into a multi-year award agreement, at the outset it will provide funding only for the first year of the award period as funds are made available by Congress. The Corporation has no obligation to provide additional funding in subsequent years. Funding for the second and third years of an award period is contingent upon satisfactory performance, the availability of funds and any other criteria established in the award agreement.

D. Legal Authority

Section 198 of the National and Community Service Act of 1990, as amended, 42 U.S.C. 12653, authorizes the Corporation to provide, directly or through contracts or cooperative agreements, training and technical assistance in support of activities under the national service laws.

IV. Scope of Training and Technical Assistance Activities to Be Supported

A. Tasks

Providers selected under this Notice are to provide training services, training curriculum development and dissemination, materials development and ongoing technical assistance to Corporation grantees and their sub-grantees. The Corporation requires all selected providers to integrate all of the deliverables and principles listed below into their service delivery.

1. Training and Technical Assistance Delivery Process

a. Systems

i. Using a template developed by the Corporation, track training and technical assistance requests, referrals and services provided.

ii. Develop a system for referring grantees to local content area experts who can provide member and volunteer training. This system should include the development and use of a database of content area training specialists and peer experts by county, state and region.

b. Audience and Outreach

i. Respond to ongoing requests for training and technical assistance from national service grantees, sub-grantees and Corporation staff.

ii. With guidance from the Corporation’s Department of Evaluation and Effective Practices, develop and implement a plan to promote services to grantees, sub-grantees and Corporation staff.

iii. Develop and maintain a web-site of training and technical assistance resources and effective practices in a provider’s area of specialization with links to national service sites, as directed by the Corporation.

iv. Work with the national service grantees and sub-grantees who request assistance to identify and clarify their needs and determine an appropriate service response.

C. Training Delivery

i. Prepare and deliver one and two-day customized training courses and training-of-trainer courses for 75-100 participants within each of the Corporation’s five regions (referred to as “clusters”). The provider must undertake an assessment which identifies participants’ skill levels, training delivery preferences, and program stream needs and assets before designing each course. Courses must reflect the findings of the assessment and the broad range of content and skill areas stated in Section IV B of this Notice. (Note: this does not apply to the Leadership Development provider.)

ii. Submit course outlines and descriptions to the Corporation for approval and inclusion in the Corporation’s training and technical assistance resource guide which we will distribute to all national service grantees.

iii. Coordinate scheduling and training delivery with the provider’s training and technical assistance officer (the Corporation first contact with area managers, and staffs of the state commissions, the state education
agencies, and the Corporation state offices where training events are to be held.

iv. Deliver training that is interactive, experiential, consistent with the principles of adult learning, and sensitive to program and audience diversity, skill level and learning style.

v. Submit training event dates to the National Service Resource Center for posting on its national training calendar.

vi. Ensure that all training and technical assistance is accessible to persons with disabilities as required by law to include the following:

— Notifying potential participants that reasonable accommodations will be provided upon request.

— Providing reasonable accommodations when requested to do so, including provision of sign language interpreters, special assistance, and documents in alternate formats.

— Using only accessible locations for training events.

vii. Deliver training that enhances the capacity of grantees to function independently and effectively, which includes, but is not limited to, the following:

— Using transfer-of-skills methods and train-the-trainer models in delivering services following guidelines provided by the Corporation.

— Providing structured opportunities for peer-to-peer assistance during and after all on-request and scheduled training events.

— Developing and disseminating training event packets that include the training agenda, script, handouts and list of training event participants.

— Including community partners in all aspects of the training event.

— Submitting training event packets to the Corporation for National Service (2 copies) and the National Service Resource Center (hard copy and electronic form) within 30 days of a training event.

d. Peer Assistance

i. Develop and manage a peer-to-peer system that uses staff of national service programs and others affiliated with national service programs and makes use of a full range of service delivery options, e.g., phone consultations, teleconferences, videoconferences and other electronic communication; materials' development and shipment; and site visits.

ii. Create and use a database of skilled content area peers by state and cluster.

iii. Document system’s operation, including peer selection criteria, preparation process, and assignment procedure.

iv. Require that the peer prepare an after-action report outlining the issues addressed, actions taken, results achieved and follow-up actions required. Reports must be submitted in a timely manner with copies provided to all interested parties, including state commission staff and Corporation program officers.

v. Provide opportunities for peer assistance in scheduled and on-request training events.

e. Effective Practices

i. Research, identify, document and transmit effective tools and practices through all provider's training and technical assistance services.

ii. Submit effective tools and practices in stipulated format to the National Service Resource Center and, if appropriate, to the National Service-Learning Clearinghouse and encourage grantee use of same.

iii. Use technology as a creative and cost-effective tool for sharing effective practices with large numbers of grantees and subgrantees. Technology should be part of a training strategy that includes people to people contact.

iv. Develop and implement a dissemination plan for all materials (e.g., publications, videotapes, etc.) produced under this agreement.

2. Evaluation

a. Evaluation Plan

Develop and submit a plan for evaluating the impact of training and technical assistance services, particularly the impact of training events relative to each training event’s objectives and the principles and deliverables of this Notice.

b. Evaluation Records

i. Conduct an assessment after each training and technical assistance event using an assessment instrument approved by the Corporation.

ii. Maintain records of these evaluations and provide them to the Corporation, or an authorized representative, upon request.

iii. Submit aggregate evaluation summaries of training-and-technical-assistance events’ evaluations as part of the required quarterly report to the Corporation.

c. Independent Assessment

The Corporation may conduct an independent assessment of each provider’s performance.

3. Reporting Requirements

a. Quarterly Reports

Submit a quarterly report that, at minimum, provides the information below. The provider will develop the capacity to submit this information electronically.

i. A comparison of accomplishments with the goals and objectives for the reporting period.

ii. An annotated version of the approved budget that compares actual costs with budgeted costs by line item, and explains differences. The explanation should include, as appropriate, an analysis of cost overruns and high-cost units and a description of service requests not anticipated in your original budget.

iii. A description of the services provided to include:

(1) number of requests received by topic area and service stream.

(2) the activity conducted to address each request (e.g., training, on-site technical assistance, phone consultation and other electronic communication and materials development and shipment) and mode of delivery (e.g., staff member, consultant, peer assistant and/or other provider).

(3) number of participants in each training and technical assistance event.

(4) cost of each training event based on the direct costs to the provider.

(5) average cost per delivery mode (e.g., on-site consultations, conference calls, training events, and peer-to-peer interventions).

(6) client feedback on the services rendered (including the aggregate evaluation of each training event).

(7) problems encountered in delivering services with recommendations for correcting them.

(8) list of upcoming activities and events.

(9) recommended training and technical assistance focus areas as suggested by analyses of service activity and trends.

(10) discussion of developments that hindered, or may hinder, compliance with the cooperative agreement.

(11) list of materials that have been submitted to the National Service Resource Center.

b. Communication With Training and Technical Assistance Staff

With training and technical assistance officer, develop a plan for on-going communication with the Corporation regarding training and technical assistance activities and the needs of the field.

4. Other Requirements

a. Staff and Consultant Training

Train provider staff and consultants in the background, approach, vocabulary, assets, needs and objectives
of the Corporation and each of its program streams (National Senior Service Corps, Learn and Serve America, and AmeriCorps) and sub-streams (the Foster Grandparent, Senior Companion, and Retired and Senior Volunteer Programs; Learn and Serve America K–12 School- and Community-based Programs, Learn and Serve America Higher Education Programs; AmeriCorps*State and National Direct Programs, AmeriCorps*VISTA, and the AmeriCorps*National Civilian Community Corps).

b. Provider Meetings

Participate in the planning and implementation of national provider meetings and training events as requested by the Corporation.

c. Collaboration With Others

i. Collaborate in materials’ development and training events organized by other providers or the Corporation, as requested.

ii. Share best practices with other providers through the training and technical assistance listserv and other mechanisms (e.g., the National Service-Learning Clearinghouse and the National Service Resource Center).

d. Use of Technology

Creatively and effectively use technology as a cost-effective strategy for reaching large numbers of grantees and subgrantees.

e. Accessible Materials

Provide training and technical assistance materials that are accessible to persons with disabilities, by using accessible technology, providing materials in alternate formats upon request, captioning videos and not using solely a non-voice-over format, and when indicating a telephone number, including a non-voice telephone alternative such as TDD or e-mail.

B. Training and Technical Assistance Categories

The Corporation will evaluate proposals in each of the five categories listed below. These categories were identified in 1999 through an assessment of the training and technical assistance needs of the Corporation’s grantees and subgrantees. The funding ranges listed are approximate and reflect resource availability for the first year only.

1. National Service Program Management (up to $850,000).
2. Leadership Development (up to $425,000).
3. Training Design and Materials Development (up to $250,000).
4. Evaluation (up to $1,000,000).
5. Increasing Participation of Persons with Disabilities in National Service (up to $500,000).

Specific requirements for each category follow:

1. National Service Program Management (up to $850,000)

Background

National Service program directors handle a wide range of responsibilities including, but not limited to: (1) recruiting, training, and supervising their staff and the program’s volunteers, participants, or students; (2) selecting and monitoring subgrantees; (3) training and managing subgrantee staff; (4) developing and maintaining sound financial and reporting systems; (5) effectively participating in “cross-stream” collaboration; (6) developing and maintaining community partnerships; (7) assessing subgrantees’ and participants’ assets and needs; and (8) measuring program impact. Levels of skill and expertise for all of these tasks vary from individual to individual—some program directors have been working in national service for years and others have just recently been hired. Resources vary from program to program and from state to state.

Services Needed

The provider in this category will deliver training and technical assistance specifically targeted to grantees and subgrantees on the “nuts and bolts” of managing national service programs and supervising national service program staff. The means for delivering services is expected to include at a minimum, training for grantee and subgrantee program staff, peer exchange among program staff and others (e.g., commissioners, board members), coaching through telephone consultation, and on-line assistance through individual e-mail, participation in listservs and information provided by web page.

The provider will work with the field to design, pilot and deliver basic and advanced curricula for inexperienced and experienced grantee and subgrantee program directors. Curricula will include, at a minimum, the following content areas: volunteer and participant recruitment, placement, retention and management (including requirements related to civil rights and placement); volunteer and participant development and training; recruitment, retention, training and supervision of staff (with particular attention to supervisory skills); program design, implementation and management; basic grant and subgrant management (including civil rights compliance); multi-site program management; crew-based program management; strategies for working with community partners to develop programs that meet community needs; impact and outcome measurement; effective use of computers for program managers; development of effective grantees networks; strategies for working with other national service program streams; strategies for dealing with staff turnover.

The provider will also provide expert consultant services in a variety of program content areas including the environment, youth leadership, volunteer leadership, risk management and public safety.

The Corporation expects that the provider will provide training within the context of events sponsored by the Corporation’s headquarters and field offices, by other national providers, or by state commissions (among other venues). When working with service-learning programs, the provider will be expected to collaborate with the Learn and Serve America Exchange.

Specific tasks include, but are not limited to the following:

Training

a. Design and deliver training in various settings and of various durations and levels of expertise. Such training may be organized by the provider in response to a request from a group of states or in the context of events organized by a single state commission or another provider or the Corporation.

b. At minimum, the provider must conduct or provide five regional training sessions (one in each of the Corporation’s five clusters) and 50 state-based training sessions per year.

Technical Assistance

a. Provide, arrange for, or connect a minimum of 450 programs to information, training, and technical assistance in program management and organizational development. Peer assistance from other Corporation-funded programs is the preferred method of service delivery.

b. Provide technical assistance on-site, on-line and by telephone in the form of one-time or multiple interventions as required. At minimum, the provider must conduct 75 on-site technical assistance visits per year. The provider will prepare an after-action report outlining the issues addressed, actions taken, results achieved and follow-up actions required. Reports must be submitted within 30 days of visit with copies provided to all
interested parties including commission staff and Corporation program officers.

- Organize and support a minimum of five (one per cluster) affinity groups (i.e., groups of programs defined by their common focus or needs).
- Collaborate with and broker services of other training and technical assistance providers (including the Learn and Serve America Exchange and the National Service-Learning Clearinghouse) to meet the needs of grantees and subgrantees.
- Provide expert assistance in support of Corporation-funded national service programs as requested.
- Develop training and technical assistance materials (e.g., resource lists, publications, training curricula, web-based documents, etc.) based on assessment of stream and substream needs and assets and that reflect effective practices in this training and technical assistance category. Prepare these materials in electronic format and submit them in prescribed format to the National Service Resource Center and to the National Service-Learning Clearinghouse, if appropriate.

2. Leadership Development (up to $425,000)

Background

Leadership training for grantee and subgrantees is currently offered by the AmeriCorps Leaders and VISTA Leaders programs and by the National Service Leadership Institute (NSLI). NSLI and Leaders training events take place at various sites across the country. The provider hired under this category will work under the direction of the National Service Leadership Institute and in coordination with the AmeriCorps Leaders and AmeriCorps*VISTA Leaders programs in delivering the leadership training events available to national service program staff.

Services Needed

Under the direction of the National Service Leadership Institute and Leaders programs, the provider selected in this category will provide curricula design assistance, training delivery, technical consultation and support for the ongoing development of leadership skills of participants in national service programs, including 75 AmeriCorps Leaders and 75 VISTA Leaders. The provider must have the capability to provide logistical support for events ranging from 25-300 participants including providing materials, coordinating training logistics, and arranging for travel and other support services.

Specific tasks include, but are not limited to, the following:

- Provide consultation and group facilitation experts for meetings.
- Develop curriculum and training for special audiences or targeted events.
- The provider must be capable of obtaining and supporting consultants with specialized skills to work on events of high priority to grantees. These activities will require collaboration and the ability to work with diverse groups. For example, working with the National Service Leadership Institute, the provider will develop and deliver a leadership track at the National Senior Service Corps Conference scheduled for June 2000.
- Other activities and events may be identified and funded throughout the term of the agreement, as the need and resources permit.

- Deliver on-line and telephone assistance as well as written resource materials to a minimum of 100 grantees or subgrantees.
- Develop training and technical assistance materials (e.g., resource lists, publications, training curricula, web-based documents, etc) based on assessment of stream and substream needs and that reflect effective practices in this training and technical assistance category. Prepare these materials in prescribed, electronic format to the National Service Resource Center and, if appropriate, to the National Service-Learning Clearinghouse.

3. Training Design and Materials Development (up to $250,000)

Background

It is important for this provider to know that most national service training takes place at the local and state levels and that every national service grantee is responsible for training someone—subgrantees, members, volunteers, participants, teachers, or students, etc. Although some grantees are experienced in this area, many need help developing and implementing training plans and events that effectively meet the needs of their subgrantees or participants. In addition, most grantees handle training as one of many competing responsibilities and work with limited training funds.

Services Needed

The provider in this category will work with grantees in all streams and substreams of Corporation-funded programs to develop effective training plans and provide direct assistance in organizing and delivering training events. Particular emphasis will be placed on identifying and lining up
effective local and peer trainers for members.

When working with service-learning programs, the provider will be expected to collaborate with the Learn and Serve America Exchange.

Technical Assistance

a. Provide technical assistance to state commissions, state education agency staff and other Corporation-funded programs in the following areas:
   (1) assessing trainees’ needs and developing a systematic training plan;
   (2) designing effective training events (i.e., assessing trainee needs and assets, setting training objectives and outcomes, identifying trainers, managing event logistics, developing training materials, preparing trainers prior to the event, and evaluating training events); (3) planning and facilitating large and small group meetings; (4) identifying local training resources (e.g., trainers, training space, etc.); (5) using peer trainers effectively; (6) evaluating training events. The provider should budget for at least 12 consultancies of this type per year.

b. Provide telephone and on-line technical assistance to a minimum of 120 grantees or subgrantees.

c. Develop and maintain a network of geographically-dispersed expert resource people that includes staff from Corporation-funded programs.

d. Develop technical assistance materials (e.g., resource lists, publications, assessment tools, model curricula, web-based documents, etc.) based on assessment of stream and substream needs and that reflect effective practices in this training and technical assistance category. Prepare these materials in a prescribed, electronic format and submit to the National Service Resource Center and, if appropriate, to the National Service-Learning Clearinghouse.

e. Develop technical assistance materials (e.g., resource lists, publications, assessment tools, model curricula, web-based documents, etc.) based on assessment of stream and substream needs and that reflect effective practices in this training and technical assistance category. Prepare these materials in a prescribed, electronic format and submit to the National Service Resource Center and, if appropriate, to the National Service-Learning Clearinghouse.

4. Evaluation (up to $1,000,000)

Background

Programs funded by the Corporation must support and participate in program evaluation activities to meet grant requirements. The Corporation also encourages grantees to incorporate evaluation into program management and to view it as an effective tool to improve services, optimize results, and demonstrate the value of national service efforts. Although some grantees are experienced in evaluation, others have limited skills, knowledge, or resources in this area. The provider hired under this category will work with grantees to build their evaluation capacities.

Services Needed

The provider will deliver outcome evaluation related training and technical assistance to grantees and subgrantees in all streams and substreams of service, including AmeriCorps*State and National programs, AmeriCorps*VISTA, AmeriCorps*NCCC, Learn and Serve America K–12 and Higher Education, and the National Senior Service Corps. The primary means for delivering services is expected to be training for grantees and subgrantee staff at workshops or on-site, peer exchanges, development of materials, coaching through telephone consultation, presentations, publication of a newsletter, and maintenance of a resource library and web site for dissemination of training materials. The provider will be expected to work in collaboration with the Learn and Serve America Exchange when working with service-learning programs.

Specific tasks include, but are not limited to:

Training

a. Develop and disseminate training materials, evaluation tools, and literature, and maintain a resource library.

b. Plan and deliver a minimum of 40 training-of-trainer workshops on request during FY2000. The provider may organize such training events in response to requests from grantees, subgrantees or the Corporation. Workshops will be on evaluation topics tailored to the needs of the requesting organization and may vary in duration and complexity. In general, workshops will be at least one-half day or one day in duration.

c. Plan and deliver at least five (one for each cluster) regional workshops on basic and advanced evaluation topics addressing particular content areas or initiatives to a cross-stream audience. Workshops may vary between one-half and two days in duration.

d. Develop and implement a peer exchange strategy or strategies for a minimum of 50 grantees and subgrantees who provide similar services, work with special needs populations, or form part of large-scale initiatives in order to develop, share, and utilize evaluation plans and data collection instruments that measure outcomes for beneficiaries, members, institutions, and communities.

e. Develop and maintain a network of geographically-dispersed expert resource people, including staff from Corporation-funded programs, that will assist all streams of service to sustain evaluation capacity and efforts at and across various organizational levels (i.e., grantee, subgrantee, etc.).

5. Increasing Participation of Persons With Disabilities in National Service (up to $500,000)

Background

We are committed to increasing the participation and retention of persons with disabilities in national service.
It is important to note that at the time of publication of this announcement, disability funds can only be used to provide training and technical assistance services to competitively-selected AmeriCorps*State and National Direct programs. Services are not currently available to state formula or other national service programs.

Services Needed

The provider will work with the Corporation’s Equal Opportunity Office to develop and implement strategies to increase participation of people with disabilities in AmeriCorps state competitive and national direct programs by providing information on: (1) compliance with applicable federal laws, (2) reasonable accommodation, recruitment and retention of people with disabilities, and (3) national and community service. The provider selected in this category must have expertise across disabilities or a strategy for developing or accessing such expertise.

Specific tasks include, but are not limited to, the following:

Training

a. Work in close collaboration with state commissions and national direct grantees in the implementation of at least five cluster-based training workshops of 50–75 participants each. Workshops should enhance disability awareness, enhance staff skills to develop and support teams that include people with disabilities, enhance the competence of state commissions and parent organizations of national grantees to assess and select effective disability trainers and training.

b. Design and deliver customized training on disability issues and strategies for at least 15 state commissions or parent organizations of national direct programs.

c. Design and deliver ten program-specific training events or on-site technical assistance.

d. Develop and disseminate disability-related training materials.

Technical Assistance

a. Assist the Corporation in the design and delivery of a National Conference on Disability and National Service to be held in January 2001. This meeting will be attended by approximately 500 persons, including commission staff, disability coordinators from national direct grantees, representatives from disability organizations, and representatives from all Corporation-funded programs.

b. Develop and implement a strategy for outreach to national disability organizations in order to make such organizations aware of opportunities that exist for people with disabilities to participate in national service. The Corporation anticipates that as a result of such outreach disability organizations and their constituents will become more knowledgeable about national service and will actively consider their service options.

c. Develop annually, in coordination with identified Corporation, national direct parent organization, and commission executive directors, a disability-focused training and technical-assistance plan for each state commission and national direct parent organization.

d. Develop materials, including information on effective practices, that are suitable for electronic or print publication.

V. Application Guidelines

A. Proposal Content and Submission

Applicants are requested to submit one unbound, original proposal and two copies. Proposals may not be submitted by facsimile. Proposals must include the following:

1. Cover Page

   The cover page must include the name, address, phone number, fax number, e-mail address and world wide web site URL (if available) of the applicant organization and contact person; a 25–50 word summary of proposed training and technical assistance activities; and, the total funding amount requested for the first year.

2. Outline

   A one-two page outline of all proposed training and technical assistance activities and materials.

3. Training and Technical Assistance Delivery Plan

   A bulleted narrative of no more than 20 double-spaced, single-sided, typed pages in no smaller than 12-point font that includes:

   a. Proposed Strategy

      The applicant’s proposed strategy and rationale for providing training and technical assistance to a diverse multi-stream national service audience for one year. The applicant should include the specific deliverables and requirements outlined in Section IV of this Notice as well as the following details (as appropriate) for each proposed training and technical assistance activity, product, and event: Type, learning objectives, desired learning outcomes, estimated audience size, number, frequency, content, skill level, and proposed needs assessment strategy.

   b. Work Plan

      A detailed one-year work plan and timeline for completing all training and technical assistance activities. The work plan should include all deliverables and the tasks leading to them.

   c. Evaluation Plan

      A plan for regularly evaluating performance and reporting findings and proposed improvements to the Corporation.

4. Course Outlines and Descriptions

   A 75–100 word sample course description and a course outline for each of two courses in the provider’s content area. One course should be a basic two-day introductory level training course for 75–100 inexperienced grantees and the other should be a two-day advanced level training course for 75–100 experienced grantees. Course outlines should include desired learning objectives and outcomes and the activities that will lead to them.

5. Description of Organizational Capacity

   a. Organizational Chart

      An organizational chart that clearly shows the place of the training and technical assistance provider in the parent organization’s structure.

   b. Narrative

      A narrative of no more than three double-spaced, single-sided, typed pages in no smaller than 12-point font which describes:

      i. The organization’s capacity to provide training and technical assistance services to five clusters nationwide, including descriptions of recent work similar to that being proposed.

      ii. The organization’s knowledge of and experience with each stream of national service.

      iii. References that can be contacted related to that work.

      iv. Staff strengths and backgrounds (lists and resumes, along with anticipated rates of pay of proposed staff and expert consultants shall be included in an appendix; this information is not subject to the page limits that are otherwise applicable).

6. Budget

   A detailed, line-item budget with hours and costs organized by personnel, task and sub-task and related to the activities and deliverables outlined in the introductory narrative and work
plan. Costs in proposed budgets must consist solely of costs allowable under applicable cost principles found in OMB Circulars. Applicants should be mindful that a demonstrated commitment to providing services in the most cost-effective manner possible will be a major consideration in the evaluation of proposals. (Provider match is not required.) The budget should indicate:

a. Hours
   Staff and expert-consultant hours and pay rates being proposed by task and sub-task.

b. Direct Costs
   Types and quantities of other direct costs being proposed by task and subtask (for example, amounts of travel; volume of other task-related resources, such as communications, postage, etc.).

7. Budget Narrative
   Provide a budget narrative that is organized to parallel all items in the line-item budget and that includes the explanation and cost basis for all cost estimates that appear in the line-item budget. The narrative should clearly show the following:

a. Explanation
   How each cost was derived, using equations to reflect all factors considered.

b. Unit Cost
   The anticipated unit cost (with derivation) of the various deliverables (such as training events and technical assistance interventions).

B. Selection Criteria
   To ensure fairness to all applicants, the Corporation reserves the right to take remedial action, up to and including disqualification, in the event a proposal fails to comply with the requirements relating to page limits, line spacing, and font size. The Corporation will assess applications based on the criteria listed below.

1. Quality (30%)
   The Corporation will consider the quality of the proposed activities based on:

a. Understanding of the Corporation’s Programs
   Evidence of the applicant’s understanding of the goals of the Corporation, effective principles of adult learning, the goals of all of the Corporation’s program streams (see Section VI. “Glossary”), and the Corporation’s training and technical assistance requirements and principles as outlined in this Notice.

b. Soundness of Proposed Strategy
   Evidence of the educational soundness, audience appropriateness, strategic nature (i.e., broad reaching), effectiveness and creativity of applicant’s approach.

2. Organizational and Personnel Capacity (30%)
   The Corporation will consider the organizational capacity of the applicant to deliver the proposed services based on:

a. Experience
   Evidence of organizational experience in delivering research-based high-quality training and technical assistance, particularly in the area under consideration, in a flexible, responsive, collaborative and creative manner; experience or knowledge of national or community service.

b. Staff
   Evidence of training or experience in the providers’ content area and in providing training and technical assistance to adults.

c. Grant Experience
   Demonstrated ability to manage a federal grant or apply sound fiscal management principles to grants and cost accounting.

d. Capacity
   Demonstrated ability to provide training and technical assistance services nationwide.

3. Evaluation (10%)
   The Corporation will consider how the applicant:

a. Scope of Plan
   Proposes to assess the effectiveness and need for its services and products delivered under the award.

b. Continuous Improvement
   Plans to use assessments of its services and products to modify and improve subsequent services and products.

4. Budget (30%)
   The Corporation will consider the budget based on:

a. Cost-Effectiveness
   Cost of each proposed training and technical assistance activity in relation to the scope and depth of the services proposed (i.e., the number of states, programs and individuals the proposed activities are intended to reach).

b. Scope
   Scope of the proposed training and technical assistance activity (e.g., the number of states, programs and individuals the proposed activities are intended to reach).

   a. Clarity
      The clarity and thoroughness of the budget and budget narrative (see specifications under “Budget Narrative”).

VI. Glossary of Terms

Clusters
   The Corporation’s field offices are organized into five regions (“clusters”) as follows:

   Atlantic

   North Central
      Illinois, Indiana, Iowa, Michigan, Minnesota, Nebraska, North/South Dakota, Ohio, Wisconsin.

   Pacific

   Southwest
      Arizona, Arkansas, Colorado, Kansas, Louisiana, Missouri, New Mexico, Oklahoma, Texas.

   Southern
      Alabama, Florida, Georgia, Kentucky, Mississippi, North Carolina, South Carolina, Tennessee, Virginia/District of Columbia, West Virginia.

Cluster-Based Training
   Training events planned in conjunction with the Corporation’s regional training and technical assistance officer and the commissions, state offices, state education agencies or national direct and higher education grantees in a particular region. First priority for participation in cluster-based training events is usually given to the grantees and subgrantees within that particular region.

Grantees
   Entities funded directly by the Corporation. These include and are not limited to: state commissions; state education agencies; Tribes and U.S. Territories; national direct parent organizations; institutions, consortia and organizations of higher education;
local governments; and non-profit organizations. Many grantees also subgrant a significant portion of their funds to others (e.g., a state commission conducts a competition and review process and funds AmeriCorps programs throughout a state; a state education agency (SEA) conducts a competition and review process and funds school systems throughout a state). None of the 1300 Senior Corps grantees are permitted by regulation to subgrant.

Learn and Serve America National Service-Learning Clearinghouse

The Learn and Serve America National Service-Learning Clearinghouse is a collaborative effort among twelve national partner organizations to collect and disseminate information on service-learning for national service grantees and the general public engaged in service-learning. Housed at the University of Minnesota, the Clearinghouse maintains and operates a web site and service-learning listservs, a library of print and media materials related to service-learning, and a toll-free information and referral service. Providers will be required to submit copies of service-learning related training materials and training scripts to the Learn and Serve America National Service-Learning Clearinghouse.

Learn and Serve America Training and Technical Assistance Exchange

The Learn and Serve America Training and Technical Assistance Exchange, led by the National Youth Leadership Council, supports service-learning programs in schools, institutions of higher education, and community organizations through peer-based training and technical assistance. The Exchange links programs with local peer mentors, refers programs to regional trainers, and informs programs of regional service-learning events and initiatives. When providing training and technical assistance to Learn and Serve America grantees or subgrantees, providers will be required to coordinate with the Exchange.

National Service Resource Center (NSRC)

Currently managed by ETR Associates, Inc., Santa Cruz, California, the National Service Resource Center (NSRC) serves as a repository of information on all aspects of national service. The NSRC manages most of the Corporation’s listservs and its web site includes a calendar of training events and links to all current providers. The NSRC also has a lending library.

Training and technical assistance publications are posted or distributed by the NSRC. Providers will be required to submit copies of their training materials and training scripts to the National Service Resource Center.

Stream of Service

Refers to the Corporation’s three main programs: AmeriCorps, Learn and Serve America and National Senior Service Corps. Cross-stream activities, therefore, refer to activities conducted or attended by representatives from more than one program stream.

Subgrantees

Many Corporation grantees competitively award a significant portion of their funds to other entities known as subgrantees. State commissions, for example, subgrant to local non-profit organizations. Senior Corps programs do not subgrant (see “Grantees”).

Substream of Service

Refers to the categories within each of the above streams and includes the following:

AmeriCorps

AmeriCorps’ State
AmeriCorps’ National
AmeriCorps’ VISTA
AmeriCorps’ National Civilian Community Corps

Learn and Serve America

Learn and Serve America K–12 School-Based and Community-Based Programs
Learn and Serve America Higher Education programs

National Senior Service Corps

Foster Grandparent Program
Retired and Senior Volunteer Program (RSVP)
Senior Companion Program

Training and Technical Assistance Listserv

Currently managed by the National Service Resource Center, the training and technical assistance listserv is one of the ways providers share best practices with one another. Providers also share effective practices through the National Service Resource Center and the National Service-Learning Clearinghouse.

(CFDA No. 94.009 Training and Technical Assistance)


William Bentley,

Director, Department of Evaluation and Effective Practices, Corporation for National and Community Service.

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DELAWARE RIVER BASIN COMMISSION

Notice of Commission Meeting and Public Hearing

Notice is hereby given that the Delaware River Basin Commission will hold an informal conference followed by a public hearing on Wednesday, December 8, 1999. The hearing will be part of the Commission’s regular business meeting. Both the conference and business meeting are open to the public and will be held in the Goddard Conference Room of the Commission’s offices at 25 State Police Drive, West Trenton, New Jersey.

The conference among the Commissioners and staff will begin at 9:30 a.m. and will include a presentation on the inaugural meeting of the Water Management Advisory Committee, including a presentation on trends in potable water supplied by the DRBC. Additional items for the conference session include a report on hydrologic conditions in the Basin; a report on activities of the Flow Management Technical Advisory Committee; a report on the Flood Response Meeting of December 2, 1999; a report on talks with the U.S. Army Corps of Engineers regarding alternative funding for DRBC and temporary drought storage at F.E. Walter Reservoir; and revisions to the Commission’s proposed meeting schedule for 2000.

In addition to the dockets below, which are scheduled for public hearing at the 1:00 p.m. business meeting, the Commission will address the following: Minutes of the October 27, 1999 business meeting; announcements; report on Basin hydrologic conditions; reports by the Executive Director and General Counsel; and public dialogue. The Commission will also consider resolutions to: establish a Monitoring Advisory Committee; renew the Toxics Advisory Committee; expand the Water Quality Advisory Committee by adding members of the regulated community; authorize the Executive Director to contract for a flow management study; and amend Docket No. D–68–20 CP (Revised) – PSE&G Salem Nuclear Generating Station—to extend the expiration date of the docket to provide adequate time for its review.

The subjects of the hearing will be as follows:

Holdover: Bucks County Water & Sewer Authority D–99–13 CP. A project to rerate the Harvey Avenue sewage treatment plant (STP) from 0.9 million gallons per day (mgd) to 1.2 mgd for treatment of wet weather inflow. Located at the end of Harvey
Avenue in Doylestown Borough, Bucks County, Pennsylvania, the STP will continue to serve Doylestown Township, Doylestown Borough and Plumstead Township. Following high quality secondary treatment, effluent will continue to discharge to Cooks Run, a tributary of Nesquehiny Creek.

2. Telford Borough Authority D–86–7 CP RENEWAL. A renewal of a ground water withdrawal project to supply up to 38.6 million gallons (mg)/30 days of water to the applicant’s distribution system from Wells No. 1, 3, 4, 5 and 6. Commission approval on September 28, 1988 was extended to 10 years. The applicant requests that the total withdrawal from all wells remain limited to 38.6 mg/30 days. The project is located in Telford Borough, Bucks and Montgomery Counties and West Rockhill Township and Hilltown Township, Bucks County, in the Southeastern Pennsylvania Ground Water Protected Area.

3. Panther Creek Partners D–87–66 (Revision to D–87–66 CP) RENEWAL. A renewal of a water allocation to supply up to 67 mg/30 days to the applicant’s 84 megawatt culm-fired power plant which supplies electricity to the Metropolitan Edison power grid. Commission approval on June 27, 1990 was limited to ten years and will expire unless renewed. No expansion of the approved withdrawal is proposed. A seasonal alternate water source will be provided by the Nesquehiny Borough Authority to offset pre-treatment costs of the applicant’s existing Lusann Tunnel mine water withdrawal. Since treated wastewater will continue to be used to stabilize ash, no effluent discharge will occur. The project is located just west of the Nesquehiny Creek in Nesquehiny Borough, Carbon County, Pennsylvania.

4. Borough of East Stroudsburg D–92–72 CP. A ground water withdrawal project to supply up to 28.2 mg/30 days of water to the applicant’s distribution system from new Well No. 4, and to increase the withdrawal limit from all wells from 28.2 mg/30 days to 56.4 mg/30 days. The total combined withdrawal for the applicant’s ground water and surface water withdrawals will remain at 75 mg/30 days. The project is located in the Borough of East Stroudsburg, Monroe County, Pennsylvania.

5. Citizens Utilities Water Company of Pennsylvania D–99–30 CP. A project to transfer up to 2 mgd of potable water to the applicant’s Glen Alsace District service area through an interconnection with the Reading Area Water Authority. Maitland Plant which draws from Lake Ontelaunee Reservoir; no increase in Reading’s allocation is needed. The applicant will continue to serve development in Exeter Township and St. Laurence Borough, and has included design capacity for a projected future service area expansion in Robeson Township, all within Berks County, Pennsylvania. The applicant currently supplies an average of 1.125 mgd from 17 wells and an existing interconnection with Mount Penn Water Authority, Berks County.

6. Lonza, Inc. D–99–38. A project to upgrade and expand the applicant’s existing 0.06 mgd industrial wastewater treatment plant (IWTP) to provide Best Available Technology for treatment of 0.08 mgd for the applicant’s Riverside Plant organic chemical manufacturing facility located on River Road in Upper Merion Township, Montgomery County, Pennsylvania. Treated effluent will continue to discharge to the Schuylkill River via the Matsunk Creek culvert.

7. Municipal Authority of the Borough of Minersville D–99–44 CP. A project to modify the applicant’s existing potable well water treatment plant residual/wastewater management system by constructing two filter backwash holding tanks to replace the existing slow sand filter process. The 0.11 mgd treated effluent will be conveyed to the applicant’s Reservoir No. 3 on Dyer Run, a tributary of the West Branch Schuylkill River, located in Cass Township, Schuylkill County, Pennsylvania. No expansion of capacity is proposed.

8. Gladys Brittingham Farm D–99–58. A ground water withdrawal project to supply a maximum of 5.6 mg/30 days of water for irrigation of the applicant’s farm crops from new Wells No. 162541 and 167042 in the Columbia aquifer. The water will irrigate approximately 26 acres of grain and vegetables. The project is located near the Town of Milton, Sussex County, Delaware.

Submission for OMB Review; Comment Request

DEPARTMENT OF EDUCATION

Submission for OMB Review; Comment Request

AGENCY: Department of Education

SUMMARY: The Leader, Information Management Group, Office of the Chief Information Officer invites comments on the submission for OMB review as required by the Paperwork Reduction Act of 1995.

DATES: Interested persons are invited to submit comments on or before January 3, 2000.

ADDRESSES: Written comments should be addressed to the Office of Information and Regulatory Affairs, Attention: Danny Werfel, Desk Officer, Department of Education, Office of Management and Budget, 725 17th Street, N.W., Room 10235, New Executive Office Building, Washington, D.C. 20503 or should be electronically mailed to the internet address DWERFEL@OMB.EOP.GOV.

SUPPLEMENTARY INFORMATION: Section 3506 of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35) requires that the Office of Management and Budget (OMB) provide interested Federal agencies and the public an early opportunity to comment on information collection requests. OMB may amend or waive the requirement for public consultation to the extent that public participation in the approval process would defeat the purpose of the information collection, violate State or Federal law, or substantially interfere with any agency’s ability to perform its statutory obligations. The Leader, Information Management Group, Office of the Chief Information Officer, publishes that notice containing proposed information collection requests prior to submission of these requests to OMB. Each proposed information collection, grouped by office, contains the following: (1) Type
of review requested, e.g. new, revision, extension, existing or reinstatement; (2) Title; (3) Summary of the collection; (4) Description of the need for, and proposed use of, the information; (5) Respondents and frequency of collection; and (6) Reporting and/or Recordkeeping burden. OMB invites public comment.


William E. Burrow,
Leader, Information Management Group, Office of the Chief Information Officer.

Office of Special Education and Rehabilitative Services

Type of Review: New.
Title: Special Education Expenditure Project.
Frequency: On occasion.
Affected Public: State, local or Tribal Gov't, SEAs or LEAs.
Reporting and Recordkeeping Hour Burden:
Responses: 24,474
Burden Hours: 12,391

Abstract: This package is to request clearance for The Special Education Expenditures Project (SEEP). The purpose of the study is to provide information about resource allocation to special education programs. The study will provide information on how resources are allocated among various special education programs, and how the use of resources varies across states, schools and districts (e.g., by school poverty levels and size of allocation). The study will report total expenditures on special education, average per pupil expenditures for special education programs and services, patterns of resource allocation, and patterns of services to different categories of students. Respondents will include state, district, and school staff including teachers and instructional aides.

Requests for copies of the proposed information collection request should be addressed to Vivian Reese, Department of Education, 400 Maryland Avenue, SW. Room 5624, Regional Office Building 3, Washington, D.C. 20202–4651, or should be electronically mailed to the internet address OCIO_IMG__Issues@ed.gov or should be faxed to 202–708–9346.

For questions regarding burden and/or the collection activity requirements, contact Sheila Carey at 202–708–6287 or electronically at her internet address Sheila_carey@ed.gov. Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339.

Office of Vocational and Adult Education

Type of Review: Reinstatement.
Title: Vocational Technical Education Annual Performance and Financial Reports.
Frequency: Annually.
Affected Public: State, local or Tribal Gov't, SEAs and LEAs.
Reporting and Recordkeeping Hour Burden:
Responses: 54
Burden Hours: 7,030

Abstract: The information contained in the Annual Performance Reports for Vocational Technical Education is needed to monitor the performance of the activities and services funded under the Carl D. Perkins Vocational and Technical Education Act of 1998, Report to Congress on the Levels of Performance Achieved on the core indicators of performance, provide necessary outcome information to meet the Office of Vocational and Adult Education’s (OVAE’s) Government Performance and Results Act (GPRA) goals for Vocational Technical Education, and provide documentation for incentive awards under Title V of the Workforce Investment Act. The respondents include eligible agencies in 59 states and insular areas.

Requests for copies of the proposed information collection request should be addressed to Vivian Reese, Department of Education, 400 Maryland Avenue, SW. Room 5624, Regional Office Building 3, Washington, D.C. 20202–4651, or should be electronically mailed to the internet address OCIO_IMG__Issues@ed.gov or should be faxed to 202–708–9346.

For questions regarding burden and/or the collection activity requirements, contact Sheila Carey at 202–708–6287 or electronically at her internet address Sheila_carey@ed.gov. Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339.

DEPARTMENT OF EDUCATION

Submission for OMB Review; Comment Request

AGENCY: Department of Education.
SUMMARY: The Leader, Information Management Group, Office of the Chief Information Officer invites comments on the submission for OMB review as required by the Paperwork Reduction Act of 1995.

DATES: Interested persons are invited to submit comments on or before January 3, 2000.

ADDRESSES: Written comments should be addressed to the Office of Information and Regulatory Affairs, Attention: Danny Werfel, Desk Officer, Department of Education, Office of Management and Budget, 725 17th Street, N.W., Room 10235, New Executive Office Building, Washington, D.C. 20503 or should be electronically mailed to the internet address DWERFEL@OMB.EOP.GOV.

SUPPLEMENTARY INFORMATION: Section 3506 of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35) requires that the Office of Management and Budget (OMB) provide interested Federal agencies and the public an early opportunity to comment on information collection requests. OMB may amend or waive the requirement for public consultation to the extent that public participation in the approval process would defeat the purpose of the information collection, violate State or Federal law, or substantially interfere with any agency's ability to perform its statutory obligations. The Leader, Information Management Group, Office of the Chief Information Officer, publishes that notice containing proposed information collection requests prior to submission of these requests to OMB. Each proposed information collection, grouped by office, contains the following: (1) Type of review requested, e.g. new, revision, extension, existing or reinstatement; (2) Title; (3) Summary of the collection; (4) Description of the need for, and proposed use of, the information; (5) Respondents and frequency of collection; and (6) Reporting and/or Recordkeeping burden. OMB invites public comment.


William E. Burrow,
Leader, Information Management Group, Office of the Chief Information Officer.

Office of the Chief Financial Officer

Type of Review: Reinstatement.
Title: Applicants Proposed Budget Information.
Frequency: Annually.
Affected Public: Businesses or other for-profit; Not-for-profit institutions; State, local or Tribal Gov't, SEAs and LEAs.
Reporting and Recordkeeping Burden:
Responses: 17,248.
Burden Hours: 301,840.

Abstract: This collection is necessary for the award and administration of discretionary and formula grants. The collections specific to ED forms are part
DEPARTMENT OF EDUCATION

DEPARTMENT OF LABOR

The Advisory Council for School-to-Work Opportunities; Notice of Renewal

In accordance with the Federal Advisory Committee Act, the Secretaries of Labor and Education have renewed the charter for the Advisory Council for School-to-Work Opportunities.

The Advisory Council for School-to-Work Opportunities shall provide advice to the Departments of Education and Labor on a number of matters pertaining to implementation of the School-to-Work Opportunities Act of 1994. The Council shall be responsible for: Assessing the progress of School-to-Work Opportunities systems development and program implementation toward achieving the goals for the School-to-Work Opportunities initiative; providing feedback and making recommendations to the Executive Committee regarding the progress and direction of implementation of the School-to-Work Opportunities initiative; advising the Executive Committee on the effectiveness of the Federal role in providing venture capital to States and localities to develop School-to-Work systems; and reporting periodically to the Executive Committee on emerging issues, actions, and findings and providing input into policy issues, as requested.

The Council will meet two times a year. It will be composed of approximately 40 members, with the following representation: educators, employers, labor, community groups, the general public, students (secondary and post-secondary), parents, State officials (current Governors, State legislators, State STWO officials), and local officials (mayors, county administrators, local STWO officials). None of these members shall be deemed to be employees of the United States. The Council will report to the Departments of Education and Labor through the School-to-Work Opportunities Executive Committee, composed of senior executive Federal officials from the Departments of Education and Labor. It will function solely as an advisory body and in compliance with the provisions of the Federal Advisory Committee Act.

Interested persons are invited to submit comments regarding the renewal of The Advisory Council for School-to-Work Opportunities. Such comments should be addressed to: Stephanie Powers, National School-to-Work Office, 400 Virginia Avenue, SW, Room 210, Washington, DC 20024.

Signed at Washington, D.C. this 29th day of November, 1999.

Alexis M. Herman,
Secretary of Labor.

Richard W. Riley,
Secretary of Education.

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket Nos. ER00–33–000; ER00–38–000; ER00–56–000; ER00–107–000; and ER00–136–000 (Not consolidated)]

AES Placerita, Inc.; Broad River Energy LLC; FPL Energy Wisconsin Wind, LLC; LA Paloma Generating Company, LLC; FortisUS Energy Corporation, LLC; Notice of Issuance of Order

November 29, 1999.

AES Placerita, Inc., Broad River Energy LLC, FPL Energy Wisconsin Wind, LLC, LA Paloma Generating Company, LLC and FortisUS Energy Corporation, LLC (hereafter, “the Applicants”) filed with the Commission rate schedules in the above-captioned proceedings, respectively, under which the Applicants will engage in wholesale electric power and energy transactions at market-based rates, and for certain waivers and authorizations. In particular, certain of the Applicants may also have requested in their respective applications that the Commission grant blanket approval under 18 CFR Part 34 of all future issuances of securities and assumptions of liabilities by the Applicants. On November 23, 1999, the Commission issued an order that accepted the rate schedules for sales of capacity and energy at market-based rates (Order), in the above-docketed proceedings.

The Commission’s November 23, 1999 Order granted, for those Applicants that sought such approval, their request for blanket approval under Part 34, subject to the conditions found in Appendix B in Ordering Paragraphs (2), (3), and (5):

(2) Within 30 days of the date of this order, any person desiring to be heard or to protest the Commission’s blanket approval of issuances of securities or assumptions of liabilities by the Applicants should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 888 First Street, N.E., Washington, D.C. 20426, in accordance with Rules 211 and 214 of the Commission’s Rules of Practice and Procedure, 18 CFR 385.211 and 385.214.

(3) Absent a request to be heard within the period set forth in Ordering Paragraph (2) above, if the Applicants have requested such authorization, the Applicants are hereby authorized to issue securities and assume obligations and liabilities as guarantor, indorser, surety or otherwise in respect of any security of another person; provided that such issue or assumption is for some lawful object within the corporate purposes of the Applicants, compatible with the public interest, and reasonably necessary or appropriate for such purposes.

(5) The Commission reserves the right to modify this order to require a further showing that neither public nor private interests will be adversely affected by continued Commission approval of the Applicants’ issuances of securities or assumptions of liabilities * * *.

Notice is hereby given that the deadline for filing motions to intervene or protests, as set forth above, is December 23, 1999.

Copies of the full text of the Order are available from the Commission’s Public Reference Branch, 888 First Street, N.E., Washington, D.C. 20426. This issuance may also be viewed on the Internet at
DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket Nos. CP98–107–001 and CP98–109–001]

Continental Natural Gas, Inc.; Notice of Corporate Name Change

November 29, 1999.

Take notice that on November 16, 1999, CMS Continental Natural Gas, Inc. (CMS Continental) tendered for filing in the above-docketed proceedings a notice concerning a change in its corporate name. CMS Continental informs the Commission that effective October 16, 1998, the name of CMS Continental Natural Gas, Inc. has been changed to CMS Field Services, Inc. CMS Continental requests that the Commission modify its records in the above-docketed proceedings, including the certificates granted to CMS Continental under the name Continental Natural Gas, Inc. to reflect the new name. CMS Continental states that its corporate name change is a change in name only and does not reflect any substantive change in operation.

Any person desiring to be heard or to protest said filing should file a motion to intervene or a protest with the Federal Energy Regulatory Commission, 888 First Street, N.E., Washington, D.C. 20426, in accordance with Sections 385.214 or 385.211 of the Commission’s Rules and Regulations. All such motions or protests must be filed in accordance with Section 154.210 of the Commission’s Regulations. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceedings. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection in the Public Reference Room. This filing may be viewed on the web at http://www.ferc.gov/online/rims.htm (call 202–208–2222 for assistance).

David P. Boergers,
Secretary.
[FR Doc. 99–31330 Filed 12–2–99; 8:45 am]
BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. EL95–49–000; Project No. 6032–028]

Fourth Branch Associates (Mechanicville) v. Niagara Mohawk Power Corporation; Notice of Issuance of Order

November 29, 1999.

On November 23, 1999, the Commission issued an “Order Dismissing Complaint, On Petition For Declaratory Order, Rejecting Offer Of Settlement, And Giving Notice Of Intention To Accept Surrender of License” (Order), in the above-docketed proceedings.

Ordering paragraph (G) of the Order gives notice of the Commission’s intent to accept the surrender of the license for Project No. 6032.

Any reply the licensees wish to make must be filed on or before December 23, 1999.

Copies of the full text of the Order are available from the Commission’s Public Reference Branch, 888 First Street, N.E., Washington, D.C. 20426. This issuance may also be viewed on the Internet at http://www.ferc.gov/online/rims.htm (call 202–208–2222 for assistance).

David P. Boergers,
Secretary.
[FR Doc. 99–31330 Filed 12–2–99; 8:45 am]
BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. EG00–27–000, et al.]

AmerGen Energy Company, L.L.C., et al.; Electric Rate and Corporate Regulation Filings


Take notice that the following filings have been made with the Commission:
1. AmerGen Energy Company, L.L.C.
[Docket No. EG00–27–000]


Comment date: December 14, 1999, in accordance with Standard Paragraph E at the end of this notice. The Commission will limit its consideration of comments to those that concern the adequacy or accuracy of the application.

2. Dominion Equipment, Inc.
[Docket No. EG00–28–000]

Take notice that on November 17, 1999, Dominion Equipment, Inc. (Dominion Equipment) filed with the Federal Energy Regulatory Commission an application for determination of exempt wholesale generator status pursuant to Part 365 of the Commission’s regulations.

Dominion Equipment will own, as lessor under a net lease, two eligible facilities to be constructed in Ohio, one eligible facility to be constructed in Pennsylvania and one eligible facility to be constructed in West Virginia. Dominion Equipment will lease the eligible facilities to operating companies that will operate the facilities as exempt wholesale generators.

Comment date: December 14, 1999, in accordance with Standard Paragraph E at the end of this notice. The Commission will limit its consideration of comments to those that concern the adequacy or accuracy of the application.

[Docket No. EG00–29–000]

Take notice that on November 19, 1999, First Security Bank, National Association, not in its individual capacity, but solely as Certificate Trustee under the Trust Agreement (DRI Trust No. 1999–A) (the Trust) filed with the Federal Energy Regulatory Commission an application for determination of exempt wholesale generator status pursuant to Part 365 of the Commission’s regulations.

The Trust will own two eligible facilities to be located in Ohio, one eligible facility to be located in Pennsylvania and one eligible facility to be located in West Virginia. The Trust will lease all four of the eligible facilities to Dominion Equipment, Inc., which in turn will sublease the facilities to operating companies that will operate the eligible facilities as exempt wholesale generators.

Comment date: December 14, 1999, in accordance with Standard Paragraph E at the end of this notice. The Commission will limit its consideration of comments to those that concern the adequacy or accuracy of the application.

4. Sierra Pacific Energy Company
[Docket No. ER99–500–000]

Take notice that on November 17, 1999, Sierra Pacific Energy Company (SPEC), tendered for filing an amendment to its November 4, 1999,
application for an order accepting its FERC Electric Rate Schedule No. 1 which will permit SPEC to make wholesale sales of electric power at market rates to eligible customers located outside of its two Nevada control areas and to sell ancillary services at market-based rates within the California ISO control area. The amendments incorporate changes to the proposed Market-Based Tariff and Code-of-Conduct necessary to reflect the announcement by SPEC’s parent company that it had entered into an agreement to acquire Portland General Electric Company.

Comment date: December 7, 1999, in accordance with Standard Paragraph E at the end of this notice.

5. Commonwealth Edison Company
[Docket No. ER00–589–000]
Take notice that on November 17, 1999, Commonwealth Edison Company (ComEd), tendered for filing a Service Agreement for Network Integration Service (Service Agreement) and a Network Operating Agreement (Operating Agreement) between ComEd and MidAmerican Energy Company. These agreements will govern ComEd’s provision of network service to serve retail load under the terms of ComEd’s Open Access Transmission Tariff (OATT).

ComEd requests an effective date of November 1, 1999, and accordingly, seeks waiver of the Commission’s notice requirements.

Copies of this filing were served on MEC.

Comment date: December 7, 1999, in accordance with Standard Paragraph E at the end of this notice.

6. Illinova Power Marketing, Inc.
[Docket No. ER00–590–000]
Take notice that on November 17, 1999, Illinova Power Marketing, Inc. (IPMI), tendered for filing an Electric Power Transaction Service Agreement under which certain customers will take service pursuant to IPMI’s power sales tariff, Rate Schedule FERC No. 1.

IPMI has requested an effective date of October 18, 1999, for each service agreement.

Comment date: December 7, 1999, in accordance with Standard Paragraph E at the end of this notice.

[Docket No. ER00–591–000]
Take notice that on November 17, 1999, Electric Energy, Inc. (EEInc.), tendered for filing changes to its Open Access Transmission Tariff to correct and reduce the per MW-Month rate applicable to Schedule 1, Scheduling, System Control and Dispatch Service.

EEInc., also requests waiver of any applicable regulations to permit its proposed tariff change to become effective on December 1, 1999.

Comment date: December 7, 1999, in accordance with Standard Paragraph E at the end of this notice.

8. TXU Electric Company
[Docket No. ER00–592–000]
Take notice that on November 17, 1999, TXU Electric Company (TXU Electric) tendered for filing executed transmission service agreements (TSAs) with Central Power and Light Company and West Texas Utilities Company, for certain Planned Service and Unplanned Service transactions under TXU Electric’s Tariff for Transmission Service To, From and Over Certain HVDC Interconnections.

TXU Electric requests an effective date for the TSAs that will permit them to become effective as of January 1, 1997. Accordingly, TXU Electric seeks waiver of the Commission’s notice requirements.

Copies of the filing were served on Central Power and Light Company and West Texas Utilities Company, as well as the Public Utility Commission of Texas.

Comment date: December 7, 1999, in accordance with Standard Paragraph E at the end of this notice.

9. Tucson Electric Power Company
[Docket No. ER00–593–000]

Comment date: December 7, 1999, in accordance with Standard Paragraph E at the end of this notice.

10. Central Power and Light Company
[Docket No. ER00–594–000]
Take notice that on November 17, 1999, Central Power and Light Company submitted for filing a letter agreement for the exchange of electricity between CPL, for whom Central & South West Services, Inc. (CSWS) is acting as agent, Small Hydro of Texas, Inc. (SHOT), and TXU Electric Company (TXU Electric).

CPL states that a copy of the filing has been served on SHOT, TXU Electric, and the Public Utility Commission of Texas.

Comment date: December 7, 1999, in accordance with Standard Paragraph E at the end of this notice.

11. Rochester Gas and Electric Corporation
[Docket No. ER00–595–000]
Take notice that on November 17, 1999, Rochester Gas and Electric Corporation filed a Notice of Cancellation of Point to Point Service Agreements. The Transmission Customers are listed in an attachment to the filing.

RG&E requests waiver of the Commission’s notice requirements, expedited resolution, and that the termination be made effective as of the effective date of the NYISO tariff.

RG&E has served copies of the filing on the New York State Public Service Commission and the Transmission Customers listed in the attachment to the filing.

Comment date: December 7, 1999, in accordance with Standard Paragraph E at the end of this notice.

12. PJM Interconnection, L.L.C.
[Docket No. ER00–596–000]
Take notice that on November 17, 1999, PJM Interconnection, L.L.C. (PJM), tendered for filing a notice by Allegheny Power Service Corporation (APS) to PJM requesting that APS be removed as a signatory to the Reliability Assurance Agreement among Load Serving Entities in the PJM Control Area (RAA), and a revised Schedule 17 to the RAA removing APS from the list of parties to the RAA.

PJM requests a waiver of the 60-day notice requirement to permit its withdrawal of APS as a signatory to the RAA and the revised Schedule 17 of the RAA to become effective as of November 18, 1999.

PJM states that it served a copy of its filing on all parties to the RAA, including APS, and each of the state regulatory commissions within the PJM Control Area.

Comment date: December 7, 1999, in accordance with Standard Paragraph E at the end of this notice.

13. Central Maine Power Company
[Docket No. ER00–597–000]
between CMP and Constellation Power Source, Inc., dated November 5, 1999, for the purchase if CMP’s entitlements to energy, capacity, and certain other benefits associated with its undivested generation assets.

Comment date: December 7, 1999, in accordance with Standard Paragraph E at the end of this notice.

14. UtiliCorp United Inc.

[Docket No. ES00–10–000]

Take notice that on November 18, 1999, UtiliCorp United Inc. (“UtiliCorp”), filed an application seeking authorization pursuant to Section 204(a) of the Federal Power Act to issue corporate guarantees in support of Debt Securities in an amount of up to and including $160,000,000 (Australian) (and any associated currency and interest rate hedges) to be issued by a UtiliCorp Subsidiary at some time(s) before March 31, 2000. UtiliCorp also requests an exemption from the Commission’s competitive bidding and negotiated placement requirements of 18 CFR 34.2.

Comment date: December 14, 1999, in accordance with Standard Paragraph E at the end of this notice.


[Docket No. ES00–9–000]

Take notice that on November 16, 1999, Electric Energy, Inc. filed an application with the Commission seeking authorization pursuant to Section 204 of the Federal Power Act, to issue corporate guarantees in support of Debt Securities in an amount of up to and including $160,000,000 (Australian) (and any associated currency and interest rate hedges) to be issued by a UtiliCorp Subsidiary at some time(s) before March 31, 2000. UtiliCorp also requests an exemption from the Commission’s competitive bidding and negotiated placement requirements of 18 CFR 34.2.

Comment date: December 14, 1999, in accordance with Standard Paragraph E at the end of this notice.

Standard Paragraphs

e. Any person desiring to be heard or to protest such filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 888 First Street, N.E., Washington, D.C. 20426, in accordance with Rules 211 and 214 of the Commission’s Rules of Practice and Procedure (18 CFR 385.211 and 385.214). All such motions or protests should be filed on or before the comment date. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding.

Any person wishing to become a party must file a motion to intervene. Copies of these filings are on file with the Commission and are available for public inspection. This filing may also be viewed on the Internet at http://www.ferc.gov comenz/online/rims.htm (call 202–208–2222 for assistance).

David P. Boergers, Secretary.

[FR Doc. 99–3129 Filed 12–2–99; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

(EIR–FRL–6248–6)

Environmental Impact Statements;
Notice of Availability


EIS No. 990446, DRAFT EIS, COE, SC, Daniel Island Marine Cargo Terminal, Implementation, South Carolina State Ports Authority, (SCSPA), Charleston, Berkeley County, SC, Due: January 18, 2000, Contact: Tina Hadden (843) 727–4330.


EIS No. 990448, FINAL EIS, FAA, NC, Charlotte/Douglas International Airport, Construction and Operation, New Runway 17/35 (Future 18L/36R Associated Taxiway Improvements, Master Plan Development, Approval Airport Layout Plan (ALP) and COE Section 404 Permit, Mecklenburg County, NC, Due: January 03, 2000, Contact: Thomas M. Roberts (404) 305–7153.


EIS No. 990450, FINAL EIS, FHW, NV, US–95 Improvements, Along S. Virginia Parkway to certain Local and Arterial Road Network in the Northwest Region of Las Vegas, Construction and Operation, Clark County, NV, Due: January 03, 2000, Contact: John T. Price (775) 687–1204.

EIS No. 990451, DRAFT SUPPLEMENT, AFS, CA, WA, OR, Northern Spotted Owl Management Plan, Updated Information for Amendment to the Survey and Manage, Protection Buffer and Other Mitigating Measures, Standards and Guidelines (to the Northwest Forest Plan), Late–Successional and Old Growth Forest Related Species Within the Range of the Northern Spotted Owl, OR, WA and CA, Due: January 18, 2000, Contact: Hugh Snook (503) 808–2197.

The U.S. Department of Agriculture’s Forest Service and the U.S. Department of Interior’s Bureau of Land Management are Joint Lead for this project.

Dated: November 30, 1999.

Ken Mittelholtz,
Environmental Protection Specialist, Office of Federal Activities

[FR Doc. 99–31443 Filed 12–2–99; 8:45 am]

BILLING CODE 6560±60±U

ENVIRONMENTAL PROTECTION AGENCY

(EIR–FRL–6248–7)

Environmental Impact Statements and Regulations; Availability of EPA Comments

Availability of EPA comments prepared November 15, 1999 Through November 19, 1999 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 (EIs) was published in the Federal Register, dated April 10, 1999 (63 FR 17856).

Draft EISs


Summary: EPA expressed environmental concerns with environmental impacts of proposed noxious weed treatments and lack of information on the rationale for selected treatment methods and implementation of the monitoring plan.

**Summary:** EPA expressed environmental concerns about the lack of information on the monitoring program implementation and also recommends improved disclosure of air quality impacts and mitigation for prescribed burning. Additional information is needed to fully assess and adequately mitigate potential impacts of the management actions.


**Summary:** EPA expressed lack of objection; the FEIS responds to our concerns on the draft EIS.

Final EISs


**Summary:** EPA expressed lack of objection; the FEIS responds to our concerns on the draft EIS.

For Further Information Contact:

Philip H. Gray, SFIREG Executive Secretary, P. O. Box 1249, Hardwick, VT 05843–1249; (802) 472–6956; fax: (802) 472–6957; e-mail address: aapco@plainfield.bypass.com or Elaine Y. Lyon, Field and External Affairs Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460; telephone number: (703) 305–5306; fax number: (703) 308–1850; e-mail address: lyon.elaine@epa.gov.

**SUPPLEMENTAL INFORMATION:**

1. Does this Action Apply to Me?

This action is directed to the public in general, but all parties interested in SFIREG’s information exchange relationship with EPA regarding important issues related to human health, environmental exposure to pesticides, and insight into the EPA’s decision-making process are invited and encouraged to attend the meetings and participate as appropriate.

2. How Can I Get Additional Information, Including Copies of this Document and Other Related Documents?

**Electronically**. You may obtain electronic copies of the minutes, and certain other related documents that might be available electronically, from the EPA Internet Home Page at http://www.epa.gov/. To access this document, on the Home Page select “Laws and Regulations” and then look up the entry for this document under the “Federal Register–Environmental Documents.” You can also go directly to the Federal Register listings at http://www.epa.gov/fedrgstr/. You may also obtain electronic copies of the minutes, and certain other related documents that might be available electronically, from the Association of American Pesticide Control Officials (AAPCO) Internet Home Page at http://aapco.ceris.purdue.edu/doc/index.html. To access this document, on the Home Page select “SFIREG” and then look up the entry for this document under the “SFIREG Meetings.”

**III. Purpose of Meeting**

2. In person. The Agency has established an administrative record for this meeting under docket control number OPP–00634. The administrative record consists of the documents specifically referenced in this notice, any public comments received during an applicable comment period, and other information related to the SFIREG meeting topic, including any information claimed as Confidential Business Information (CBI). This administrative record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the administrative record, which includes printed, paper versions of any electronic comments that may be submitted during an applicable comment period, is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

1. Update and discussion of Pesticide Field Data Plan.
2. Update on the Food Quality Protection Act (FQPA).
3. EPA’s role/involvement in the Invasive Species Management Plan (Executive Order 13112).
4. Rodenticide Stakeholder process and impacts (meetings and outcomes).
6. Establishment of the Tribal Pesticide Program Council (TPPC).
7. Label Accountability Project.

Dated: November 30, 1999

Ken Mittelholz, Environmental Protection Specialist, Office of Federal Activities.

[FR Doc. 99–1444 Filed 12–2–99; 8:45 am]

BILLING CODE 6560–60–U

**ENVIRONMENTAL PROTECTION AGENCY**

(OPP–00634; FRL–6397–7)

**State FIFRA Issues Research and Evaluation Group (SFIREG); Notice of Public Meeting**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice of public meeting.

**SUMMARY:** The State FIFRA Issues Research and Evaluation Group (SFIREG) will hold a 2–day meeting, beginning on December 6, 1999 and ending on December 7, 1999. This notice announces the location and times for the meeting and sets forth the tentative agenda topics.

**DATES:** The SFIREG will meet on Monday, December 6, 1999 from 8:30 a.m. to 5 p.m. and on Tuesday, December 7, 1999 from 8:30 a.m. to 12 noon.

**ADDRESSES:** The meeting will be held at The Doubletree Hotel, 300 Army Navy Drive, Arlington-Crystal City, VA.

FURTHER INFORMATION CONTACT:

Philip H. Gray, SFIREG Executive Secretary, P. O. Box 1249, Hardwick, VT 05843–1249; (802) 472–6956; fax: (802) 472–6957; e-mail address: aapco@plainfield.bypass.com or Elaine Y. Lyon, Field and External Affairs Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460; telephone number: (703) 305–5306; fax number: (703) 308–1850; e-mail address: lyon.elaine@epa.gov.

**SUPPLEMENTAL INFORMATION:**

I. Does this Action Apply to Me?

This action is directed to the public in general, but all parties interested in SFIREG’s information exchange relationship with EPA regarding important issues related to human health, environmental exposure to pesticides, and insight into the EPA’s decision-making process are invited and encouraged to attend the meetings and participate as appropriate.

II. How Can I Get Additional Information, Including Copies of this Document and Other Related Documents?

1. Electronically. You may obtain electronic copies of the minutes, and
8. Strategy to address the authority over pesticide use on Federal Facilities - California.
11. Committee reports and introduction of issue/discussion papers.
12. Updates from the Office of Pesticide Programs and the Office of Enforcement and Compliance Assurance.
13. SFIREG issues update report.
14. Other topics as appropriate.

List of Subjects
Environmental protection.


Jay Ellenberger,
Director, Field and External Affairs Division,
Office of Pesticide Programs.

[FR Doc. 99-31352 Filed 12-2-99; 8:45 am]
BILLING CODE 6560-50-F

ENVIRONMENTAL PROTECTION AGENCY
[OPP-64043; FRL-6394-8]

Azinphos Methyl; Receipt of Requests For Amendments to Delete Uses; Request For Cancellation, and Advance Notification of Tolerance Revocation and Modifications

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The companies that hold the pesticide registrations of pesticide products containing azinphos methyl \((O,O-dimethyl-S-(4-oxo-1,2,3-benzotriazin 3(4H)-yl)methyl) phosphorothioate\) have asked EPA to amend their registrations to delete use on cotton in Louisiana and east of the Mississippi River, sugarcane, ornamentals (except for nursery stock), Christmas trees, shade trees, and forest trees. One company has also asked EPA to cancel some of its registrations of pesticide products containing azinphos methyl. Pursuant to section 6(f)(1) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), EPA is announcing the Agency’s receipt of these requests from the registrants. The requests to cancel certain uses from the registrations are the result of an agreement between EPA and several registrants regarding the registration of products containing azinphos methyl. Given the potential risks that azinphos methyl use on cotton in Louisiana and east of the Mississippi River, sugarcane, ornamentals (except for nursery stock), Christmas trees, shade trees, and forest trees has on drinking water and ecosystems, EPA intends to grant the requested amendments to delete uses. The Agency also intends to grant the requested registration cancellations. In addition, EPA plans to issue a cancellation order for the deleted uses and the canceled registrations at the close of the comment period for this announcement. After publication of the cancellation order, any distribution, sale, or use of azinphos methyl products will only be permitted if such distribution, sale, or use is consistent with the terms of that order.

DATE: Comments on the requested amendments to delete uses and the requested registration cancellations must be submitted to the address provided below by January 3, 2000.

ADDRESSES: Comments may be submitted by mail, electronically, or in person. Please follow the detailed instructions for each method as provided in Unit I.C. of the “SUPPLEMENTARY INFORMATION” section. To ensure proper receipt by EPA, it is imperative that you identify docket control number OPP-64043 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Barry O’Keefe, Special Review and Reregistration Division (7508C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460, telephone number: 703-308-8035, e-mail address: okeefe.barry@epa.gov.

SUPPLEMENTARY INFORMATION: This announcement consists of five parts. The first part contains general information. The second part addresses the registrants’ requests for amendments to delete uses and for voluntary cancellation of registrations. The third part proposes existing stock provisions that will be set forth in the cancellation order that the Agency intends to issue at the close of the comment period for this announcement. The fourth part provides advance notification of tolerance revocation and modifications the Agency intends to propose. And the fifth part sets forth the Agency’s import tolerance guidance.

I. General Information
A. Does this Action Apply to Me?

You may be potentially affected by this action if you manufacture, sell, distribute, or use azinphos methyl products. The Congressional Review Act, 5 U.S.C. 801 et seq., as added by the Small Business Regulatory Enforcement Fairness Act of 1996, does not apply because this action is not a rule, for purposes of 5 U.S.C. 804(3). If you have any questions regarding the applicability of this action to a particular entity, consult the technical person listed in the “FOR FURTHER INFORMATION CONTACT” section.

B. How Can I Get Additional Information, Including Copies of this Document and Other Related Documents?

1. Electronically. You may obtain copies of this document and certain other available support documents from the EPA Internet Home Page at http://www.epa.gov/. You may access this document by selecting “Laws and Regulations” on EPA’s Home Page and then looking up the entry for this document under the “Federal Register - Environmental Documents.” You can also go directly to the “Federal Register” listings at http://www.epa.gov/fedrgstr/. To access information about the risk assessment for azinphos methyl, go to the Home Page for the Office of Pesticide Programs or go directly http://www.epa.gov/oppsrrd1/op/aqm.htm.

2. In person. The Agency has established an official record for this action under docket control number [OPP-64043]. The official record consists of the documents specifically referenced in this action, any public comments received during an applicable comment period, and other information related to this action, including any information claimed as confidential business information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period, is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is 703-305-5805.

C. How and to Whom Do I Submit Comments?

You may submit comments through the mail, in person, or electronically. To ensure proper receipt by EPA, it is imperative that you identify docket control number [OPP-64043] in the subject line on the first page of your response.
1. By mail. Submit your comments to: Public Information and Records Integrity Branch (PIRIB), Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, 401 M St., SW., Washington, DC 20460.

2. In person or by courier. Deliver your comments to: Public Information and Records Integrity Branch (PIRIB), Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA. The PIRIB is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is 703-305-5805.

3. Electronically. You may submit your comments electronically by e-mail to: “opp-docket@epa.gov,” or you can submit a computer disk as described above. Do not submit any information electronically that you consider to be CBI. Avoid the use of special characters and any form of encryption. Electronic submissions will be accepted in Wordperfect 6.1/8.0 or ASCII file format. All comments in electronic form must be identified by the docket control number 34161. Electronic comments may also be filed online at many Federal Depository Libraries.

D. How Should I Handle CBI That I Want to Submit to the Agency?

Do not submit any information electronically that you consider to be CBI. You may claim information that you submit to EPA in response to this request as CBI by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. In addition to one complete version of the comment that includes any information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public version of the official record. Information not marked confidential will be included in the public version of the official record without prior notice. If you have any questions about CBI or the procedures for claiming CBI, please consult the person identified in the “FOR FURTHER INFORMATION CONTACT” section.

E. What Should I Consider as I Prepare My Comments for EPA?

You may find the following suggestions helpful for preparing your comments:

• Explain your views as clearly as possible.
• Describe any assumptions that you used.
• Provide copies of any technical information and/or data you used that support your views.
• If you estimate potential burden or costs, explain how you arrived at the estimate that you provide.
• Provide specific examples to illustrate your concerns.
• Make sure to submit your comments by the deadline in this announcement.
• To ensure proper receipt by EPA, be sure to identify the docket control number assigned to this action in the subject line on the first page of your response. You may also provide the name, date, and Federal Register citation.

II. Receipt of Requests to Delete Uses And to Cancel Registrations

A. Requests for Amendments to Delete Uses

In a memorandum of agreement ("Agreement") effective August 2, 1999, EPA and a number of registrants of pesticide products containing azinphos methyl to delete such uses pursuant to section 6(f)(1)(A) of FIFRA. In addition, a registrant that did not sign the Agreement has also submitted a request to amend its registrations of pesticide products containing azinphos methyl to delete such uses. The registrations for which amendments were requested are identified in the following Table 1.

<table>
<thead>
<tr>
<th>Company</th>
<th>Reg. No</th>
<th>Product</th>
<th>SLNs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bayer Corporation</td>
<td>3125–108</td>
<td>85% Technical</td>
<td></td>
</tr>
<tr>
<td></td>
<td>3125–102</td>
<td>22.2% Emulsifiable Concentrate</td>
<td></td>
</tr>
<tr>
<td></td>
<td>3125–301</td>
<td>50% Wettable Powder</td>
<td>NJ94000300</td>
</tr>
<tr>
<td>Makhteshim Chemical Works, Ltd.</td>
<td>11678–4</td>
<td>85% Technical</td>
<td></td>
</tr>
<tr>
<td></td>
<td>11678–53</td>
<td>85% Formulation Intermediate</td>
<td></td>
</tr>
<tr>
<td>Makhteshim-Agan of North America, Inc.</td>
<td>66222–11</td>
<td>50% Wettable Powder</td>
<td></td>
</tr>
<tr>
<td></td>
<td>66222–12</td>
<td>22.1% Emulsifiable Concentrate</td>
<td></td>
</tr>
<tr>
<td></td>
<td>66222–16</td>
<td>22.1% Emulsifiable Concentrate</td>
<td></td>
</tr>
<tr>
<td>Gowan Company</td>
<td>10163–78</td>
<td>50% Wettable Powder</td>
<td>AZ94000800</td>
</tr>
<tr>
<td></td>
<td>10163–80</td>
<td>22.2% Emulsifiable Concentrate</td>
<td></td>
</tr>
<tr>
<td></td>
<td>10163–95</td>
<td>85% Technical</td>
<td></td>
</tr>
<tr>
<td></td>
<td>10163–138</td>
<td>35% Wettable Powder</td>
<td></td>
</tr>
<tr>
<td></td>
<td>10163–139</td>
<td>35% Wettable Powder</td>
<td></td>
</tr>
</tbody>
</table>
Under section 6(f)(1)(A) of FIFRA, registrants may request, at any time, that their pesticide registrations be amended to delete one or more pesticide uses. Section 6(f)(1)(B) of FIFRA requires that EPA provide a 30-day period in which the public may comment before the Agency may act on the request for voluntary cancellation. However, such comment period may be waived upon a registrant’s request. In addition, section 6(f)(1)(C) of FIFRA requires that EPA provide a 180-day comment period on a request for voluntary termination of any minor agricultural use before granting the request, unless (1) the registrants request a waiver of the comment period, or (2) the Administrator determines that continued use of the pesticide would pose an unreasonable adverse effect on the environment. The registrants have requested that EPA waive the 180–day comment period. In light of this request, EPA is granting the request to waive the 180–day comment period and is providing a 30–day public comment period before taking action on the requested amendments to delete uses.

As part of the Agreement negotiated with the registrants, the registrants agreed to relabel all stocks of azinphos methyl products that are under their control by December 1, 1999. Any distribution or sale of existing stocks of azinphos-methyl products by the registrants will be unlawful after December 1, 1999. Any distribution or sale of such stocks by persons other than the registrants will be unlawful after December 31, 1999. Given the potential risks that azinphos methyl use on cotton in Louisiana and east of the Mississippi River, sugarcane, ornamentals (except nursery stock), Christmas trees, shade trees, and forest trees has on drinking water and ecosystems, EPA intends to grant the requested amendments to delete uses at the close of the comment period for this announcement.

B. Request for Voluntary Cancellation

In addition to requesting amendments to delete uses, one registrant has submitted a request for voluntary cancellation of some of its registrations of pesticide products containing azinphos methyl. The registrations for which cancellation was requested are identified in the following Table 2.

<table>
<thead>
<tr>
<th>Company</th>
<th>Reg. No</th>
<th>Product</th>
<th>SLNs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Micro-Flo Corporation</td>
<td>51036–76</td>
<td>22.2% Emulsifiable Concentrate</td>
<td>AZ99000500</td>
</tr>
<tr>
<td></td>
<td>51036–130</td>
<td>35% Wettable Powder</td>
<td>AZ99000500</td>
</tr>
<tr>
<td></td>
<td>51036–164</td>
<td>50% Water Dispensable Granules</td>
<td>AZ99000500</td>
</tr>
<tr>
<td>Platte Chemical Company</td>
<td>34704–691</td>
<td>22.2% Emulsifiable Concentrate</td>
<td></td>
</tr>
</tbody>
</table>

Under section 6(f)(1)(A) of FIFRA, registrants may request, at any time, that EPA cancel any of their pesticide registrations. The registrant has requested that EPA waive any applicable comment periods before taking action on its request for cancellation. In light of this request, EPA is granting the request to waive the 180–day comment period and is providing a 30–day public comment period before taking action on the requested cancellations. Given the potential risks that azinphos methyl use poses, EPA intends to grant the requested cancellations at the close of the comment period for this announcement.

III. Proposed Existing Stocks Provisions

The registrants have requested voluntary amendment of the azinphos methyl registrations identified in Table 1 and voluntary cancellation of the azinphos methyl registrations identified in Table 2. Pursuant to section 6(f) of FIFRA, EPA intends to grant the requests for voluntary amendment and cancellation. For purposes of the cancellation order that the Agency intends to issue at the close of the comment period for this announcement, the term “existing stocks” will be defined, pursuant to EPA’s existing stocks policy at 56 FR 29362, Wednesday, June 26, 1991, as those stocks of a registered pesticide product which are currently in the United States and which have been packaged, labeled, and released for shipment prior to the effective date of the amendment or cancellation. Any distribution, sale, or use of existing stocks after the effective date of the cancellation order that the Agency intends to issue that is not consistent with the terms of that order will be considered a violation of section 12(a)(2)(K) and /or 12(a)(1)(A) of FIFRA. Unless existing stocks of products identified in Table 2 by registrants will not be lawful under FIFRA after December 31, 1999, except for the purposes of returns and relabeling, shipping such stocks for export consistent with the requirements of section 17 of FIFRA, or for proper disposal. In addition, the distribution or sale of existing stocks of products identified in Table 2 by registrants will not be lawful under FIFRA after December 31, 1999, except for the purposes of shipping such stocks for export consistent with the requirements of section 17 of FIFRA or for proper disposal.

B. Distribution or Sale by Other Persons

Unless existing stocks of products identified in Table 1 are relabeled in a manner consistent with the Agreement, the distribution or sale of such stocks by registrants will not be lawful under FIFRA after December 31, 1999, except for the purposes of returns and relabeling, shipping such stocks for export consistent with the requirements of section 17 of FIFRA, or for proper disposal.
manner consistent with the Agreement, the distribution or sale of such stocks by persons other than registrants will not be lawful under FIFRA after December 31, 1999, except for the purposes of returns and relabeling, shipping such stocks for export consistent with the requirements of section 17 of FIFRA, or for proper disposal. The distribution or sale of existing stocks of products identified in Table 2 by persons other than registrants will not be lawful under FIFRA after December 31, 1999, except for the purposes of shipping such stocks for export consistent with the requirements of section 17 of FIFRA or for proper disposal.

C. Use of Existing Stocks

The use of existing stocks of products identified in Tables 1 and 2 on cotton in Louisiana and east of the Mississippi River, sugarcane, ornamentals (except nursery stock), Christmas trees, shade trees, and forest trees will be lawful under FIFRA until stocks are depleted provided that the use is in accordance with either the directions for use contained in the Agreement or the existing labeling of that product.

IV. Notification of Intent to Revoke Tolerances

This document also serves to give notice that the Agency intends to propose to revoke the tolerance found in 40 CFR 180.154 for residues of azinphos-methyl in or on apples, crabapples, cranberries, grapes, pears, and quinces. The Agency will issue such a proposed rule to be published in the Federal Register. In the August 2, 1999, Agreement, the registrants agreed to submit a petition requesting specific tolerance modifications for these fruits to be effective January 1, 2000. The Agency has received such a petition and intends to lower these tolerances to help reduce acute dietary risks that currently exceed the margins of safety deemed acceptable by the Agency. The Agreement states that azinphos-methyl in or on sugarcane made with methyl manufacturing-use products may not be reformulated for use on sugarcane, and that end-use product labels intended for use in the 2000 growing season shall not have sugarcane listed as a use site in the directions for use section.

In addition, this document serves to give notice that the Agency intends to propose to lower tolerances found in 40 CFR 180.154 for residues of azinphos-methyl in or on apples, crabapples, cranberries, grapes, pears, and quinces. The Agency will issue such a proposed rule to be published in the Federal Register. In the August 2, 1999, Agreement, the registrants agreed to submit a petition requesting specific tolerance modifications for these fruits to be effective January 1, 2000. The Agency has received such a petition and intends to lower these tolerances to help reduce acute dietary risks that currently exceed the margins of safety deemed acceptable by the Agency.

V. Import Tolerance Guidance

The Agency recognizes that interested parties may want to retain a tolerance in the absence of a U.S. registration, to allow legal importation of food into the United States. To assure that all food marketed in the United States is safe, under the FFDCA, EPA may require the same technical chemistry and toxicology data for such import tolerances (tolerances without related U.S. registrations) as required to support U.S. food use registrations and any resulting tolerances. In addition, EPA may require residue chemistry data (crop field trials) that are representative of growing conditions in exporting countries in the same manner that the Agency requires representative residue chemistry data from different U.S. regions to support domestic use of the pesticides and the tolerance. Interested parties should contact the Agency for written guidance on adapting U.S. residue chemistry data requirements to non-U.S. growing conditions in order to support an import tolerance.

List of Subjects

Environmental protection, Memorandum of Agreement, Pesticides and pests.


Lois Rossi,

Director, Special Review and Reregistration Division, Office of Pesticide Programs.

[FR Doc. 99–31350 Filed 11–30–99; 3:02 pm]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[OPP–34209; FRL–6395–6]

Availability of Reregistration Eligibility Decision Documents for Comment

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces availability and starts a 60–day public comment period on the Reregistration Eligibility Decision (RED) documents for the pesticide active ingredients Captan, S-Ethyl dipropylthiocarbamate (EPCT), Folpet, Niclosamide and 3-trifluoromethyl-4-nitrophenol (TFM or Lamprecide), and Pebulate. The RED represents EPA’s formal regulatory assessment of the health and environmental data base of the subject chemical, and presents the Agency’s determination regarding which pesticidal uses are eligible for reregistration.

DATES: Comments, identified by docket control number OPP–34210, must be received on or before February 1, 2000.

ADDRESSES: Comments may be submitted by mail, electronically, or in person. Please follow the detailed instructions for each method as provided in Unit I.C. of the “SUPPLEMENTARY INFORMATION.” To ensure proper receipt by EPA, it is imperative that you identify docket control number OPP–34210 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Carol Stangel, Special Review and Reregistration Division (7508C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460; telephone number: (703) 308–8007; and e-mail address: stangel.carol@epa.gov.
SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

This action is directed to the public in general. This action may, however, be of particular interest to those persons who are or may be required to conduct testing of chemical substances under the Federal Food, Drug and Cosmetic Act (FFDCA), or the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and those persons who use these chemicals in agricultural production. Since other entities may also be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action. If you have any questions regarding the applicability of this action to a particular entity, consult the people listed under "FOR FURTHER INFORMATION CONTACT."

B. How Can I Get Additional Information, Including Copies of this Document and Other Related Documents?

1. Electronically. You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at http://www.epa.gov/. To access this document, on the Home Page select "Laws and Regulations" and then look up the entry for this document under the "Federal Register--Environmental Documents." You can also go directly to the Federal Register listings at http://www.epa.gov/fedregstr/.

To access the RED documents and RED fact sheets electronically, go to the REDs table on the EPA Office of Pesticide Programs' home page, http://www.epa.gov/REDs. For related information, see http://www.epa.gov/pesticides.

2. In person. The Agency has established an official record for this action under docket control number OPP–34210. The official record consists of the documents specifically referenced in this action, and other information related to this action, including any information claimed as Confidential Business Information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period is available for inspection in the Public Information and Records Integrity Branch (PIRIB). This official record includes copies of all electronic comments submitted during an applicable comment period.

C. How and to Whom Do I Submit Comments?

You may submit comments through the mail, in person, or electronically. To ensure proper receipt by EPA, it is imperative that you identify docket control number OPP–34210 in the subject line on the first page of your response.

1. By mail. Submit your comments to: Public Information and Records Integrity Branch (PIRIB), Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, 401 M St., SW., Washington, DC 20460.

2. In person or by courier. Deliver your comments to: Public Information and Records Integrity Branch (PIRIB), Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm. 119, CM #2, 1921 Jefferson Davis Highway, Arlington, VA. The PIRIB is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

3. Electronically. You may submit your comments electronically by e-mail to: opp-docket@epa.gov, or you can submit a computer disk as described above. Do not submit any information electronically that you consider to be CBI. Avoid the use of special characters and any form of encryption. Electronic submissions will be accepted in Wordperfect 6.1/8.0 or ASCII file format. All comments in electronic form must be identified by docket control number OPP–34210. Electronic comments may also be filed online at many Federal Depository Libraries.
D. How Should I Handle CBI That I Want to Submit to the Agency?

Do not submit any information electronically that you consider to be CBI. You may claim information that you submit to EPA in response to this document as CBI by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. In addition to one complete version of the comment that includes any information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public version of the official record. Information not marked confidential will be included in the public version of the official record without prior notice. If you have any questions about CBI or the procedures for claiming CBI, please consult the person identified under “FOR FURTHER INFORMATION CONTACT.”

E. What Should I Consider as I Prepare My Comments for EPA?

You may find the following suggestions helpful for preparing your comments:
1. Explain your views as clearly as possible.
2. Describe any assumptions that you used.
3. Provide copies of any technical information and/or data you used that support your views.
4. If you estimate potential burden or costs, explain how you arrived at the estimate that you provide.
5. Provide specific examples to illustrate your concerns.
6. Offer alternative ways to improve the notice or collection activity.
7. Make sure to submit your comments by the deadline in this document.
8. To ensure proper receipt by EPA, be sure to identify the docket control number assigned to this action in the subject line on the first page of your response. You may also provide the name, date, and Federal Register citation.

II. Background

A. What Action is the Agency Taking?

The Agency has issued RED documents for the pesticide active ingredients Captan, S-Ethyl dipropylthiocarbamate (EPTC), Folpet, Niclosamide and 3-trifluoromethyl-4-nitrophenol (TFM or Lamprecide), and Pebulate. Under FIFRA, as amended in 1988, EPA is conducting an accelerated reregistration program to reregister existing pesticides initially registered before November 1984, to make sure they meet current scientific and regulatory standards. The data base to support the reregistration of each of the chemicals listed in this document is substantially complete. These RED documents address issues raised by the Food Quality Protection Act of 1996 (FQPA), and any tolerance assessment procedures required under FQPA.

All registrants of pesticide products containing the active ingredients Captan, EPTC, Folpet, Niclosamide, TFM, and Pebulate have been or will be sent the appropriate RED document and must respond to labeling requirements and product specific data requirements within 8 months of receipt. Products containing other pesticide active ingredients in addition to Captan, EPTC, Folpet, Niclosamide, TFM, and Pebulate will not be reregistered until those other active ingredients are determined to be eligible for reregistration.

The reregistration program is being conducted under Congressionally-mandated time frames, and EPA recognizes both the need to make timely reregistration decisions and to involve the public. Therefore, EPA is issuing these REDs as final documents with a 60-day comment period. Although the 60-day public comment period does not affect the registrant’s response due date, it is intended to provide an opportunity for public input and a mechanism for initiating any necessary amendments to the REDs. All comments will be carefully considered by the Agency. If any comment significantly affects a RED, EPA will amend the RED by publishing the amendment in the Federal Register.

B. What is the Agency’s Authority for Taking this Action?

The legal authority for these reregistration eligibility decisions falls under FIFRA, as amended in 1988, which directs that “the Administrator shall determine whether pesticides containing such active ingredient are eligible for reregistration” before calling in data on products and either reregistering products or taking “other appropriate regulatory action.”

List of Subjects

Environmental protection.

Dated: November 22, 1999.

Jack E. Housenger,
Acting Director, Special Review and Reregistration Division, Office of Pesticide Programs.

[FR Doc. 99–31295 Filed 12–2–99; 8:45 am]
BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

[OPP–66272A; FRL–6394–3]

Methyl Parathion, Correction and Clarification of Cancellation Order

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice; correction and clarification.

SUMMARY: This document notifies the public that certain text was erroneously included in the October 27, 1999, Methyl Parathion Cancellation Order (64 FR 57877–57881) (FRL–6387–8). Such text is identified in Unit II.B. of the October 27, 1999 document. Today’s document corrects the October 27, 1999 Methyl Parathion Cancellation Order by removing Unit II.B. and clarifying that nothing in the October 27, 1999 Methyl Parathion Cancellation Order or this document alters the parties’ obligations set forth in the Methyl Parathion Memorandum of Agreement (MOA) signed August 2, 1999.

FOR FURTHER INFORMATION CONTACT:
Dennis Deziel, Special Review and Reregistration Division (7508), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460, telephone number: 703–308–8173, e-mail address: deziel.dennis@epa.gov.

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you manufacture, sell, distribute, or use methyl parathion products. If you have any questions
regarding the applicability of this action to a particular entity, consult the person listed in the “FOR FURTHER INFORMATION CONTACT” section. The Congressional Review Act, 5 U.S.C. 801 et seq., as added by the Small Business Regulatory Enforcement Fairness Act of 1996, does not apply because this action is not a rule, for purposes of 5 U.S.C. 804(3).

B. How Can I Get Additional Information, Including Copies of this Document and Other Related Documents?

1. Electronically. You may obtain copies of this document and certain other available support documents from the EPA Internet Home Page at http://www.epa.gov/. You may access this document by selecting “Laws and Regulations” on EPA’s Home Page and then looking up the entry for this document under the “Federal Register - Environmental Documents.” You can also go directly to the “Federal Register” listings at http://www.epa.gov/fedrgstr/. To access information about the risk assessment for methyl parathion, go to the Home Page for the Office of Pesticide Programs or go directly to: http://www.epa.gov/oppsrrd1/op/methyl-parathion.htm.

2. In person. The Agency has established an official record for this action under docket control number 66272A. The official record consists of the documents specifically referenced in this action, any public comments received during an applicable comment period, and other information related to this action, including any information claimed as confidential business information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period, is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is 703–305–5805.

II. Correction

FR Doc. 99–27800, published in the Federal Register of October 27, 1999, at page 57877, is corrected by removing from the first column of page 57881, “Unit III.B. Notification of Possession of Canceled Products,” and the following text:

No later than November 1, 1999, and pursuant to section 6(g) of FIFRA, any producer or exporter, registrant, applicant for a registration, applicant or holder of an experimental use permit, commercial applicator, or any person who distributes or sells any pesticide, who after the publication of this Notice possesses any stocks of the pesticide products identified on Table 2 of this notice, shall notify EPA and appropriate State and local officials of: (1) Such possession; (2) the quantity of canceled methyl parathion pesticide product possessed; and (3) the place at which the canceled methyl parathion pesticide product is stored.

List of Subjects

Environmental protection, Pesticides and pest.

Dated: November 24, 1999.

Jack E. Housenger,

Acting Director, Special Review and Registration Division.

[FR Doc. 99–31296 Filed 12–2–99; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

[PF–900; FRL–6392–6]

Notice of Filing Pesticide Petitions To Establish a Tolerance for Certain Pesticide Chemicals in or on Food

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces the initial filing of pesticide petitions proposing the establishment of regulations for residues of certain pesticide chemicals in or on various food commodities.

DATES: Comments, identified by docket control number PF–900, must be received on or before January 3, 2000.

ADDRESSES: Comments may be submitted by mail, electronically, or in person. Please follow the detailed instructions for each method as provided in Unit I.C. of the “SUPPLEMENTARY INFORMATION” section. To ensure proper receipt by EPA, it is imperative that you identify docket control number PF–900 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Shaja Brothers, Registration Support Branch, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460; telephone number: (703) 308–3194; and e-mail address: brothers.shaja@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does This Action Apply to Me?

You may be affected by this action if you are an agricultural producer, food manufacturer or pesticide manufacturer. Potentially affected categories and entities may include, but are not limited to:

<table>
<thead>
<tr>
<th>Category</th>
<th>NAICS</th>
<th>Examples of potentially affected entities</th>
</tr>
</thead>
<tbody>
<tr>
<td>Industry</td>
<td>111</td>
<td>Crop production</td>
</tr>
<tr>
<td></td>
<td>112</td>
<td>Animal production</td>
</tr>
<tr>
<td></td>
<td>311</td>
<td>Food manufacturing</td>
</tr>
<tr>
<td></td>
<td>32532</td>
<td>Pesticide manufacturing</td>
</tr>
</tbody>
</table>

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in the table could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether or not this action might apply to certain entities. If you have questions regarding the applicability of this action to a particular entity, consult the person listed in the “FOR FURTHER INFORMATION CONTACT” section.

B. How Can I Get Additional Information, Including Copies of This Document and Other Related Documents?

1. Electronically. You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at http://www.epa.gov/. To access this document, on the Home Page select “Laws and Regulations” and then look up the entry for this document under the “Federal Register–Environmental Documents.” You can also go directly to the Federal Register listings at http://www.epa.gov/fedrgstr/.

2. In person. The Agency has established an official record for this action under docket control number PF–900. The official record consists of the documents specifically referenced in this action, any public comments received during an applicable comment period, and other information related to this action, including any information claimed as confidential business information (CBI). This official record
includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period, is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

C. How and to Whom Do I Submit Comments?

You may submit comments through the mail, in person, or electronically. To ensure proper receipt by EPA, it is imperative that you identify docket control number PF–900 in the subject line on the first page of your response.

1. By mail. Submit your comments to: Public Information and Records Integrity Branch (PIRIB), Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, 401 M St., SW., Washington, DC 20460.

2. In person or by courier. Deliver your comments to: Public Information and Records Integrity Branch (PIRIB), Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA. The PIRIB is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

3. Electronically. You may submit your comments electronically by E-mail to: “opp-docket@epa.gov,” or you can submit a computer disk as described above. Do not submit any information electronically that you consider to be CBI. Avoid the use of special characters and any form of encryption. Electronic submissions will be accepted in Wordperfect 6.1/8.0 or ASCII file format. All comments in electronic form must be identified by docket control number PF–900. Electronic comments may also be filed online at many Federal Depository Libraries.

D. How Should I Handle CBI That I Want To Submit to the Agency?

Do not submit any information electronically that you consider to be CBI. You may claim information that you submit to EPA in response to this document as CBI by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. In addition to one complete version of the comment that includes any information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public version of the official record.

Information not marked confidential will be included in the public version of the official record without prior notice. If you have any questions about CBI or the procedures for claiming CBI, please consult the person identified in the “FOR FURTHER INFORMATION CONTACT” section.

E. What Should I Consider as I Prepare My Comments for EPA?

You may find the following suggestions helpful for preparing your comments:

1. Explain your views as clearly as possible.
2. Describe any assumptions that you used.
3. Provide copies of any technical information and/or data you used that support your views.
4. If you estimate potential burden or costs, explain how you arrived at the estimate that you provide.
5. Provide specific examples to illustrate your concerns.
6. Make sure to submit your comments by the deadline in this notice.
7. To ensure proper receipt by EPA, be sure to identify the docket control number assigned to this action in the subject line on the first page of your response. You may also provide the name, date, and Federal Register citation.

II. What Action is the Agency Taking?

EPA has received pesticide petitions as follows proposing the establishment and/or amendment of regulations for residues of certain pesticide chemicals in or on various food commodities under section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a. EPA has determined that these petitions contain data or information regarding the elements set forth in section 408(d)(2) of the FFDCA; however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data support granting of the petitions. Additional data may be needed before EPA rules on the petitions.

List of Subjects

Environmental protection, Agricultural commodities, Feed additives, Food additives, Pesticides and pests, Reporting and recordkeeping requirements.


James Jones,
Director, Registration Division, Office of Pesticide Programs.

Summaries of Petitions

The petitioner summaries of pesticide petitions are printed below as required by section 408(d)(3) of the FFDCA. The summaries of petitions was prepared by the petitioner and represents the views of the petitioner. EPA is publishing the petition summaries verbatim without editing them in any way. The petition summary announces the availability of a description of the analytical methods available to EPA for the detection and measurement of the pesticide chemical residues or an explanation of why no such method is needed.

1. Interregional Research Project Number 4

1E4019, 7E4857, and 9E6009

EPA has received pesticide petitions (1E4019, 7E4857, and 9E6009) from the Interregional Research Project Number 4 (IR-4) New Jersey Agricultural Experiment Station, Rutgers University, New Brunswick, New Jersey 08903 proposing, under section 408(d) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(d), to amend 40 CFR part 180 by establishing tolerances for residues of the herbicide paraquat (1,1-dimethyl-4,4’-bipyridinium) derived from the application of the dichloride salt (calculated as the cation) in or on the raw agricultural commodities (RAC) globe artichoke, dry peas, and persimmon at 0.05, 0.3, and 0.05 parts per million (ppm), respectively. EPA has determined that the petitions contain data or information regarding the elements set forth in section 408(d)(2) of the FFDCA; however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data support granting of the petitions. Additional data may be needed before EPA rules on the petitions. This notice includes a summary of the petitions prepared by Zeneca Ag Products, the registrant, 1800 Concord Pike, P.O. Box 15458, Wilmington, Delaware 19850-5458.
A. Residue Chemistry

1. Plant metabolism. The qualitative nature of the residue in plants is adequately understood based on studies depicting the metabolism of paraquat in carrots and lettuce following pre-emergence treatments and in potatoes and soybeans following desiccant treatment. The residue of concern in plants is the parent chemical, paraquat.

2. Analytical method. An adequate analytical method (spectrometric method) has been accepted and published in the Pesticide Analytical Manual (PAM Vol. II) for the enforcement of tolerances in plant commodities.

3. Magnitude of residues. Magnitude of residue data were collected from three sites in the major globe artichoke producing region of the United States. No residues exceed the proposed tolerance of 0.05 ppm, when globe artichokes are treated with 3.0 to 3.6 lb active ingredient/acre (ai/acre) of paraquat applied as three applications directed between the rows at approximately 7-day intervals and the last application 1-day prior to harvest. Residue data have been obtained from Washington and Idaho which represent 91% of the dry pea production in the United States. Mature dry peas were treated once with paraquat at either 0.5 or 1.0 lb ai/acre of paraquat 7 days prior to harvest. The highest residue recovered in the dry pea was 0.25 ppm. The other treated samples all had residues of ≤ 0.2 ppm. IR-4 is requesting the establishment of a tolerance for persimmon based on the 0.05 ppm tolerance established on guava. Applications of paraquat in persimmon would be the same as those in the Gramoxone Extra label for use on guava, utilizing a directed, postemergence application.

B. Toxicological Profile

1. Acute toxicity. Acute toxicity studies conducted with the 45.6% paraquat dichloride technical concentrate give the following results: oral lethal dose (LD₅₀) in the rat of 344 milligrams/kilograms (mg/kg) (males) and 283 mg/kg (females) (Category II); dermal LD₅₀ in the rat of > 2,000 mg/kg for males and females (Category III); the primary eye irritation study showed corneal involvement with clearing within 17 days (Category II); and dermal irritation of slight erythema and edema at 72 hours (Category IV). Paraquat is not a dermal sensitizer. Acute inhalation studies conducted to EPA guideline with aerosolized sprays result in lethal concentration (LC₅₀) of 0.6 to 1.4 μg paraquat cation/L (Category I). However, since paraquat dichloride has no measurable vapor pressure; and hydraulic spray droplets are too large to be respirable, inhalation exposure is not a concern in practice.

2. Genotoxicity. Paraquat dichloride was not mutagenic in the Ames test using Salmonella typhimurium strains TA1535, TA1538, TA98, and TA100; the chromosomal aberrations in the bone marrow test system; or in the dominant lethal mutagenicity study with CD-1 mice. Additionally, paraquat dichloride was negative for unscheduled DNA synthesis (UDS) in rat hepatocytes in vitro and in vivo. Paraquat was weakly positive in the mouse lymphoma cell assay only in the presence of metabolic activation. Paraquat dichloride was weakly positive in mammalian cells (lymphocytes) and positive in the sister chromatid exchange (SCE) assay in Chinese hamster lung fibroblasts. Paraquat is non-mutagenic.

3. Reproductive and developmental toxicity. A 3-generation reproduction study in rats fed diets containing 0, 25, 75, and 150 ppm (0, 1.25, 3.75 or 7.5 mg of paraquat cation/kg/day, respectively) showed no effect on body weight gain, food consumption and utilization, fertility and length of gestation of the F₁, F2, and F3 parents at any dose. The no observed adverse effect level (NOAEL) and lowest observed adverse effect level (LOAEL) for systemic toxicity are 25 ppm (1.25 mg/kg/day) and 75 ppm (3.75 mg/kg/day), respectively, expressed as paraquat cation, based on high mortality due to lung damage. The NOAEL for reproductive toxicity is 130 ppm (7.5 mg/kg/day; highest dose tested [HDT]) expressed as paraquat cation, as there were no reproductive effects observed.

Two developmental toxicity studies were conducted in rats given gavage doses of 0, 1, 5, or 10 mg/kg/day and 0, 1, 3, or 8 mg/kg/day, respectively, expressed as paraquat cation. In the first study, the NOAEL for maternal toxicity was 1 mg/kg/day based on clinical signs of toxicity and decreased body weight gain at 5 mg/kg/day (the LOAEL). The NOAEL for developmental toxicity was set at 5 mg/kg/day based on delayed ossification of the forelimb and hindlimb digits. In the second study, the maternal and developmental NOAEL is 8 mg/kg/day HDT as there were no effects observed at any dose level. Based on both studies, the overall NOAEL for maternal and developmental toxicity is at least 3 mg/kg/day.

Two developmental toxicity studies were conducted in mice given gavage doses of 0, 1, 5, or 10 mg/kg/day and 7.5, 15, or 30 mg/kg/day paraquat ion, respectively. In the first study, the NOAEL and LOAEL for maternal toxicity are 5 mg/kg/day and, 10 mg/kg/day, respectively, based on reductions in body weight gain and death (range-finding study). The NOAEL and LOAEL for developmental toxicity are 5 mg/kg/day and 10 mg/kg/day, respectively based on an increased number of litters and fetuses with partial ossification of the 4th sternebra at 10 mg/kg/day HDT. Both the maternal and developmental NOAELs are at 15 mg/kg/day in the second study. The maternal LOAEL of 25 mg paraquat cation/kg/day is based on death, decreases in body weight and body weight gain, and other clinical signs. The developmental LOAEL of 25 mg/kg/day is based on decreases in mean fetal weights, retarded ossification and other skeletal effects. According to the registrant, the developmental/maternal NOAEL should be based on the second study and is 15 mg/kg/day. Paraquat dichloride is not a developmental toxin.

4. Subchronic toxicity. A 90-day feeding study in dogs fed doses of 0, 0.7, 20, 60, or 120 ppm with a NOAEL of 20 ppm based on lung effects such as alveolitis and alveolar collapse seen at the LOAEL of 60 ppm. A 21-day inhalation toxicity study in rats were exposed to respirable aerosols of paraquat at doses of 0, 0.01, 0.1, 0.5, or 1.0 μg/L with a NOAEL of 0.01 μg/L and a LOAEL of 0.10 μg/L based on histopathological changes to the epithelium of the larynx and nasal discharge.

5. Chronic toxicity. In a 12-month feeding study in dogs fed dose levels of 0, 30, 50, or 100 ppm, expressed as paraquat cation. These levels corresponded to 0, 0.45, 0.93, or 1.51 mg of paraquat cation/kg/day, respectively, in male dogs or 0, 0.48, 1.00, or 1.58 mg of paraquat cation/kg/day, respectively for female dogs. There was a dose-related increase in the severity and extent of chronic pneumonitis in the mid-dose and high-dose male and female dogs. This effect was also noted in the low-dose male group, but was minimal when compared with the male controls. The systemic LOAEL is 30 ppm (0.93 mg/kg/day for males and 1.00 mg/kg/day for females, expressed as paraquat cation). The systemic NOAEL is 30 ppm (0.93 mg/kg/day for males and 1.00 mg/kg/day for females, expressed as paraquat cation).

In a 2-year chronic feeding/carcinogenicity study, rats were fed doses of paraquat dichloride at 0, 25, 75, or 150 ppm which correspond to 0, 1.25, 3.75, or 7.5 mg of paraquat cation/kg/day. Paraquat enhanced the development of cataracts in all of the treated groups. The predominant lesions detected ophthalmoscopically...
were lenticular opacities and cataracts. At test week 103, dose-related statistically significant (P < 0.001) increases in the incidence of ocular lesions were observed only in the mid-dose and high-dose male and female groups. Based on these findings, the NOAEL (approximate) and the LOAEL for systemic toxicity, for both sexes, are 25 ppm (1.25 mg/kg/day) and 75 ppm (3.75 mg/kg/day), respectively.

In another 2-year chronic feeding/ carcinogenicity study, rats were dosed at 0, 6, 30, 100, or 300 ppm, expressed as paraquat dichloride (nominal concentrations), equivalent to 0, 0.25, 1.26, 4.15, or 12.25 mg/kg/day, respectively (males) and 0, 0.30, 1.5, 5.12 or 15.29 mg/kg/day respectively (females), expressed as paraquat dichloride. The incidence of ocular changes were low and not caused by paraquat in this study. The systemic NOAEL is 100 ppm of paraquat dichloride (4.15 and 5.12 mg/kg/day, for males and females, respectively); or 3.0 mg/kg/day (males) and 3.7 mg/kg/day (females), expressed as paraquat cation. The systemic LOAEL is 300 ppm of paraquat dichloride (12.25 and 15.29 mg/kg/day, for males and females, respectively); or 9.0 mg/kg/day (males) and 11.2 mg/kg/day (females), expressed as paraquat cation.

A chronic feeding/carcinogenicity study in rats fed dose levels of 0, 25, 75, or 150 ppm, expressed as paraquat cation (nominal concentrations). These doses corresponded to 0, 1.25, 3.75, or 7.5 mg paraquat cation/kg/day, respectively. There was uncertain evidence of carcinogenicity (squamous cell carcinomas in the head region; ears, nasal cavity, oral cavity and skin) in males at 7.5 mg/kg/day HDT with a systemic NOAEL of 1.25 mg/kg/day. Upon submission of additional data to EPA, the incidence of pulmonary adenomas and carcinomas was well within historical ranges and it was determined that paraquat was not carcinogenic in the lungs and head region of the rat.

In another chronic feeding/ carcinogenicity study, rats were fed paraquat dichloride at dose levels of 0, 12.5, 37.5, or 100/125 ppm, expressed as paraquat dichloride. There were no carcinogenic findings in this study at the HDT. In a 2-year chronic feeding/convincing study, SPF Swiss derived mice were fed paraquat dichloride at dose levels of 0, 12.5, 37.5, or 100/125 ppm, expressed as paraquat cation. These rates correspond to 0, 1.87, 5.62, and 15 mg/kg/day as cation. Because no toxic signs appeared after 35 weeks of dosing, the 100 ppm level was increased to 125 ppm at week 36. There were no carcinogenic effects observed in this study. The systemic NOAEL for both sexes is 12.5 ppm (1.87 mg/kg/day) and the systemic LOAEL is 37.5 ppm (5.6 mg/kg/day), each expressed as paraquat cation based on renal tubular degeneration in males and weight loss and decreased food intake in females.

Paraquat is classified Category E for carcinogenicity (no evidence of carcinogenicity in animal studies).

6. Animal metabolism. The qualitative nature of the residue in animals is adequately understood based on the combined studies conducted with ruminants (goats and cows), swine, and poultry. The residue of concern in eggs, milk, and poultry and livestock tissues is the parent, paraquat.

C. Aggregate Exposure

In examining aggregate exposure, FQPA directs EPA to take into account available information concerning exposures from the pesticide residue in food and all other exposures for which there is reliable information. These other sources of exposure include drinking water, and non-occupational exposures, e.g., to pesticides used in and around the home. For estimating acute and chronic risks the Agency considers aggregate exposures from the diet and from drinking water. Exposures from uses in and around the home that may be short term, intermediate, or other durations may also be aggregated as appropriate for specific chemicals.

1. Dietary exposure. For purposes of assessing the potential dietary exposure under the proposed tolerance, Zeneca has estimated aggregate exposure based on the tolerance levels of 0.05 ppm, 0.3 ppm, and 0.05 ppm in or on globe artichokes, dry peas, and persimmons and from all other established tolerances. Percent crop treated was also incorporated into the assessment to derive an upper bound anticipated residue contribution (ARC). The registrant has concluded that there are no acute endpoints of concern for paraquat, and an acute aggregate assessment is not required. The chronic population adjusted dose (cPAD) for chronic dietary assessments is 0.0045 mg/kg/day, based on a NOAEL of 0.45 mg/kg/day from a 1-year dog study and the addition of a standard uncertainty factor of 100.

ii. Acute dietary assessment. A chronic dietary exposure analysis was performed using current and reassessed tolerance level residues, contributions from the proposed tolerance for use on globe artichoke, cotton, and persimmons and current percent crop treated revised data to estimate the ARF for the general population and 22 subgroups. The tolerance in globe artichoke resulted in a ARC of 0.0000001 mg/kg/day (0.002% of the cPAD) for the general population. The resulting ARC for the general U.S. population from all established uses is 0.000367 mg/kg/day (8.2% of the cPAD). For children ages 1-6, the most highly exposed subgroup, the resulting ARC is 0.001077 mg/kg/day (23.9% of the cPAD).

iii. Drinking water. The Registration Eligibility Document (RED) for paraquat has stated the following:

Paraquat is not expected to be a contaminant of ground water. Paraquat dichloride binds strongly to soil clay particles and it did not leach from the surface in terrestrial field dissipation studies. There were, however, detections of paraquat in drinking water wells from two states cited in the Pesticides in Ground Water Database (1991). These detections are not considered to be representative of normal paraquat use. Therefore, paraquat is not expected to be a ground water contaminant or concern based on normal use patterns. Due to its persistent nature, paraquat could potentially be found in surface water systems associated with soil particles carried by erosion; however, paraquat is immobile in most soils, and at very high application rates (50-1,000x), there was no desorption of paraquat from soils.

Based on paraquat’s normal use patterns and unique environmental fate characteristics, exposures to paraquat in drinking water are not expected to be obtained from surface water sources. Therefore, the only exposures considered in aggregate risk assessment for paraquat is chronic dietary,

2. Non-dietary exposure. Paraquat dichloride has no residential or other non-occupational uses that might result in non-occupational, non-dietary exposure for the general population. Paraquat products are Restricted Use, for use by Certified Applicators only, which means the general public cannot buy or use paraquat products.

D. Cumulative Effects

In assessing the potential risk from cumulative effects of paraquat and other chemical substances, the Agency has considered structural similarities that exist between paraquat and other bipyridyl compound such as diquat dibromide. Examination of the toxicology data presented for paraquat and diquat dibromide, indicates that the two compounds have clearly different target
organs. Based on available data, the registrant does not believe that the toxic effects produced by paraquat would be cumulative with those of diquat dibromide.

E. Safety Determination

1. U.S. population. Based on the Paraquat RED, the only exposure route of concern for paraquat is chronic dietary. Using the conservation assumptions presented earlier, EPA has established a cPAD of 0.0045 mg/kg/day. This was based on the NOAEL for the 1–year dog study of 0.45 mg/kg/day and employed a 100-fold uncertainty factor. Results of this aggregate exposure assessment, which includes EPA’s reassessment of tolerances for existing crops and the tolerance for use on globe artichokes, dry peas, and persimmons utilize 8.2% of the cPAD. Generally, exposures below 100% of the cPAD are of no concern because it represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risk to human health. Thus, the registrant has concluded that there is reasonable certainty that dietary exposure to paraquat will not cause harm to infants and children.

2. Infants and children. Zeneca has determined that the established tolerances for paraquat, with amendments and changes as specified in this notice, meet the safety standards under the FQPA amendments to section 408(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 346a(d)) for infants and children. The safety determination for infants and children considers the factors noted above for the general population, but also takes into account the possibility of increased dietary exposure due to specific consumption patterns of infants and children, as well as the possibility of increased susceptibility to the toxic effects of paraquat residues in this population subgroup.

In determining whether or not infants and children are particularly susceptible to toxic effects from paraquat residues, Zeneca considered the completeness of the data base for developmental and reproductive effects, the nature and severity of the effects observed, and other information. Based on the current data requirements, paraquat has a complete data base for developmental and reproductive toxicity. In the developmental studies, effects were seen (delayed ossification in the forelimb and hindlimb digits) in the fetuses only at the same or higher dose levels than effects in the mother. In the reproduction study, no effects on reproductive performance were seen. Also because the NOAELs from the developmental and reproduction studies were equal to or greater than the NOAEL used for establishing the cPAD, the registrant concluded that it is unlikely that there is additional risk concern for immature or developing organisms. Finally, there is no epidemiological information suggesting special sensitivity of infants and children to paraquat. Therefore, the registrant found that an additional safety factor for infants and children is not warranted for paraquat.

Zeneca estimates that paraquat residues in the diet of non-nursing infants (less than 1–year) account for 17.6% of the cPAD and 23.9% of the cPAD for children aged 1–6 years. Further, residues in drinking water are not expected. Therefore, Zeneca has determined that there is reasonable certainty that dietary exposure to paraquat will not cause harm to infants and children.

F. International Tolerances

There is no approved CODEX maximum residue level (MRL) established for residues of paraquat on globe artichokes, dry peas, and persimmons.

2. Interregional Research Project Number 4

PP 9E6042

EPA has received a pesticide petition (9E6042) from the Interregional Research Project Number 4 (IR-4), Center for Minor Crop Pest Management, at the Technology Centre of New Jersey, 681 U.S. Highway #1, South, North Brunswick, NJ 08902-3390 proposing, pursuant to section 408(d) of the FFDCA, 21 U.S.C. 346a(d), to amend 40 CFR part 180 by establishing a tolerances for residues of fenpropathrin, alpha-cyano-3-phenoxybenzyl 2,2,3,3-tetramethylcyclopropanecarboxylate, in or on the food commodities cucurbit vegetables (Crop Group 9) commodities at 0.5 ppm. EPA has determined that the petition contains data or information regarding the elements set forth in section 408(d)(2) of the FFDCA; however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data supports granting of the petition. Additional data may be needed before EPA rules on the petition. This notice includes a summary of the petition prepared by Valent USA Corporation, the registrant, P.O. Box 8025, Walnut Creek, CA 94596-8025.

A. Residue Chemistry

1. Plant metabolism. The plant metabolism of fenpropathrin has been studied in five different crops: cotton, apple, tomato, cabbage, and bean. Fenpropathrin, a cyanohydrin ester, has been labeled with radiocarbon in three positions -- cyclopropyl ring, aryl rings, and nitrile. The permutations of plant species and radiocarbon label position yield a total of 17 separate, reviewed studies. Each of the studies involved foliar treatment of the plants under either greenhouse or field conditions and, while the actual treatment conditions and times to harvest and analyses varied from study to study, the results of the many studies are consistent. The total toxic residue is best defined as parent, fenpropathrin.

Fenpropathrin remains associated with the site of application and only traces are found in seeds (e.g., bean or cotton) or in other parts of the plant not directly exposed to the application. Much of the parent residue can be removed from the plant material with a mild hexane/acetone or hexane rinse, demonstrating that the residue is located on or near the outside surface of the plant material. The primary metabolic pathway for fenpropathrin in plants is similar to that in mammals. There are no qualitatively unique plant metabolites; the primary aglycones are identical in both plants and animals.

2. Analytical method. Adequate analytical methodology is available to detect and quantify fenpropathrin (and its metabolites) at residue levels in numerous matrices. The methods use solvent extraction and partition and/or column chromatography clean-up steps, followed by separation and quantitation using capillary column gas-liquid chromatography with flame ionization detection. The extraction efficiency has been validated using radiocarbon samples from the plant and animal metabolism studies. The enforcement methods have been validated at independent laboratories and by EPA. The limit of quantitation (LOQ) for fenpropathrin is 0.01 ppm.

3. Magnitude of residues. The field residue data to support the proposed fenpropathrin tolerance on the cucumber vegetables crop grouping includes data on melons (cantaloupe) from 10 sites, cucumbers from 8 sites and summer squash from 7 sites providing data from 25 sites across the United States. Exaggerated rate and residue decline studies were included. In the samples that fit the proposed use pattern the average residue is 0.078 ppm with a maximum value of 0.31 ppm. Samples with measured residue values below the 0.01 ppm LOQ were assumed, for the purposes of calculation, to contain residue values of 0.005 ppm (1/2 the LOQ).
B. Toxicological Profile

1. Acute toxicity. Acute toxicity studies with technical fenpropatrin: Oral lethal dose (LD₅₀) in the rat is 54.0 mg/kg for males and 48.5 mg/kg for females - Toxicity Category I; dermal LD₅₀ is 1,600 mg/kg for males and 870 mg/kg for females - Category II; acute inhalation (impossible to generate sufficient test article vapor or aerosol to elicit toxicity) - Category IV; primary eye irritation (no corneal involvement, mild iris and conjunctival irritation) - Category III; and primary dermal irritation (no irritation) - Category IV. Fenpropatrin is not a sensitizer.

2. Genotoxicity. An Ames Assay was negative for Salmonella TA98, TA100, TA1535, TA1537, and TA1538; and negative for E. coli WP2uvrA (trp-) with or without metabolic activation. Sister Chromatid Exchange in Chinese hamster ovary (CHO) cells there were no increases in sister chromatid exchanges seen. Cytogenetics in vitro - negative for chromosome aberrations in CHO cells exposed in vitro to toxic doses (≥30 µg/ml) without activation; and to limit of solubility (1,000 µg/ml) with activation. In Vitro Assay in Mammalian Cells - equivocal results - no concern. DNA Damage/Repair in Bacillus subtilis - not equivocal results - of no concern. DNA lesions in bacteria are not considered genotoxic.

3. Reproductive and developmental toxicity. A 3-generation reproduction study was performed with rats dosed with fenpropatrin at concentrations of 0, 40, 120, or 360 ppm (0, 3.0, 8.9, or 26.9 mg/kg/day in males; 0, 3.4, 10.1, or 32.0 mg/kg/day in females, respectively). The parental (male/female) systemic NOAEL is 40 ppm (3.0/3.4 mg/kg/day). The systemic LOAEL is 120 ppm (8.9/10.1 mg/kg/day) based on body tremors with spasmodic muscle twitches, increased sensitivity and maternal lethality. The reproductive NOAEL is 120 ppm (8.9/10.1 mg/kg/day), and the reproductive LOAEL is 360 ppm (26.9/32.0 mg/kg/day) based on decrease mean F₁ pup weight, increased F₂ mortality. The pups (male/female) developmental NOAEL is 40 ppm (3.0/3.4 mg/kg/day), and the developmental LOAEL is 120 ppm (8.9/10.1 mg/kg/day) based on body tremors, increased mortality.

In a developmental toxicity study in rats, pregnant female rats were dosed by gavage on gestation days 7 through 15 at 0 (corn oil control) 0.4, 1.5, 2.0, 3.0, 6.0, or 10.0 mg/kg/day. The maternal NOAEL is 6 mg/kg/day and the LOAEL is 10 mg/kg/day based on death, morbidity, sensitivity to external stimuli, spastic jumping, tremors, prostration, convulsions, hunched posture, squinted eyes, chromatocytorrhea, and lacrimation. The developmental NOAEL is > 10 mg/kg/day.

In a developmental toxicity study in rabbits, pregnant female New Zealand rabbits were dosed by gavage on gestation days 7 through 19 at 0, 4, 12, or 36 mg/kg/day. Maternal NOAEL is 4 mg/kg/day and the maternal LOAEL is 12 mg/kg/day based on grooming, anorexia, flicking of the forepaws. The developmental NOAEL is > 36 mg/kg/day - highest dose tested (HDT).

4. Subchronic toxicity. In a subchronic oral toxicity study, rats were dosed at concentrations of 0, 3, 30, 100, 300, or 600 ppm in the diet. The LOAEL is 600 ppm (30 mg/kg/day) based on body weight reduction (female), body tremors, and increased brain (female) and kidney (male) weights. The NOAEL is 300 ppm (15 mg/kg/day).

5. Chronic toxicity. In a chronic feeding/carcinogenicity study, rats were dosed at 0, 50, 150, 450, or 600 ppm in the diet (0, 1.93, 5.71, 17.06, or 22.80 mg/kg/day in males, and 0, 2.43, 7.23, 19.45, or 23.98 mg/kg/day in females). There was no evidence of carcinogenicity at any dose up to and including 600 ppm. The systemic NOAEL (male) is 450 ppm (17.06 mg/kg/day). The systemic NOAEL (female) is 150 ppm (7.23 mg/kg/day), and the systemic LOAEL (male) is 600 ppm based on increased mortality, body tremors, increased pituitary, kidney, and adrenal weights. The systemic LOAEL (female) is 450 ppm (19.45 mg/kg/day) based on increased mortality and body tremors.

In a chronic feeding/carcinogenicity study, mice were fed diets containing 0, 1.93, 5.71, 17.06, or 22.80 mg/kg/day in males, and 0, 2.43, 7.23, 19.45, or 23.98 mg/kg/day in females). There was no evidence of carcinogenicity at any dose up to and including 600 ppm. The systemic NOAEL (male) is 450 ppm (17.06 mg/kg/day). The systemic NOAEL (female) is 150 ppm (7.23 mg/kg/day), and the systemic LOAEL (male) is 600 ppm based on increased mortality, body tremors, increased pituitary, kidney, and adrenal weights. The systemic LOAEL (female) is 450 ppm (19.45 mg/kg/day) based on increased mortality and body tremors.

6. Animal metabolism. In a metabolism study in rats, animals were dosed with fenpropatrin radiolabelled in either the alcohol or acid portion of the molecule. Rats received 14 daily oral low-doses of 2.5 mg/kg/day of unlabelled fenpropatrin followed by a 15th dose of either the alcohol or acid radiolabelled fenpropatrin. Groups of rats received a single dose of either of the two radiolabelled test articles at 2.5 mg/kg or 25 mg/kg. The major biotransformed metabolite was oxidation at the methyl group of the acid moiety, hydroxylation at the 4'-position of the alcohol moiety, cleavage of the ester linkage, and conjugation with sulfuric acid or glucuronic acid. Four metabolites were found in the urine of rats dosed with alcohol labeled fenpropatrin. The major metabolites were the sulfate conjugate of 3-(4'-hydroxyphenoxy)benzoic acid and 3-phenoxybenzoic acid (22-44% and 3-9% of the administered dose, respectively). The major urinary metabolites of the acid-labeled fenpropatrin were TMPA-glucuronic acid and TMPA-CH₂OH (11-26% and 6-10% of the administered dose, respectively). None of the parent chemical was found in urine. The major elimination products in the feces included the parent chemical (13-34% of the administered dose) and four metabolites. The fecal metabolites (and the percentage of administered dose) included CH₂OH-fenpropatrin (9-20%), 4'-OH-fenpropatrin (4-11%), COOH-fenpropatrin (2-7%), and 4'-OH-CH₂OH-fenpropatrin (2-7%). There are no qualitatively unique plant metabolites. The primary aglycones are identical in both plants and animals; the only difference is in the nature of the conjugating moieties employed.

7. Metabolite toxicology. The metabolism and potential toxicity of the small amounts of terminal plant metabolites have been tested on mammals. Glucoside conjugates of 3-phenoxy-benzyl alcohol and 3-phenoxybenzoic acid, administered orally to rats, were absorbed as the corresponding aglycones following cleavage of the glycoside linkage in the gut. The free or conjugated aglycones were rapidly and completely eliminated by normal metabolic pathways. The glucoside conjugates of 3-phenoxybenzyl alcohol and 3-phenoxy-benzoic acid are less toxic to mice than the corresponding aglycones.

8. Endocrine disruption. No special studies to investigate the potential for estrogenic or other endocrine effects of fenpropatrin have been performed. However, as summarized above, a large and detailed toxicology data base exists for the compound in all required categories. These studies include evaluations of reproduction and reproductive toxicity and detailed pathology and histology of endocrine organs following repeated or long-term exposure. According to the registrant, these studies are considered capable of revealing endocrine effects and no such effects were observed.

C. Aggregate Exposure

1. Dietary exposure. The chronic population adjusted dose (cPAD) is established at 0.025 mg/kg/day. The acute population adjusted dose (aPAD)
is established at 6.0 mg/kg/day (systemic). Thus, both chronic and acute dietary exposure and risk analyses are necessary.

Chronic and acute dietary exposure analyses were performed for fenpropathrin using anticipated residues and accounting for proportion of the crop treated. The crops included in the analyses are the cottonseed, currants, peanuts, strawberries, soybeans and grapes, and the crop groupings head and stem brassica, fruiting vegetables, cucurbit vegetables, citrus fruits, and pome fruits; processed products from these crops; and the resulting secondary residues in meat, milk, and eggs. Currants and soybeans (and soybean products) were entered into the analyses using tolerance-level residues and 100% or 1% of the crop treated, respectively. The fruiting vegetables (Crop Group 9), was substituted for tomatoes in the dietary exposure and risk analyses. IR-4 is presently working on this use expansion, and a tolerance petition adding fruit vegetables and using these same dietary exposure analyses will be forthcoming. The various proportion of crop treated values were derived from published marketing data for crops for which there are existing fenpropathrin uses, and extrapolated from the uses of other pyrethroid insecticides for pending crops.

Proportion of crop treated was assumed to be equal for all crops in a crop grouping. A report of these exposure/ risk analyses has been submitted to the Agency including a detailed description of the methodology and assumptions used.

i. Food. Chronic dietary exposure was at or below 2.7% of the cPAD with apples and grapes the commodities contributing the most to chronic exposure. The anticipated residue contribution (ARC) is estimated to be 0.000204 milligrams/kilograms/body weight/day (mg/kg/bwt/day) and utilize 0.8% of the cPAD for the overall U.S. population. The ARC for children 1-6 years old and children 7-12 years old (subgroups most highly exposed) are estimated to be 0.000079 mg/kg bwt/day and 0.000035 mg/kg bwt/day and utilizes 2.7 and 1.3% of the cPAD, respectively. The ARC for females (13+/Nursing) 0.0000248 mg/kg bwt/day and utilizes 1.0% of the cPAD. The ARC for all infants (<1-year old) and non-nursing infants (<1-year old) is 0.0000243 mg/kg bwt/day and is 0.0000284 mg/kg bwt/day, respectively, and utilizes 1.0% of the cPAD. The ARC for nursing infants (<1-year old) is 0.000103 and utilizes 0.4% of the cPAD. Generally speaking, the registrant has no cause for concern if total residue contribution for published and proposed tolerances is less than 100% of the cPAD.

Acute dietary exposure was calculated at the 99.9th percentile of exposure and margins of exposure (MOE) were calculated for the U.S. population and the subpopulations with the highest risk, as follows: U.S. population (MOE of 490), females (13+) (MOE 927), all infants (MOE 347), nursing infants (<1) (MOE 384), non-nursing infants (MOE 328), children 1-6 years old (MOE 238), and children 7-12 years old (MOE 410). In all cases, margins of exposure exceed one-hundred.

ii. Drinking water. Since fenpropathrin is applied outdoors to growing agricultural crops, the potential exists for fenpropathrin or its metabolites to reach ground or surface water that may be used for drinking water. Because of the physical properties of fenpropathrin, the registrant has determined that it is unlikely that fenpropathrin or its metabolites can leach to potable ground water.

To further quantify potential exposure from drinking water, surface water concentrations for fenpropathrin were estimated using genetic expected environmental concentration (GENEEC) 1.2, and the most intense field use scenario. The average 56-day concentration predicted in the simulated pond water was 0.22 parts per billion (ppb). The residence time of fenpropathrin in surface water has been measured and is short. In pond studies, fenpropathrin half-life in the water column were less than 1.5 days, thus this 56-day modeled half-lives probably considerably overestimates any real surface water concentration. Using standard assumptions about body weight (bwt) and water consumption, the chronic exposure from drinking water would be 6.3 x 10⁻⁶ and 2.2 x 10⁻⁵ mg/kg bwt/day for adults and children, respectively; less than 0.09% of the cPAD for children. Based on this worse case analysis, the contribution of water to the dietary risk is negligible.

2. Non-dietary exposure.

Fenpropathrin, as the product TAME 2.4 EC Spray, is a restricted use material and registered for professional non-food use both indoors and outdoors on ornamentals and non-bearing nursery fruit trees. Fenpropathrin has no animal health, homeowner, turf, termite, indoor pest control, or industrial uses. Quantitative information concerning human exposure from this ornamental use is not available, but exposure to the general public from this use of fenpropathrin is expected to be minimal. No endpoints of concern were identified for occupational or residential, dermal or inhalation exposures of any duration. Thus, no risk assessment is needed.

D. Cumulative Effects

Section 408(b)(2)(D)(iv) requires that the Agency must consider “available information” concerning the cumulative effects of a particular pesticide’s residues and “other substances that have a common mechanism of toxicity.” Available information in this context include not only toxicity, chemistry, and exposure data, but also scientific policies and methodologies for understanding common mechanisms of toxicity and conducting cumulative risk assessments. For most pesticides, although the Agency has some information in its files that may turn out to be helpful in eventually determining whether a pesticide shares a common mechanism of toxicity with any other substances, EPA does not at this time have the methodologies to resolve the complex scientific issues concerning common mechanism of toxicity in a meaningful way.

E. Safety Determination

1. U.S. population—i. Chronic risk—adults. Using the dietary exposure assessment procedures described above for fenpropathrin, calculated chronic dietary exposure resulting from residue exposure from existing and proposed uses of fenpropathrin is minimal. The estimated chronic dietary exposure from food for the overall U.S. population is less than 1% of the cPAD. Addition of the small but worse case potential chronic exposure from drinking water (calculated above, 6.3 x 10⁻⁶ mg/kg bwt/day) to the highest chronic dietary exposure value from food increases the maximum occupancy of the cPAD only slightly from 0.99% to 1.02%. Generally, the Agency has no cause for concern if total residue contribution is less than 100% of the cPAD.

ii. Acute Risk—adults. The potential acute exposure from food to the U.S. population and various non-child/infant populations subgroups (shown above) provide MOE values greatly exceeding 100. Addition of the worse case, but very small “background” dietary exposure from water is not sufficient to change the MOE values significantly. The registrant concludes that there is a reasonable certainty that no harm will result to the overall U.S. population from aggregate, acute exposure to fenpropathrin residues.

2. Infants and children—safety factor for infants and children. In assessing the potential for additional sensitivity of
infants and children to residues of fenpropathrin. FFDCA section 408 provides that EPA shall apply an additional margin of safety, up to tenfold, for added protection for infants and children in the case of threshold effects unless EPA determines that a different margin of safety will be safe for infants and children.

1. Chronic risk—infants and children.
Using the dietary exposure assessment procedures described above, calculated chronic dietary exposure resulting from residue exposure from existing and proposed uses of fenpropathrin is minimal. The estimated chronic dietary exposure from food to infant and child subgroups ranges from 2.7% (children 1-6 years), 0.000678 mg/kg bwt/day) to 0.4% [nursing infants (<1 year), 0.001103 mg/kg bwt/day] of the cPAD. Addition of the small but worse case potential chronic exposure from drinking water (calculated above, 2.2 x 10^{-5} mg/kg bwt/day) to the highest chronic exposure value from food increases the maximum occupancy of the cPAD only slightly from 2.7% to 2.8%. The registrant concludes that there is a reasonable certainty that no harm will result to infant and child subgroups of the U.S. population from aggregate, chronic exposure to fenpropathrin residues.

The potential acute exposure from food to the various child and infant population subgroups all provide MOE values exceeding 100. Addition of the worse-case, but very small “background” dietary exposure from water (2.2 x 10^{-5} mg/kg bwt/day) is not sufficient to change the MOE values significantly. The registrant concludes that there is a reasonable certainty that no harm will result to infants and children from aggregate, acute exposure to fenpropathrin residues.

F. International Tolerances
There are no Codex, Canadian, or Mexican residue limits for residues of fenpropathrin in or on cucurbit vegetables (Crop Group 9).

ENVIRONMENTAL PROTECTION AGENCY

[FRL-6500-3]

Regulatory Reinvention (XL) Pilot Projects

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of availability of Albuquerque Pretreatment Project XL Draft Final Project Agreement.

SUMMARY: EPA is today requesting comments on a draft Project XL Final Project Agreement (FPA) for the City of Albuquerque. The FPA is a voluntary agreement developed collaboratively by Albuquerque, stakeholders, the State of New Mexico, and EPA. Project XL announced in the Federal Register on May 23, 1995 (60 FR 27282), gives regulated sources the flexibility to develop alternative strategies that will replace or modify specific regulatory requirements on the condition that they produce greater environmental benefits.

If implemented, the draft FPA and a site specific rulemaking would allow Albuquerque to conduct pollution prevention outreach and implementation up to 50 new businesses per year, and integrate stormwater pollution prevention aspects with their pretreatment program. Albuquerque would attempt to initially reduce loadings of 13 pollutants of concern, and optimize resources to achieve competitive institutional integration of pollution prevention and pretreatment program work. Albuquerque would start the project by conducting sewer sub-basin monitoring to determine where 13 pollutants predominate within the collection system. Through this approach, Albuquerque will focus its efforts to identify and address the most significant industrial, commercial, and residential areas, or conduct project outreach. Albuquerque also proposes to conduct workshops and case studies demonstrating implementation of best management practices (BMPs) for pretreatment dischargers, problem areas, and follow-up needs. One way Albuquerque will demonstrate greater environmental benefit is by monitoring pollutant loadings before and after its pollution prevention outreach and implementation efforts. One of Albuquerque’s initial goals would be to try to reduce aluminum, cadmium, chromium, copper, cyanide, fluoride, lead, mercury, molybdenum, nickel, selenium, silver, and zinc by 10–25%. The site specific rulemaking setting forth the specific regulatory flexibility to be implemented will be developed with the assistance of stakeholders and will ensure that the project will fully comply with applicable federal requirements under the Clean Water Act.

DATES: The period for submission of comments ends on December 27, 1999.

ADDRESSES: All comments on the draft Final Project Agreement should be sent to: Adele Cardenas, 6EN–XP, U.S. EPA REGION 6, 1445 Ross Avenue, Suite # 1200, Dallas, TX 75202–2733, or Chad Carbone, U.S. EPA, 401 M Street, SW, Room 1027WT (1802), Washington, DC 20460. Comments may also be faxed to Ms. Cardenas at (214) 665–3177 or Mr. Carbone at (202) 401–2474. Comments will also be received via electronic mail sent to: cardenas.adele@epa.gov or carbone.chad@epa.gov.

FOR FURTHER INFORMATION CONTACT: To obtain a copy of the draft Final Project Agreement, contact: Adele Cardenas, 6EN–XP, U.S. EPA REGION 6, 1445 Ross Avenue, Suite # 1200, Dallas, TX 75202–2733, or Chad Carbone, U.S. EPA, 401 M Street, SW, Room 1027WT (1802), Washington, DC 20460. The documents are also available via the Internet at the following location: “http://www.epa.gov/ProjectXL”. In addition, public files on the Project are located at EPA Region 6 in Dallas. Questions to EPA regarding the documents can be directed to Adele Cardenas at (214) 665–7210 or Chad Carbone at (202) 260–4296. Additional information on Project XL, including documents referenced in this notice, other EPA policy documents related to Project XL, application information, and descriptions of existing XL projects and proposals, is available via the Internet at “http://www.epa.gov/ProjectXL”.


Lisa Lund,
Deputy Associate Administrator, for Reinvention Programs, Office of Reinvention.

[FR Doc. 99–31353 Filed 12–2–99; 8:45 am]
BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

Certain New Chemicals; Receipt and Status Information

[OPPTS–51937; FRL–5694–4]

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: Section 5 of the Toxic Substances Control Act (TSCA) requires any person who intends to manufacture (defined by statute to include import) a new chemical (i.e., a chemical not on the TSCA Inventory) to notify EPA and comply with the statutory provisions pertaining to the manufacture of new chemicals. Under sections 5(d)(2) and 5(d)(3) of TSCA, EPA is required to publish a notice of receipt of a premanufacture notice (PMN) or an application for a test marketing exemption (TME), and to publish periodic status reports on the chemicals manufactured or imported under the TSCA.

The following new chemical notices were received by EPA:

[List of notices]

Dated: October 1, 1999.

Barbara A. Clevenger,
Director, Office of Pollution Prevention and Toxics.
under review and the receipt of notices of commencement to manufacture those chemicals. This status report, which covers the period from October 11, 1999 to October 22, 1999, consists of the PMNs, pending or expired, and the notices of commencement to manufacture a new chemical that the Agency has received under TSCA section 5 during this time period.

ADDRESS: Comments may be submitted by mail, electronically, or in person. Please follow the detailed instructions for each method as provided in Unit I. of the “SUPPLEMENTARY INFORMATION.”

To ensure proper receipt by EPA, it is imperative that you identify docket control number OPPTS–51937 and the specific PMN number in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: Joe Carra, Deputy Director, Office of Pollution Prevention and Toxics (7401), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460; telephone numbers: (202) 554–1404 and TDD: (202) 554–0551; e-mail address: TSCA-Hotline@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

This action is directed to the public in general. As such, the Agency has not attempted to describe the specific entities that this action may apply to. Although others may be affected, this action applies directly to the submitter of the premanufacture notices addressed in the action. 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. How Can I Get Additional Information, Including Copies of this Document and Other Related Documents?

1. Electronically. You may obtain copies of this document and certain other available documents from the EPA Internet Home Page at http://www.epa.gov/. On the Home Page select “Laws and Regulations” and then look up the entry for this document under the “Federal Register -- Environmental Documents.” You can also directly go to the “Federal Register” listings at http://www.epa.gov/fedregstbl.

2. In person. The Agency has established an official record for this action under docket control number OPPTS–51937. The official record consists of the documents specifically referenced in this action, any public comments received during an applicable comment period, and other information related to this action, including any information claimed as confidential business information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period, is available for inspection in the TSCA Nonconfidential Information Center, North East Mall Rm. B–607, Waterside Mall, 401 M St., SW., Washington, DC. The Center is open from noon to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number of the Center is (202) 260–7099.

C. How and to Whom Do I Submit Comments?

You may submit comments through the mail, in person, or electronically. To ensure proper receipt by EPA, it is imperative that you identify docket control number OPPTS–51937 and the specific PMN number in the subject line on the first page of your response.

1. By mail. Submit your comments to: Document Control Office (7407), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, 401 M St., SW., Washington, DC 20460.

2. In person or by courier. Deliver your comments to: OPPT Document Control Office (DCO) in East Tower Rm. G–099, Waterside Mall, 401 M St., SW., Washington, DC. 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) 260–7093.

3. Electronically. You may submit your comments electronically by e-mail to: “oppt.ncic@epa.gov.” or mail your computer disk to the address identified in this unit. Do not submit any information electronically that you consider to be CBI. Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Comments and data will also be accepted on standard disks in WordPerfect 6.1/8.0 or ASCII file format. All comments in electronic form must be identified by docket control number OPPTS–51937 and the specific PMN number. Electronic comments may also be filed online at many Federal Depository Libraries.

D. How Should I Handle CBI that I Want to Submit to the Agency?

Do not submit any information electronically that you consider to be CBI. You may claim information that you submit to EPA in response to this document as CBI by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. In addition to one complete version of the comment that includes any information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public version of the official record. Information not marked confidential will be included in the public version of the official record without prior notice. If you have any questions about CBI or the procedures for claiming CBI, please consult the person listed under “FOR FURTHER INFORMATION CONTACT.”

E. What Should I Consider as I Prepare My Comments for EPA?

You may find the following suggestions helpful for preparing your comments:

1. Explain your views as clearly as possible.
2. Describe any assumptions that you used.
3. Provide copies of any technical information and/or data you used that support your views.
4. If you estimate potential burden or costs, explain how you arrived at the estimate that you provide.
5. Provide specific examples to illustrate your concerns.
6. Offer alternative ways to improve the notice or collection activity.
7. Make sure to submit your comments by the deadline in this document.
8. To ensure proper receipt by EPA, be sure to identify the docket control number assigned to this action in the subject line on the first page of your response. You may also provide the name, date, and Federal Register citation.

II. Why is EPA Taking this Action?

Section 5 of TSCA requires any person who intends to manufacture (defined by statute to include import) a new chemical (i.e., a chemical not on the TSCA Inventory to notify EPA and comply with the statutory provisions pertaining to the manufacture of new chemicals. Under sections 5(d)(2) and 5(d)(3) of TSCA, EPA is required to publish a notice of receipt of a PMN or...
an application for a TME and to publish periodic status reports on the chemicals under review and the receipt of notices of commencement to manufacture those chemicals. This status report, which covers the period from October 11, 1999 to October 22, 1999, consists of the PMNs, pending or expired, and the notices of commencement to manufacture a new chemical that the Agency has received under TSCA section 5 during this time period.

II. Receipt of PMNs

This status report identifies the PMNs, pending or expired, and the notices of commencement to manufacture a new chemical that the Agency has received under TSCA section 5 during this time period. If you are interested in information that is not included in the following tables, you may contact EPA as described in Unit II. to access additional non-CBI information that may be available.

### III. Receipt and Status Report for PMNs

In table I, EPA provides the following information (to the extent that such information is not claimed as CBI) on the PMNs received by EPA during this time period: the EPA case number assigned to the PMN; the date the PMN was received by EPA; the projected end date for EPA’s review of the PMN; the submiting manufacturer; the potential uses identified by the manufacturer in the PMN; and the chemical identity.

<table>
<thead>
<tr>
<th>Case No.</th>
<th>Received Date</th>
<th>Projected Notice End Date</th>
<th>Manufacturer/Importer</th>
<th>Use</th>
<th>Chemical</th>
</tr>
</thead>
<tbody>
<tr>
<td>P–00–0029</td>
<td>10/12/99</td>
<td>01/10/00</td>
<td>Sivento Inc.</td>
<td>(G) Chemical intermediate</td>
<td>(S) Siloxanes and silicones, ethoxyoctyl, ethoxy-terminated*</td>
</tr>
<tr>
<td>P–00–0030</td>
<td>10/12/99</td>
<td>01/10/00</td>
<td>Wacker Biochem</td>
<td>(S) Pigment</td>
<td>(G) Modified polyacrylate</td>
</tr>
<tr>
<td>P–00–0031</td>
<td>10/13/99</td>
<td>01/11/00</td>
<td>CBI</td>
<td>(G) Open, non-dispersive (intermediate)</td>
<td>(G) Sulfonyle urea</td>
</tr>
<tr>
<td>P–00–0032</td>
<td>10/12/99</td>
<td>01/10/00</td>
<td>Finetex, Inc.</td>
<td>(S) Textile fiber lubricant with high thermal stability; dispersant for titanium dioxide, zinc oxide; pigments etc.; plasticizer for polymer systems requiring high thermal stability</td>
<td>(S) 9-ocdecenoic acid, 12-(benzoyloxy)-, hexadecyl ester, (r- (z))-</td>
</tr>
<tr>
<td>P–00–0033</td>
<td>10/13/99</td>
<td>01/11/00</td>
<td>CBI</td>
<td>(G) Open, non-dispersive (intermediate)</td>
<td>(G) Triazolimone</td>
</tr>
<tr>
<td>P–00–0034</td>
<td>10/13/99</td>
<td>01/11/00</td>
<td>CBI</td>
<td>(G) Open, non-dispersive (intermediate)</td>
<td>(G) Thioimidocarbonate</td>
</tr>
<tr>
<td>P–00–0035</td>
<td>10/12/99</td>
<td>01/10/00</td>
<td>CBI</td>
<td>(G) Polyurethane adhesives for open, non-dispersive use</td>
<td>(G) Isocyanate-terminated urethane prepolymer</td>
</tr>
<tr>
<td>P–00–0036</td>
<td>10/13/99</td>
<td>01/11/00</td>
<td>CIBA Specialty Chemi-</td>
<td>(S) High performance printing ink</td>
<td>(G) Monoazo naphtholide pigment, aminomethoxynaphthyloltrifluoromethylamine</td>
</tr>
<tr>
<td>P–00–0037</td>
<td>10/13/99</td>
<td>01/11/00</td>
<td>Lambert Tech-</td>
<td>(S) Rubber additive</td>
<td>(S) Canola oil, hydrogenated*</td>
</tr>
<tr>
<td>P–00–0038</td>
<td>10/13/99</td>
<td>01/11/00</td>
<td>CBI</td>
<td>(G) Component of coating with open use</td>
<td>(G) Urethane acrylate</td>
</tr>
<tr>
<td>P–00–0039</td>
<td>10/13/99</td>
<td>01/11/00</td>
<td>CBI</td>
<td>(G) Component of coating with open use</td>
<td>(G) Urethane acrylate</td>
</tr>
<tr>
<td>P–00–0040</td>
<td>10/13/99</td>
<td>01/11/00</td>
<td>CBI</td>
<td>(G) Component of coating with open use</td>
<td>(G) Urethane acrylate</td>
</tr>
<tr>
<td>P–00–0041</td>
<td>10/13/99</td>
<td>01/11/00</td>
<td>CBI</td>
<td>(G) Component of coating with open use</td>
<td>(G) Urethane acrylate</td>
</tr>
<tr>
<td>P–00–0042</td>
<td>10/13/99</td>
<td>01/11/00</td>
<td>CBI</td>
<td>(G) Colorant for petroleum products and refrigerants</td>
<td>(G) N-alkyl-4 alkylaminonaphthalimide</td>
</tr>
<tr>
<td>P–00–0043</td>
<td>10/13/99</td>
<td>01/11/00</td>
<td>CBI</td>
<td>(G) Colorant for petroleum products and refrigerants</td>
<td>(G) N-alkyl-4 alkylaminonaphthalimide</td>
</tr>
<tr>
<td>P–00–0044</td>
<td>10/13/99</td>
<td>01/11/00</td>
<td>CBI</td>
<td>(G) Colorant for petroleum products and refrigerants</td>
<td>(G) N-alkyl-4 alkylaminonaphthalimide</td>
</tr>
<tr>
<td>P–00–0045</td>
<td>10/12/99</td>
<td>01/10/00</td>
<td>CBI</td>
<td>(S) Acid dye for the dyeing of leather</td>
<td>(G) Benzenediazonium, [[[[[[substituted)azophenyl)sulfonilyl]amino]-, coupled with aminophenol, diazotized aminobenzoic acid, diazotized (substituted)benzenesulfonic acid and naphthalenol</td>
</tr>
<tr>
<td>P–00–0046</td>
<td>10/13/99</td>
<td>01/11/00</td>
<td>CBI</td>
<td>(S) Specialty grease thickener</td>
<td>(G) Aromatic substituted diurea</td>
</tr>
<tr>
<td>P–00–0047</td>
<td>10/13/99</td>
<td>01/11/00</td>
<td>BASF Corporation</td>
<td>(S) Monomer/reactant for the production of lacquers/varnish which improve properties of products like artificial marble</td>
<td>(S) 2h-pyran-2-one, tetrahydro-*</td>
</tr>
<tr>
<td>P–00–0048</td>
<td>10/14/99</td>
<td>01/12/00</td>
<td>CBI</td>
<td>(G) Destructive, fuel additive</td>
<td>(G) Polysobutylene amine</td>
</tr>
<tr>
<td>P–00–0049</td>
<td>10/14/99</td>
<td>01/12/00</td>
<td>CBI</td>
<td>(G) Destructive, fuel additive</td>
<td>(G) Polysobutylene amine</td>
</tr>
<tr>
<td>P–00–0050</td>
<td>10/13/99</td>
<td>01/11/00</td>
<td>CBI</td>
<td>(G) Open, non-dispersive (intermediate)</td>
<td>(G) Triazolone</td>
</tr>
<tr>
<td>P–00–0051</td>
<td>10/14/99</td>
<td>01/12/00</td>
<td>CBI</td>
<td>(G) Resin for automotive coatings</td>
<td>(G) Modified melamine alkyd resin</td>
</tr>
<tr>
<td>P–00–0052</td>
<td>10/15/99</td>
<td>01/13/00</td>
<td>CBI</td>
<td>(S) Organic synthesis intermediate</td>
<td>(G) 1-(2,5-dimethoxyphenyl)-2-propane derivative</td>
</tr>
<tr>
<td>Case No.</td>
<td>Received Date</td>
<td>Projected Notice End Date</td>
<td>Manufacturer/Importer</td>
<td>Use</td>
<td>Chemical</td>
</tr>
<tr>
<td>----------</td>
<td>---------------</td>
<td>---------------------------</td>
<td>-----------------------</td>
<td>-----</td>
<td>----------</td>
</tr>
<tr>
<td>P-00-0053</td>
<td>10/14/99</td>
<td>01/12/00</td>
<td>CBI</td>
<td>(G) Polymer particle for dyeing</td>
<td>(G) Styrene methacrylate acrylonitrile polymer derivative</td>
</tr>
<tr>
<td>P-00-0054</td>
<td>10/13/99</td>
<td>01/11/00</td>
<td>CBI</td>
<td>(G) Open, non-dispersive (intermediate)</td>
<td>(G) Isothiocyanatidate</td>
</tr>
<tr>
<td>P-00-0055</td>
<td>10/14/99</td>
<td>01/12/00</td>
<td>CBI</td>
<td>(G) Destructive, chemical intermediate for production of organic compounds</td>
<td>(G) Polysisobutylene oxime</td>
</tr>
<tr>
<td>P-00-0056</td>
<td>10/14/99</td>
<td>01/12/00</td>
<td>CBI</td>
<td>(G) Destructive, chemical intermediate for production of organic compounds</td>
<td>(G) Polysisobutylene oxime</td>
</tr>
<tr>
<td>P-00-0057</td>
<td>10/14/99</td>
<td>01/12/00</td>
<td>CBI</td>
<td>(S) Inks; coatings</td>
<td>(G) Polyester acrylate</td>
</tr>
<tr>
<td>P-00-0058</td>
<td>10/19/99</td>
<td>01/17/00</td>
<td>CBI</td>
<td>(G) Open, non-dispersive use</td>
<td>(G) Polyester acrylate</td>
</tr>
<tr>
<td>P-00-0059</td>
<td>10/19/99</td>
<td>01/17/00</td>
<td>CBI</td>
<td>(G) Component of extruded or molded parts</td>
<td>(S) 2,5-furandione, polymer with 1-butene and ethene*</td>
</tr>
<tr>
<td>P-00-0060</td>
<td>10/19/99</td>
<td>01/17/00</td>
<td>CBI</td>
<td>(G) Component of extruded or molded parts</td>
<td>(S) 2,5-furandione, polymer with ethene, 5-ethylidenebicyclo[2.2.1]hept-2-ene and 1-propene**</td>
</tr>
<tr>
<td>P-00-0061</td>
<td>10/19/99</td>
<td>01/17/00</td>
<td>CBI</td>
<td>(S) Component of extruded or molded parts</td>
<td>(S) Bicyclo[2.2.1]hept-2-ene, 5-ethylidenebicyclo[2.2.1]hept-2-ene and 1-propene*</td>
</tr>
<tr>
<td>P-00-0062</td>
<td>10/19/99</td>
<td>01/17/00</td>
<td>CBI</td>
<td>(G) Open, non-dispersive: emulsifier for road building</td>
<td>(G) Amines, n-tallow alkylpoly-, hydrochlorides</td>
</tr>
<tr>
<td>P-00-0063</td>
<td>10/19/99</td>
<td>01/17/00</td>
<td>CBI</td>
<td>(G) Open, non-dispersive: emulsifier for road building</td>
<td>(G) Amines, n-tallow alkylpoly-, hydrochlorides</td>
</tr>
<tr>
<td>P-00-0064</td>
<td>10/19/99</td>
<td>01/17/00</td>
<td>CBI</td>
<td>(G) Open, non-dispersive: emulsifier for road building</td>
<td>(G) Amines, n-tallow alkylpoly-, hydrochlorides</td>
</tr>
<tr>
<td>P-00-0065</td>
<td>10/19/99</td>
<td>01/17/00</td>
<td>CBI</td>
<td>(G) Open, non-dispersive: emulsifier for road building</td>
<td>(G) Amines, n-tallow alkylpoly-, hydrochlorides</td>
</tr>
<tr>
<td>P-00-0066</td>
<td>10/19/99</td>
<td>01/17/00</td>
<td>CBI</td>
<td>(G) Open, non-dispersive: emulsifier for road building</td>
<td>(G) Amines, n-tallow alkylpoly-, hydrochlorides</td>
</tr>
<tr>
<td>P-00-0067</td>
<td>10/19/99</td>
<td>01/17/00</td>
<td>CBI</td>
<td>(G) Open, non-dispersive: emulsifier for road building</td>
<td>(G) Amines, n-tallow alkylpoly-, hydrochlorides</td>
</tr>
<tr>
<td>P-00-0068</td>
<td>10/19/99</td>
<td>01/17/00</td>
<td>CBI</td>
<td>(G) Open, non-dispersive: emulsifier for road building</td>
<td>(G) Amines, n-tallow alkylpoly-, hydrochlorides</td>
</tr>
<tr>
<td>P-00-0069</td>
<td>10/19/99</td>
<td>01/17/00</td>
<td>CBI</td>
<td>(G) Open, non-dispersive: emulsifier for road building</td>
<td>(G) Amines, n-tallow alkylpoly-, hydrochlorides</td>
</tr>
<tr>
<td>P-00-0070</td>
<td>10/19/99</td>
<td>01/17/00</td>
<td>CBI</td>
<td>(G) Open, non-dispersive: emulsifier for road building</td>
<td>(G) Amines, n-tallow alkylpoly-, hydrochlorides</td>
</tr>
<tr>
<td>P-00-0071</td>
<td>10/19/99</td>
<td>01/17/00</td>
<td>CBI</td>
<td>(G) Open, non-dispersive: emulsifier for road building</td>
<td>(G) Amines, n-tallow alkylpoly-, hydrochlorides</td>
</tr>
<tr>
<td>P-00-0072</td>
<td>10/19/99</td>
<td>01/17/00</td>
<td>CBI</td>
<td>(G) Open, non-dispersive: emulsifier for road building</td>
<td>(G) Amines, n-tallow alkylpoly-, hydrochlorides</td>
</tr>
<tr>
<td>P-00-0073</td>
<td>10/19/99</td>
<td>01/17/00</td>
<td>CBI</td>
<td>(G) Open, non-dispersive: emulsifier for road building</td>
<td>(G) Amines, n-tallow alkylpoly-, hydrochlorides</td>
</tr>
<tr>
<td>P-00-0074</td>
<td>10/19/99</td>
<td>01/17/00</td>
<td>CBI</td>
<td>(G) Open, non-dispersive: emulsifier for road building</td>
<td>(G) Amines, n-tallow alkylpoly-, hydrochlorides</td>
</tr>
<tr>
<td>P-00-0075</td>
<td>10/19/99</td>
<td>01/17/00</td>
<td>CBI</td>
<td>(G) Open, non-dispersive: emulsifier for road building</td>
<td>(G) Amines, n-tallow alkylpoly-, hydrochlorides</td>
</tr>
<tr>
<td>P-00-0076</td>
<td>10/19/99</td>
<td>01/17/00</td>
<td>CBI</td>
<td>(G) Open, non-dispersive: emulsifier for road building</td>
<td>(G) Amines, n-tallow alkylpoly-, hydrochlorides</td>
</tr>
<tr>
<td>P-00-0077</td>
<td>10/19/99</td>
<td>01/17/00</td>
<td>CBI</td>
<td>(G) Open, non-dispersive: emulsifier for road building</td>
<td>(G) Amines, n-tallow alkylpoly-, hydrochlorides</td>
</tr>
<tr>
<td>P-00-0078</td>
<td>10/19/99</td>
<td>01/17/00</td>
<td>CBI</td>
<td>(G) Open, non-dispersive: emulsifier for road building</td>
<td>(G) Amines, n-tallow alkylpoly-, hydrochlorides</td>
</tr>
<tr>
<td>P-00-0079</td>
<td>10/19/99</td>
<td>01/17/00</td>
<td>CBI</td>
<td>(G) Open, non-dispersive: emulsifier for road building</td>
<td>(G) Amines, n-tallow alkylpoly-, hydrochlorides</td>
</tr>
<tr>
<td>P-00-0080</td>
<td>10/22/99</td>
<td>01/20/00</td>
<td>DSM Fine Chemicals, Inc.</td>
<td>(G) Flame retardant</td>
<td>(G) Polyphosphoric acids, compounds with melamine</td>
</tr>
</tbody>
</table>
In table II, EPA provides the following information (to the extent that such information is not claimed as CBI) on the Notices of Commencement to manufacture received:

II. 15 Notices of Commencement From: 10/11/99 to 10/22/99

<table>
<thead>
<tr>
<th>Case No.</th>
<th>Received Date</th>
<th>Commencement/Im-port Date</th>
<th>Chemical</th>
</tr>
</thead>
<tbody>
<tr>
<td>P–96–0307</td>
<td>10/14/99</td>
<td>09/13/99</td>
<td>(G) Amine diol</td>
</tr>
<tr>
<td>P–97–0360</td>
<td>10/21/99</td>
<td>10/16/99</td>
<td>(G) Modified hydrocarbon resin</td>
</tr>
<tr>
<td>P–98–0475</td>
<td>10/12/99</td>
<td>09/24/99</td>
<td>(S) Benzenesulfonic acid, 2,2'-(1,2-ethenediyl)bis[5-[4-(methylamino)-6-[[4-[(methylamino)carbonyl]phenyl]amino]-1,3,5-triazin-2-yl]amino]-di-sodium salt, (e)-*</td>
</tr>
<tr>
<td>P–98–1181</td>
<td>10/20/99</td>
<td>10/18/99</td>
<td>(S) 2-butoenoic acid, 4,4'-([dibutylstannanylene)bis(oxy)]bis[4-oxo-,(z,z), dicyclopentadiene, isoalkyl esters, C8-rich*</td>
</tr>
<tr>
<td>P–99–0021</td>
<td>10/14/99</td>
<td>10/07/99</td>
<td>(G) Modified acrydyl copolymer</td>
</tr>
<tr>
<td>P–99–0478</td>
<td>10/20/99</td>
<td>10/11/99</td>
<td>(G) Acrylic emulsion polymer</td>
</tr>
<tr>
<td>P–99–0577</td>
<td>10/12/99</td>
<td>10/01/99</td>
<td>(G) Isocyanate terminated urethane polymer</td>
</tr>
<tr>
<td>P–99–0583</td>
<td>10/18/99</td>
<td>10/05/99</td>
<td>(S) Fatty acids, coco, compds. with 2-(2-aminoethoxy) ethanol*</td>
</tr>
<tr>
<td>P–99–0586</td>
<td>10/18/99</td>
<td>10/05/99</td>
<td>(S) Decanoic acid, compd. with 2-(2-aminoethoxy)ethanol (1:1)*</td>
</tr>
<tr>
<td>P–99–0618</td>
<td>10/22/99</td>
<td>09/28/99</td>
<td>(G) Polyamine chloride salt</td>
</tr>
<tr>
<td>P–99–0966</td>
<td>10/20/99</td>
<td>09/29/99</td>
<td>(G) Polymer of vinylbenzene, substituted vinylbenzene, and substituted amine</td>
</tr>
<tr>
<td>P–99–0970</td>
<td>10/12/99</td>
<td>10/01/99</td>
<td>(G) Polyoxyalkylene substituted chromophore</td>
</tr>
<tr>
<td>P–99–0977</td>
<td>10/12/99</td>
<td>10/08/99</td>
<td>(G) Organomodified polysiloxanes</td>
</tr>
<tr>
<td>P–99–0989</td>
<td>10/21/99</td>
<td>10/12/99</td>
<td>(S) Butanedioic acid, ethyl methyl ester (9ci)</td>
</tr>
</tbody>
</table>

List of Subjects

Environmental protection, Premanufacture notices.

Dated: November 17, 1999.

Deborah A. Williams,
Acting Director, Information Management Division, Office of Pollution Prevention and Toxics.

[F R Doc. 99–31351 Filed 12–2–99; 8:45 am]
BILLING CODE 6560–50–F

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.

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 December 28, 1999.

A. Federal Reserve Bank of Atlanta

(Lois Berthaume, Vice President) 104 Marietta Street, N.W., Atlanta, Georgia 30303-2713:

1. Gulf Coast Community Bancshares, Inc., Wewahitchka, Florida; to become a bank holding company by acquiring 100 percent of the voting shares of Wewahitchka State Bank, Wewahitchka, Florida.

2. Gwinnett Commercial Group, Inc., Lawrenceville, Georgia; to become a bank holding company by acquiring 100 percent of the voting shares of First Bank of Gwinnett (in organization), Lawrenceville, Georgia.


Robert deV. Frierson,
Associate Secretary of the Board.

[F R Doc. 99–31318 Filed 12–2–99; 8:45 am]
BILLING CODE 6210–01–F

FEDERAL RESERVE SYSTEM

Sunshine Act Meeting

AGENCY HOLDING THE MEETING: Board of Governors of the Federal Reserve System.

TIME AND DATE: 10:00 a.m., Wednesday, December 8, 1999.


STATUS: Closed.

MATTERS TO BE CONSIDERED:

1. Personnel actions (appointments, promotions, assignments, reassignments, and salary actions) involving individual Federal Reserve System employees.

2. Any matters carried forward from a previously announced meeting.

CONTACT PERSON FOR MORE INFORMATION: Lynn S. Fox, Assistant to the Board; 202–452–3204.

SUPPLEMENTARY INFORMATION: You may call 202–452–3206 beginning at approximately 5 p.m. two business days before the meeting for a recorded announcement of bank and bank holding company applications scheduled for the meeting; or you may contact the Board’s Web site at http://www.federalreserve.gov for an electronic announcement that not only lists applications, but also indicates procedural and other information about the meeting.

Dated: December 1, 1999.

Robert deV. Frierson,
Associate Secretary of the Board.

[F R Doc. 99–31511 Filed 12–1–99; 1:45 pm]
BILLING CODE 6210–01–P
FEDERAL RETIREMENT THRIFT INVESTMENT BOARD

Privacy Act of 1974; System of Records

AGENCY: Federal Retirement Thrift Investment Board.

ACTION: Notice of altered record system.

SUMMARY: The Executive Director of the Federal Retirement Thrift Investment Board (Board) is adopting as final the Board’s proposed alteration to the Government-wide system of records, FRTIB–1, Thrift Savings Plan Records. This alteration adds new categories of records for spouses, former spouses, and beneficiaries of Thrift Savings Plan (TSP) participants.


SUPPLEMENTARY INFORMATION:

The Board was established by the Federal Employees’ Retirement System Act of 1986 (FERSA), Pub. L. 99–335, 100 Stat. 514, which has been codified, as amended, largely at 5 U.S.C. 8351 and 8401–8479 (1994), to administer the TSP. The TSP is a tax-deferred retirement savings plan for Federal employees which is similar to cash or deferred arrangements established under section 401(k) of the Internal Revenue Code.

On May 7, 1990, initial notice of the Board’s systems of records, including FRTIB–1, was published in the Federal Register (55 FR 18949). A minor amendment to FRTIB–1 was published in the May 20, 1994, Federal Register (59 FR 26469), to delete routine use provisions allowing disclosure to the Department of Veterans Affairs, the Federal Housing Administration, and private financial institutions, because disclosure to those entities could be made at the written request of the participant. The provision allowing disclosure to beneficiaries of deceased participants was also deleted as unnecessary. Subsequently, on September 15, 1999, the Board published a proposed alteration to FRTIB–1 in the Federal Register (64 FR 50092) to add new categories of records to cover spouses, former spouses, and beneficiaries of participants, to state routine uses which may be made of records on these individuals, and to clarify that the term “participant” includes a former participant.

This alteration is necessary because the Board is updating its computerized data base for the TSP record keeping system. FRTIB–1 currently lists TSP participants as the only category of individuals covered by this system of records. Under the new TSP record keeping system, spouses, former spouses, and beneficiaries of participants will be added to this system of records.

In addition to publishing a notice of proposed alteration, the Board filed an altered record system report with the Chairman of the Committee on Government Reform of the U.S. House of Representatives, the Chairman of the Committee on Governmental Affairs of the U.S. Senate, and the Administrator, Office of Information and Regulatory Affairs, Office of Management and Budget, on September 13, 1999. The Board received no comments on the proposed alteration; therefore, it is adopting the proposed alteration without change.

Roger W. Mehle,
Executive Director, Federal Retirement Thrift Investment Board.

Accordingly, the proposed notice of alteration to record system published on September 15, 1999, in the Federal Register (64 FR 50092), adding new categories of records and stating the uses to be made of those records maintained for spouses, former spouses, and beneficiaries of TSP participants, is adopted as final without change.

[SFR Doc. 99–30924 Filed 12–2–99; 8:45 am] BILLING CODE 6760–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Advisory Committees; Filing of Annual Reports

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that, as required by the Federal Advisory Committee Act, the agency has filed with the Library of Congress the annual reports of those FDA advisory committees that held closed meetings during fiscal year 1998.

ADDRESSES: Copies are available from the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, 301–827–6860.

FOR FURTHER INFORMATION CONTACT: Donna M. Combs, Committee Management Office (HFA–306), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–5496.

SUPPLEMENTARY INFORMATION: Under section 13 of the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR 14.60(c), FDA has filed with the Library of Congress the annual reports for the following FDA advisory committees that held closed meetings during the period October 1, 1997, through September 30, 1998: Center for Biologics Evaluation and Research:

Allergenic Products Advisory Committee,
Biological Response Modifiers Advisory Committee,
Blood Products Advisory Committee,
Vaccines and Related Biological Products Advisory Committee,
Center for Drug Evaluation and Research:

Anti-Infective Drugs Advisory Committee,
Antiviral Drugs Advisory Committee,
Cardiovascular and Renal Drugs Advisory Committee,
Dermatologic and Ophthalmic Drugs Advisory Committee,
Drug Abuse Advisory Committee,
Endocrinologic and Metabolic Drugs Advisory Committee,
Center for Devices and Radiological Health:

Medical Devices Advisory Committee,
National Center for Toxicological Research:

Science Advisory Board to the National Center for Toxicological Research.

Annual reports are available for public inspection at: (1) The Library of Congress, Madison Bldg., Newspaper and Periodical Reading Room, 101 Independence Ave. SE., rm. 133, Washington, DC; and (2) the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 26, 1999.

Linda A. Suydam,
Senior Associate Commissioner.

[FR Doc. 99–31315 Filed 12–2–99; 8:45 am] BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–0514]

Guidance for industry on ANDA’s: Impurities in Drug Substances; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the
availability of a guidance for industry entitled “ANDA’s: Impurities in Drug Substances.” This guidance provides recommendations for including information in abbreviated new drug applications (ANDA’s) and supporting drug master files on the content and qualification of impurities in drug substances produced by chemical syntheses for both monograph and nonmonograph drug substances.

DATES: Written comments may be submitted at any time.

ADDRESSES: Copies of this guidance are available on the Internet at http://www.fda.gov/cder/guidance/index.htm. Submit written requests for single copies of this guidance for industry to the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist the office in processing your requests. Submit written comments on the guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.


SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a guidance for industry entitled “ANDA’s: Impurities in Drug Substances.” This guidance provides information on (1) Qualifying impurities found in a drug substance used in an ANDA by a comparison with impurities found in the related U.S. Pharmacopeia (USP) monograph, scientific literature, or innovator material; (2) qualifying impurities found at higher levels in a drug substance used for an ANDA than found in the related USP monograph, scientific literature, or innovator material; (3) qualifying impurities in a drug substance used for an ANDA that are not found in the related USP monograph, scientific literature, or innovator material; and (4) threshold levels below which qualification is not needed.

In the Federal Register of July 24, 1998 (63 FR 39880), FDA announced the availability of a draft version of this guidance. The July 1998 document gave interested persons an opportunity to submit comments through September 22, 1998. On October 19, 1998 (63 FR 53871), in response to requests from the public, the agency reopened the comment period until November 23, 1998. All comments received during the comment period have been carefully reviewed and the guidance was revised, where appropriate.

This level 1 guidance is being issued consistent with FDA’s good guidance practices (62 FR 8961, February 27, 1997). It represents the agency’s current thinking on the content and qualification of impurities in drug substances produced by chemical syntheses that are used in generic drug products. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both.

Interested persons may, at any time, submit written comments on the guidance to the Dockets Management Branch (address above). Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.


Margaret M. Dotzel, Acting Associate Commissioner for Policy.
[FR Doc. 99–31316 Filed 12–2–99; 8:45 am]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–R–0038]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Health Care Financing Administration.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), 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 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.

Type of Information Collection Request: Extension of a currently approved collection;

Title of Information Collection: Conditions of Participation for Rural Health Clinics, 42 CFR 491.9 Subpart A;

Form No.: HCFA–R–38;

Use: This information is needed to determine if rural health clinics meet the requirements for approval for Medicare participation.

Frequency: Other (Initial application for Medicare);

Affected Public: Individuals or households; business or other for profit; not for profit institutions; farms; Federal Government; and State, Local or Tribal Government;

Number of Respondents: 3,538;

Total Annual Hours: 9,456.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access HCFA’s Web Site address at http://www.hcfa.gov/regs/prdc95.htm, or E-mail your request, including your address, phone number, OMB number, and HCFA document identifier, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786–1326. Written comments and recommendations for the proposed information collections must be mailed within 60 days of this notice directly to the HCFA Paperwork Clearance Officer designated at the following address:


Dated: November 22, 1999.

John Parmigiani.
Manager, HCFA Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards.
[FR Doc. 99–31325 Filed 12–2–99; 8:45 am]
DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–R–289]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Health Care Financing Administration, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), 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 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.

Type of Information Collection Request: Extension of a currently approved collection;

Title of Information Collection: Medicare Lifestyle Modification Program Demonstration;

Form No.: HCFA–R–289 (0938–0777);

Use: The Health Care Financing Administration (HCFA) through its Office of Clinical Standards and Quality (OCSQ) is planning to conduct a new demonstration to test the feasibility and cost effectiveness of cardiovascular lifestyle modification. This demonstration will focus on Medicare provider sponsored, lifestyle modification programs designed to reverse, reduce, or ameliorate the indications of cardiovascular disease (CAD) of Medicare beneficiaries at risk for invasive treatment procedures. This demonstration will test the feasibility and cost effectiveness of providing payment for cardiovascular lifestyle modification program services to Medicare beneficiaries. In addition, the demonstration will test the use of contractual agreements for administration, claims processing and payment, and routine monitoring of quality of care.

Frequency: On occasion, weekly, monthly, and quarterly;

Affected Public: Individuals or households, and not-for-profit institutions;

Number of Respondents: 22;

Total Annual Responses: 9,000;

Total Annual Hours: 1,500.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access HCFA’s Web Site address at http://www.hcfa.gov/regs/prdact95.htm, or E-mail your request, including your address, phone number, OMB number, and HCFA document identifier, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786–1326. Written comments and recommendations for the proposed information collections must be mailed within 60 days of this notice directly to the HCFA Paperwork Clearance Officer designated at the following address: HCFA, Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards, Attention: Dawn Willingham, Room N2–14–26, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.


John Parmigiani,
Manager, HCFA Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards.

[FR Doc. 99–31326 Filed 12–2–99; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–1964]

Agency Information Collection Activities: Submission For OMB Review; Comment Request

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, has submitted to the Office of Management and Budget (OMB) the following proposal for the collection of information. Interested persons are invited to send comments regarding the 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.

Type of Information Collection Request: Extension of a currently approved collection;

Title of Information Collection: Request for Review of Part B Medicare Claim and Supporting Regulations in 42 CFR, 405.807;

Form No.: HCFA–1964 (OMB# 0938–0033);

Use: The HCFA–1964 is a form which is used nationally to request review of an initial determination made on a Part B health insurance claim. A Medicare beneficiary (or his/her physician/supplier who accepts assignment) files for Part B benefits using forms HCFA–1490S (Patient’s Request for Medicare Payment), HCFA–1491 (Request for Medicare Payment—Ambulance), or HCFA–1500 (Health Insurance Claim Form). If any benefits are denied, the claimant has the right to request a review of the initial determination by submitting this HCFA–1964, form;:

Frequency: On occasion;

Affected Public: Individuals or households, and not-for-profit institutions;

Number of Respondents: 5,600,000;

Total Annual Responses: 5,600,000;

Total Annual Hours: 1,400,000.

To obtain copies of the supporting statement for the proposed paperwork collections referenced above, access HCFA’s WEB SITE ADDRESS at http://www.hcfa.gov/regs/prdact95.htm, or E-mail your request, including your address and phone number, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786–1326. Written comments and recommendations for the proposed information collections must be mailed within 30 days of this notice directly to the OMB Desk Officer designated at the following address:

OMB Human Resources and Housing Branch, Attention: Allison Eydt, New Executive Office Building, Room 10235, Washington, D.C. 20503.


John Parmigiani,
Manager, HCFA, Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards.

[FR Doc. 99–31324 Filed 12–2–99; 8:45 am]

BILLING CODE 4120–03–P
Standards for Evaluating Intermediary and Carrier Performance During FY 2000

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: General notice with comment period.

SUMMARY: This notice describes the criteria and standards to be used for evaluating the performance of fiscal intermediaries and carriers in the administration of the Medicare program beginning January 1, 2000. The results of these evaluations are considered whenever HCFA enters into, renews, or terminates an intermediary agreement or carrier contract or takes other contract actions (for example, assigning or reassigning providers or services to an intermediary or designating regional or national intermediaries).

This notice is published in accordance with sections 1816(f) and 1842(b)(2) of the Social Security Act. We are publishing for public comment in the Federal Register those criteria and standards against which we evaluate intermediaries and carriers.

DATES: The criteria and standards are effective January 1, 2000.

Comments: Comments will be considered if we receive them at the appropriate address as provided below no later than 5 p.m. (EDT) on January 3, 2000.

ADDRESSES: Mail written comments (1 original and 3 copies) to the following address:

Health Care Financing Administration, Department of Health and Human Services (HHS), Attention: HCFA–4009–GNC, P.O. Box 8016, Baltimore, MD 21244–8016.

If you prefer, you may deliver your written comments (1 original and 3 copies) to one of the following addresses:

Room 443–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC, 20201, or 7500 Security Boulevard, Baltimore, Maryland 21244.

Because of the staffing and resource limitations, we cannot accept comments by facsimile (FAX) transmission. In commenting, please refer to file code HCFA–4009–GNC. Comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, in Room 443–G of the Department’s office at 200 Independence Avenue, SW., Washington, D.C., on Monday through Friday of each week from 8:30 a.m. to 5 p.m. (phone: (202) 690–7890).

FOR FURTHER INFORMATION CONTACT: Sue Lathroum, (410) 786–7409.

SUPPLEMENTARY INFORMATION:

I. Background

Under section 1816 of the Social Security Act (the Act), public or private organizations and agencies participate in the administration of Part A (Hospital Insurance) of the Medicare program under agreements with the Secretary of Health and Human Services. These agencies or organizations, known as fiscal intermediaries, determine whether medical services are covered under Medicare and determine correct payment amounts. The intermediaries then make payments to the health care providers on behalf of the beneficiaries. Section 1816(f) of the Act requires us to develop criteria, standards, and procedures to evaluate an intermediary’s performance of its functions under its agreement. We evaluate intermediary performance through the contract management process.

Under section 1842 of the Act, we are authorized to enter into contracts with carriers to fulfill various functions in the administration of Part B (Supplementary Medical Insurance) of the Medicare program. Beneficiaries, physicians, and suppliers of services submit claims to these carriers. The carriers determine whether the services are covered under Medicare and the payable amount for the services or supplies, and then make payment to the appropriate party. Under section 1842(b)(2) of the Act, we are required to develop criteria, standards, and procedures to evaluate a carrier’s performance of its functions under its contract. We also evaluate carrier performance through the contract management process.

We are publishing the criteria and standards in the Federal Register in order to allow the public an opportunity to comment before implementation. In addition to the statutory requirement, our regulations at 42 CFR 421.120 and 421.122 provide for publication of a Federal Register notice to announce criteria and standards for intermediaries prior to implementation. Regulation 42 CFR 421.201 provides for publication of a Federal Register notice to announce criteria and standards for carriers prior to implementation. The current criteria and standards were published in the Federal Register on September 7, 1994 (59 FR 46258).

To the extent possible, we make every effort to publish the criteria and standards before the beginning of the Federal fiscal year, which is October 1. If we do not publish a Federal Register notice before the new fiscal year begins, readers may presume that until and unless notified otherwise, the criteria and standards which were in effect for the previous fiscal year remain in effect. In those instances where we are unable to meet our goal of publishing the subject Federal Register notice before the beginning of the fiscal year, we may publish the criteria and standards notice at any subsequent time during the year. If we choose to publish a notice in this manner, the evaluation period for any such criteria and standards that are the subject of the notice will be revised to be effective on the first day of the first month following publication. Hence, any revised criteria and standards will measure performance prospectively; that is, we will not apply new measurements to assess performance on a retroactive basis.

Also, it is not our intention to revise the criteria and standards that will be used during the evaluation period once this information has been published in a Federal Register notice. However, on occasion, either because of Administrative mandate or Congressional action, there may be a need for changes that have direct impact upon the criteria and standards previously published, or which require the addition of new criteria or standards, or that cause the deletion of previously published criteria and standards. Should such changes be necessitated, we will issue a Federal Register notice prior to implementation of the changes. In all instances, necessary manual issuances will be published each year to ensure that the criteria and standards are implemented uniformly and accurately. Also, as in previous years, the Federal Register notice will be reprinted and the effective date revised if changes are warranted as a result of the public comments received on the criteria and standards.

II. Criteria and Standards—General

Basic tenets of the Medicare program are to pay claims promptly and accurately and to foster good beneficiary and provider relations. Contractors must administer the Medicare program efficiently and economically. We have developed a contractor management program for FY 2000 that sets
expectations for the contractor; measures the performance of the contractor; evaluates the performance against the expectations; and, takes appropriate contract action based upon evaluation of the contractor’s performance. The goal of performance evaluation is to ensure that contractors meet their contractual obligations. We measure contractor performance to ensure that contractors do what is required of them by law, regulation and HCFA directive. We ensure that contractors perform well and continually improve their performance. To better evaluate contractor performance, we are working to develop and refine measurable performance standards in key areas, and we will be facilitating the sharing of “best practices” among HCFA reviewers. We also are increasing the number of standardized evaluation protocols for use in FY 2000. We have structured contractor evaluation into five criteria designed to meet those objectives.

The first criterion in the FY 2000 contractor performance evaluation is “Claims Processing,” which measures contractual performance against claims processing accuracy and timeliness requirements. Within the Claims Processing criterion, we have identified those performance standards that are mandated by either legislation, regulation or judicial decision. These standards include claims processing timeliness, and the accuracy of Explanations of Medicare Benefits. Further evaluation in the Claims Processing criterion may include, but is not limited to, the accuracy of bill and claims processing, the level of electronic claims payment, and the percent of bills and claims paid with interest.

The second criterion is “Customer Service,” which assesses the completeness of the service provided to customers by the contractor in its administration of the Medicare program. Mandated standards in the Customer Service criterion include the rate of cases reversed by an Administrative Law Judge, the timeliness of intermediary reconsideration cases, the accuracy and timeliness of carrier reviews and hearings, and the accuracy and timeliness of carrier replies to beneficiary telephone inquiries. In FY 2000, customer feedback may be used to collect comparable data on customer satisfaction and identify areas in need of improvement. Among the specific contractor services that may be included in the evaluation process under the Customer Service criterion are: beneficiary relations; provider education; appropriate telephone inquiry responses; and the tone and accuracy of all correspondence.

The third criterion is “Payment Safeguards,” which evaluates whether the Medicare trust funds are safeguarded against inappropriate program expenditures. Intermediary and carrier performance may be evaluated in the areas of medical review, Medicare secondary payer, fraud and abuse, and audit and reimbursement. Mandated performance standards in the Payment Safeguards criterion are the accuracy of decisions on skilled nursing facility (SNF) demand bills, and the timeliness of processing Tax Equity and Fiscal Responsibility Act (TEFRA) target rate adjustments, exceptions, and exemptions. Further evaluation in this criterion may include, but is not limited to, some core standards for Medical Review and Benefit Integrity.

The fourth criterion is “Fiscal Responsibility,” which evaluates the contractor’s efforts to protect the Medicare program and the public interest. Contractors must effectively manage Federal funds for both payment of benefits and cost of administration under the Medicare program. Proper financial and budgetary controls, including internal controls, must be in place to ensure contractor compliance with its agreement with HHS and HCFA. Additional functions reviewed under this criterion may include, but are not limited to, adherence to approved budget, compliance with the Budget and Performance Requirements, and adherence to the Chief Financial Officers Act.

The fifth and final criterion is “Administrative Activities,” which measures a contractor’s administrative management of the Medicare program. A contractor must efficiently and effectively manage its operations to ensure constant improvement in the way it does business. Proper systems security, Automated Data Processing (ADP) maintenance, and disaster recovery plans must be in place. It must also ensure that all necessary actions and system changes have been made and tested so that it is meeting established milestones along the critical path of HCFA’s requirements for millennium compliance. Year 2000 compliant means information technology that accurately processes date and time data (including, but not limited to, calculating, comparing, and sequencing) from, into, and between the centuries (the years 1999 and 2000), and leap year calculations. Furthermore, Year 2000 compliant information technology must accurately process date and time data if the other information technology properly exchanges date and time data with it. A contractor’s evaluation under the Administrative Activities criterion may include, but is not limited to, establishment, application, documentation, and effectiveness of internal controls, which are essential in all aspects of a contractor’s operation. Administrative Activities evaluations may also include implementation reviews of performance improvement plans, change management plans, and data and reporting requirements.

We have also developed separate measures for evaluating unique activities of Regional Home Health Intermediaries (RHHIs). Section 1816(e)(4) of the Act requires the Secretary to designate regional agencies or organizations, which are already Medicare intermediaries under section 1816, to perform bill processing functions with respect to freestanding home health agency (HHA) bills. The law requires that we limit the number of such regional intermediaries (i.e., RHHIs) to not more than ten (see 42 CFR 421.117 and the Final Rule published in the Federal Register on May 19, 1988 (53 FR 17936) for more details about the RHHIs).

In addition, section 1816(e)(4) of the Act requires the Secretary to develop criteria and standards in order to determine whether to designate an agency or organization to perform services with respect to hospital affiliated HHAs. We have developed separate measures for RHHIs in order to evaluate the distinctly RHI functions. These functions include the bills processing of freestanding HHAs, hospital affiliated HHAs, and hospices. Through an evaluation using these criteria and standards we may determine whether the RHHI functions should be moved from one intermediary to another in order to ensure effective and efficient administration of the program benefit.

Below we list the criteria and standards to be used for evaluating the performance of intermediaries and carriers. In a number of instances, we identify a HCFA manual as a source of more detailed requirements. Intermediaries and carriers have copies of various Medicare manuals referenced in this notice. Members of the public also have access to our manualized instructions.

Medicare manuals are available for review at local Federal Depository Libraries (FDLs). Under the FDL Program, government publications are sent to approximately public designated public libraries throughout the United States. Interested parties may examine
the documents at any one of the FDLs. Some may have arrangements to transfer material to a local library not designated as an FDL. To locate the nearest FDL, individuals should contact any public library.

In addition, individuals may contact regional depository libraries, which receive and retain at least one copy of nearly every Federal government publication, either in printed or microfilm form, for use by the general public. These libraries provide reference services and interlibrary loans; however, they are not sales outlets. Individuals may obtain information about the location of the nearest regional depository library from any library. Information may also be obtained from the following web site: www.hcfa.gov/pubforms/progman.htm. Some manuals may be obtained from the following web site: www.hcfa.gov/pubforms/p2192toc.htm.

Finally, all HCFA regional offices maintain all Medicare manuals for public inspection. To find the location of the nearest available HCFA regional office, individuals may call the FOR FURTHER INFORMATION CONTACT individual listed at the beginning of this notice. That individual can also provide information about purchasing or subscribing to the various Medicare manuals.

III. Criteria and Standards for Intermediaries

Claims Processing Criterion

The Claims Processing criterion contains 4 mandated standards.

Standard 1—95% of clean electronically submitted non-Periodic Interim Payment (PIP) bills paid within statutorily specified time frames. Clean bills are defined as bills that do not require Medicare intermediaries and/or carriers to investigate or develop external to their Medicare operations on a prepayment basis.

Specifically, clean, non-PIP electronic claims can be paid as early as the 14th day (13 days after the date of receipt) and must be paid by the 31st day (30 days after the date of receipt).

Standard 2—95% of clean paper non-PIP bills paid within specified time frames. Specifically, clean, non-PIP paper claims can be paid as early as the 27th day (26 days after the date of receipt), and must be paid by the 31st day (30 days after the date of receipt).

Standard 3—Reversal rate by Administrative Law Judges (ALJ) is acceptable. HCFA has defined an acceptable reversal rate as one that is at or below 5.0%.

Standard 4—75% of reconsiderations are processed within 60 days and 90% are processed within 90 days. Additional functions may be evaluated under this criterion. These functions include, but are not limited to the—

• Bill processing accuracy;
• Attainment of Electronic Media Claims goals;
• Establishment and maintenance of relationship with Common Working File Host;
• Management of shared processing sub-contract; and
• Analysis and validation of data.

Customer Service Criterion

We may review the intermediary’s efforts to enhance customer satisfaction through the use of customer feedback. Results of the feedback may be used to establish comparable data on customer satisfaction and to identify areas in need of improvement. The results may be summarized for publication in the report of contractor performance and shared with individual contractors.

Functions which may be evaluated under this criterion include, but are not limited to, the—

• Accuracy, timeliness and appropriateness of responses to telephone inquiries;
• Accuracy of processing reconsideration cases with clear responses and appropriate customer-friendly tone and clarity;
• Accuracy, clearness and timeliness of responses to written inquiries with appropriate customer-friendly tone and clarity;
• Establishment and maintenance of relationships with professional and beneficiary organizations and using focus groups; and
• Conduct of educational and outreach efforts.

Payment Safeguard Criterion

The Payment Safeguard criterion contains 2 mandated standards.

Standard 1—Decisions of SNF demand bills are accurate.

Standard 2—TEFRA target rate adjustments, exceptions, and exemptions are processed within mandated time frames. Specifically, applications must be processed to completion within 75 days after receipt by the contractor or returned to the hospitals as incomplete within 60 days of receipt.

Additional functions may be evaluated under this criterion. These functions include, but are not limited to—

• Medical Review. We may evaluate if the fiscal intermediary—
  + Increased the effectiveness of medical review payment safeguard activities;
  + Exercised accurate and defensible decision making on medical reviews;
  + Educated and communicated effectively with the provider and supplier community;
  + Collaborated with other internal components and external entities to ensure correct claims payment, and to address situations of fraud, waste, and abuse.
  • Audit and Reimbursement. We may—
    + Assess the quality of a fiscal intermediary’s activities in the audit and settlement of Medicare cost reports;
    + Assess the timeliness of Medicare cost report settlements and the accuracy by which a fiscal intermediary has established interim provider payments.
  • Medicare Secondary Payer. We may—
    + Review the intermediary’s MSP processes in administering the program and for identifying and recovering mistaken Medicare payments in accordance with MIM, Part 3, §§3400ff and 3600ff, and pertinent HCFA instructions and transmittals;
    + Develop outcome measures to assess the intermediary’s accuracy in reporting savings and to determine if claim development procedures are followed;
    + Evaluate the accuracy and timeliness of claims payment and determine if the Common Working File, internal systems and required software are utilized as prescribed; and
    + Evaluate the contractor’s ability to prioritize and process recoveries in compliance with instructions, determine if recoveries of all payers are processed equally, and ensure that audit trail documentation exists.
  • Fraud and Abuse. We may evaluate if the fiscal intermediary—
    + Used proactive and reactive techniques in the detection and development of potential fraud cases;
    + Used other corrective and preventive actions (such as payment suspensions, Civil Monetary Penalties (CMPs), overpayment assessments, prepayment or post-payment claims reviews, system fixes, claim denials, etc.);
    + Properly developed fraud cases for referral to the Office of the Inspector General, HHS; and
    + Maintained a good working relationship and extensive networking with both internal components and external partners.
Fiscal Responsibility Criterion

We may review the intermediary’s efforts to establish and maintain appropriate financial and budgetary internal controls over benefit payments and administrative costs. Proper internal controls must be in place to ensure that contractors comply with their agreements with HCFA. Additional matters to be reviewed under the Fiscal Responsibility criterion may include, but are not limited to—

• Adherence to approved budget;
• Compliance with the Budget and Performance Requirements;
• Adherence to the Chief Financial Officers Act; and
• Control of administrative cost and benefit payments.

Administrative Activities Criterion

We may measure a contractor’s administrative ability to manage the Medicare program. We may evaluate the efficiency and effectiveness of its operation, its system of internal controls, and its compliance with HCFA directives and initiatives.

A contractor must efficiently and effectively manage its operations to assure constant improvement in the way it does business. Proper systems security, ADP maintenance, and disaster recovery plans must be in place. It must also ensure that all necessary actions and system changes have been made and tested so that it is meeting established milestones along the critical path of HCFA’s requirements for millennium compliance. Year 2000 compliant means information technology that accurately processes date and time data (including, but not limited to, calculating, comparing, and sequencing) from, into, and between the centuries (the years 1999 and 2000), and leap year calculations. Furthermore, Year 2000 compliant information technology, when used in combination with other information technology, must accurately process date and time data if the other information technology properly exchanges date and time data with it. A contractor must also test standard system changes to ensure the accurate implementation of HCFA instructions.

HCFA’s evaluation of a contractor under the Administrative Activities criterion may include, but is not limited to, reviews of the contractor’s—

• Systems security;
• ADP maintenance;
• Disaster recovery plan;
• Performance Improvement Plans implementation;
• Change Management Plan implementation;
• Data and reporting requirements implementation; and
• Internal controls establishment and use.

IV. Criteria and Standards for Carriers

Claims Processing Criterion

The Claims Processing criterion contains 5 mandated standards.

Standard 1—95% of clean electronically submitted claims processed within statutorily specified time frames. Specifically, clean electronic claims can be paid as early as the 14th day (13 days after the date of receipt) and must be paid by the 31st day (30 days after the date of receipt).

Standard 2—95% of clean paper claims processed within specified time frames. Specifically, clean paper claims can be paid as early as the 27th day (26 days after the date of receipt) and must be paid by the 31st day (30 days after the date of receipt).

Standard 3—98% of Explanations of Medicare Benefits (EOMBS) are properly generated.

Standard 4—95% of review determinations are accurate and clear with appropriate customer-friendly tone and clarity, and are completed within 45 days.

Standard 5—90% of carrier hearing decisions are accurate and clear with appropriate customer-friendly tone and clarity, and are completed within 120 days.

Additional functions may be evaluated under this criterion. These functions include, but are not limited to, the—

• Claims Processing accuracy;
• Attainment of Electronic Media Claims goals:
  • Management of shared processing sub-contract;
  • Establishment and maintenance of relationship with the Common Working File Host; and
• Analysis and validation of data.

Customer Service Criterion

The Customer Service criterion contains 1 mandated standard.

Standard 1—Telephone inquiries are answered timely.

Carriers are to achieve a monthly All Trunks Busy Rate of not more than 5%. For callers choosing to speak with a customer service representative, 97.5% or more of telephone calls are to be answered within 120 seconds; no less than 85% are to be answered within the first 60 seconds.

We may review the carrier’s efforts to enhance customer satisfaction through the use of customer feedback. Results of the feedback may be used to establish comparable data on customer satisfaction and to identify areas in need of improvement. The results may be summarized for publication in the report of contractor performance and shared with individual contractors.

Additional functions may be evaluated under this criterion. These functions include, but are not limited to, the carrier’s—

• Accuracy and appropriateness of responses to telephone inquiries;
• Accuracy, clearness, and timeliness of responses to written inquiries with appropriate customer-friendly tone and clarity;
• Establishment and maintenance of relationships with professional and beneficiary organizations and using focus groups; and
• Conduct of educational and outreach efforts.

Payment Safeguards Criterion

Carrier functions that may be reviewed under this criterion include, but are not limited to—

• Medical Review. We may evaluate if the carrier—
  • Increased the effectiveness of medical review payment safeguard activities;
  • Exercised accurate and defensible decision making on medical reviews;
  • Effectively educated and communicated with the provider and supplier community;
  • Collaborated with other internal components and external entities to ensure correct claims payment, and to address situations of fraud, waste, and abuse.
  • Medicare Secondary Payer. We may—
    • Review the carrier’s MSP processes in administering the program and for identifying and recovering mistaken Medicare payments in accordance with the Medicare Carriers Manual (MCM, Part 3, §§ 3375, 4306.3, and 4307–4308.1), and pertinent HCFA instructions and transmittals;
    • Develop outcome measures to assess the carrier’s accuracy in reporting savings and to determine if claim development procedures are followed;
  • Evaluate the accuracy and timeliness of claims payment and determine if the Common Working File, internal systems and required software are utilized as prescribed; and
  • Evaluate the contractor’s ability to prioritize and process recoveries in compliance with instructions, determine if recoveries of all payers are processed equally, and ensure that audit trail documentation exists.
• Fraud and Abuse. We may evaluate if the carrier—
+ Used proactive and reactive techniques in the detection and development of potential fraud cases;
+ Used other corrective and preventive actions (such as payment suspensions, CMPs, overpayment assessments, education, pre-payment or post-payment claims reviews, system fixes, edits, claim denials, etc.);
+ Properly developed fraud cases for referral to the Office of the Inspector General, HHS;
+ Maintained a good working relationship and extensive networking with both internal components and external partners.

Fiscal Responsibility Criterion

We may review the carrier’s efforts to establish and maintain appropriate financial and budgetary internal controls over benefit payments and administrative costs. Proper internal controls must be in place to ensure that contractors comply with their agreements with HCFA. Additional matters to be under the Fiscal Responsibility criterion may include, but are not limited to—

• Compliance with the Budget and Performance Requirements;
• Adherence to approved budget;
• Adherence to the Chief Financial Officers Act; and
• Control of administrative cost and benefit payments.

Administrative Activities Criterion

We may measure a carrier’s administrative ability to manage the Medicare program. We may evaluate the efficiency and effectiveness of its operation, its system of internal controls and its compliance with HCFA’s directives and initiatives.

A contractor must efficiently and effectively manage its operations to assure constant improvement in the way it does business. Proper systems security, ADP maintenance, and disaster recovery plans must be in place. It must also ensure that all necessary actions and system changes have been made and tested so that it is meeting established milestones along the critical path of HCFA’s requirements for millennium compliance. Year 2000 compliant means information technology that accurately processes date and time data (including, but not limited to, calculating, comparing, and sequencing) from, into, and between the centuries (the years 1999 and 2000), and leap year calculations. Furthermore, Year 2000 compliant information technology, when used in combination with other information technology, must accurately process date and time data if the other information technology properly exchanges date and time data with it. Also, a contractor must test standard system changes to ensure accurate implementation of HCFA instructions.

A carrier’s evaluation under this criterion may include, but is not limited to, reviews of—

• Proper systems security;
• ADP maintenance;
• Disaster recovery plan;
• Performance improvement plans implementation;
• Change management plan implementation;
• Data and reporting requirements implementation; and
• Internal controls establishment and use.

V. Regional Home Health Intermediaries’ (RHHIs’) Criterion

The following standards are mandated for the Regional Home Health Intermediaries’ criterion:

Standard 1—95% of clean electronically submitted non-PIP HHA/hospice bills paid within statutorily specified time frames. Specifically, clean, non-PIP electronic claims can be paid as early as the 14th day (13 pays after the date of receipt and must be paid by the 31st day (30 days after the date of receipt).

Standard 2—95% of clean paper non-PIP HHA/hospice bills paid within specified time frames. Specifically, clean, non-PIP paper claims can be paid as early as the 27th day (26 days after the date of receipt) and must be paid by the 31st day (30 days after the date of receipt).

Standard 3—75% of HHA/hospice reconsiderations are processed within 60 days and 90% are processed within 90 days.

We may use this criterion to review a RHHI’s performance with respect to handling the HHA/hospice workload. This includes processing HHA/hospice bills timely and accurately, properly paying and settling HHA cost reports, and timely and accurately processing reconsiderations from beneficiaries, HHAs, and hospices.

VI. Action Based on Performance Evaluations

A contractor’s performance is evaluated against applicable program requirements for each criterion. Each contractor must certify that all information submitted to HCFA relating to the contractor management process, including without limitation all records, reports, files, papers and other information, whether in written, electronic, or other form, is accurate and complete to the best of the contractor’s knowledge and belief. A contractor will also be required to certify that its files, records, documents, and data have not been manipulated or falsified in an effort to receive a more favorable performance evaluation. A contractor must further certify that, to the best of its knowledge and belief, the contractor has submitted, without withholding any relevant information, all information required to be submitted with respect to the contractor management process under the authority of applicable law(s), regulation(s), contracts, or HCFA manual provision(s). Any contractor that makes a false, fictitious, or fraudulent certification may be subject to criminal and/or civil prosecution, as well as appropriate administrative action. Such administrative action may include debarment or suspension of the contractor, as well as the termination or nonrenewal of a contract.

If a contractor meets the level of performance required by operational instructions, it meets the requirements of that criterion. Any performance measured below basic operational requirements constitutes a program deficiency. The contractor will be required to develop and implement a Performance Improvement Plan for each program deficiency identified. The contractor will be monitored to ensure effective and efficient compliance with the performance improvement plan, and to ensure improved performance where requirements are not met. The contractor will also be monitored when program vulnerability in a particular performance area is identified. A program vulnerability exists when a contractor’s performance complies with basic program requirements, but one or more weaknesses are present which could result in deficient performance if left ignored.

The results of performance evaluations and assessments under all five criteria will be used for contract management activities and will be published in the contractor’s annual performance report. We may initiate administrative actions as a result of the evaluation of contractor performance based on these performance criteria. Under sections 1816 and 1842 of the Act, we consider the results of the evaluation in our determinations when—

• Entering into, renewing, or terminating agreements or contracts with contractors;
• Deciding other contract actions for intermediaries and carriers (such as detention of an automatic renewal clause). These decisions are made on a case-by-case basis and depend primarily
on the nature and degree of performance. More specifically, they depend on the—
+ Relative overall performance compared to other contractors;
+ Number of criteria in which deficient performance occurs;
+ Extent of each deficiency;
+ Relative significance of the requirement for which deficient performance occurs within the overall evaluation program; and
+ Efforts to improve program quality, service, and efficiency.
• Deciding the assignment or reassignment of providers and designation of regional or national intermediaries for classes of providers.

We make individual contract action decisions after considering these factors in terms of their relative significance and impact on the effective and efficient administration of the Medicare program.

In addition, if the cost incurred by the intermediary or carrier to meet its contractual requirements exceeds the amount which the Secretary finds to be reasonable and adequate to meet the cost which must be incurred by an efficiently and economically operated intermediary or carrier, such high costs may also be grounds for adverse action.

VII. Response to Public Comments

Because of the large number of items of correspondence we normally receive on Federal Register documents published for comment, we are unable to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the DATES section of this preamble, and, if we proceed with a subsequent document, we will respond to the comments in the preamble of that document.

In accordance with the provisions of Executive Order 12866, this notice was reviewed by the Office of Management and Budget.

We have reviewed this notice under the threshold criteria of Executive Order 13132 of August 4, 1999, Federalism, published in the Federal Register on August 10, 1999 (64 FR 43255). The Executive Order is effective November 2, 1999, which is 90 days after the date of this Order. We have determined that the notice does not significantly affect the rights, roles, and responsibilities of States.

Section 202 of the Unfunded Mandates Reform Act of 1995 requires that agencies assess anticipated costs and benefits before issuing any rule that may result in an expenditure by State, local, or tribal governments, in the aggregate, or by the private sector, of $100 million in any one year. This notice will not have an effect on the governments mentioned, and the private sector costs will not be greater than the $100 million threshold.

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance, and Program No. 93.774. Medicare—Supplemental Medical Insurance Program)

Dated: October 6, 1999.

Michael M. Hash,
Deputy Administrator, Health Care Financing Administration.

[FR Doc. 99–31361 Filed 12–2–99; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Invention; Availability for Licensing: “Novel Method and Composition to Induce Apoptosis in Tumor Cells”

AGENCY: National Institutes of Health, Public Health Service, DHHS.

ACTION: Notice.

SUMMARY: The invention listed below is owned by an agency of the U.S. Government and is 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.

ADDRESSES: Licensing information and a copy of the U.S. patent application referenced below may be obtained by contacting J.R. Dixon, at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804 (telephone 301/496–7056 ext 206; fax 301/402–0220; E-Mail: jd212g@NIH.GOV).

A signed Confidential Disclosure Agreement is required to receive a copy of any patent application.

SUPPLEMENTARY INFORMATION: Invention Title: “Anti-Notch-1 Monoclonal Antibodies for Inducing Cellular Differentiation and Apoptosis” Inventors: Drs. Lucio L Miele (U.S.F.D.A.) and Chana Y. Fuchs (U.S.F.D.A.) USPA SN: 60/124,119—Filed with the U.S.P.T.O. March 12, 1999

Apoptosis or programmed cell death is caused by many anti-tumor drugs and by radiation therapy. These treatment modalities cause apoptosis in tumor cells and in many normal cells in the body. As cancer cells progress towards more aggressive forms, they often become highly resistant to drug or radiation-induced apoptosis, generally through the loss of function p53, a gene which can trigger apoptosis in response to DNA damage. Thus, novel strategies to induce apoptosis in tumor cells, especially p53-deficient cells, is an attractive and an active area of research.

Notch-1 is expressed at high levels in several human tumors. However, its function in tumor cells has not been characterized. So far, its role in maintaining tumor cell survival has not been identified. Using a model constituted by a p53-deficient mouse leukemia cell line, FHS scientists found that: (1) Antisense synthetic DNA oligonucleotides and stable incorporation of an antisense gene (a model for gene therapy) targeting notch-1, when given together with a differentiation-inducing antitumor drug, cause the cells to respond by massive apoptosis rather than differentiation; (2) stable incorporation of an antisense notch-1 gene increases apoptosis in these cells even in the absence of any antitumor drugs. This suggests that antisense notch-1 treatment, by antisense oligonucleotides or by gene therapy, may be used alone or together with anti-cancer drugs to cause apoptosis in tumor cells.

The notch gene belongs to a family of epidermal growth factor (“EGF”) like homeotic genes, which encode transmembrane proteins with a variable number of cysteine-rich EGF-like repeats in the extracellular region. Four notch genes have been described in mammals, which include notch-1, notch-2, notch-3, and notch-4 (Int-3), which have been implicated in the differentiation of the nervous system and other structures. The EGF-like proteins Delta and Serrate have been identified as ligands of notch-1.

Mature notch proteins are heterodimeric receptors derived from the cleavage of notch pre-proteins into an extracellular subunit (Nc) containing multiple EGF-like repeats and a transmembrane subunit including intracellular region (Nc). Notch activation results from the binding of ligands expressed by neighboring cells, and signaling from activated notch involves network of transcription regulators.

Alteration of notch-1 signaling or expression may contribute to tumorigenesis. Deletions of the extracellular portion of human notch-1 are associated with about 10% of the cases of T-Cell acute lymphoblastic leukemia. Truncated forms of notch-1 cause T-Cell lymphomas when introduced into mouse bone marrow stem cells and are found in rat kidney cells. The human notch-1 gene is in a chromosomal region (9q34).
associated with hematopoietic malignancies of lymphoid, myeloid, and erythroid lineage. Additionally, strikingly increased expression of notch-1 has been documented in a number of human tumors including cervical cancer, colon tumors, lung tumors, and pre-neoplastic lesions of the uterine cervix.

Notch antisense oligonucleotides (or other molecules that interfere with the expression or function of notch) could be therapeutically administered to treat or prevent tumors. It has not been found that adjuvant administration of notch antisense oligonucleotides alone is effective as an anti-neoplastic treatment. The present invention has overcome this problem by combining the administration of a cell differentiation agent with an antibody that antagonizes the function of a notch protein and hence interferes with the expression or function of a notch protein (such as the notch-1 protein). This combination of approaches has unexpectedly been found to induce apoptosis in neoplastic cells, and provides a useful therapeutic application of this technology.

In particular the tumor cell is one that is characterized by increased activity or increased expression of a notch protein, such as a notch-1 or notch-2 protein. Examples of tumor types that over express notch-1 include cervical cancer, breast cancer, colon cancer, melanoma, seminoma, lung cancer and hematopoietic malignancies, such as erythroid leukemia, myeloid leukemia, (such as chronic or acute myelogenous leukemia), neuroblastoma and medulloblastoma. The differentiation inducing agent to which the cell is exposed can be selected from a broad variety of agents, including retinoids, polar compounds (such as hexamethylene bisacetanmide), short chain fatty acids, organic acids, Vitamin D derivatives, cyclooxygenase inhibitors, archichidone metabolism inhibitors, ceramides, diacylglycerol, cyclic nucleotide derivatives, hormones, hormone antagonists, biologic promoters of differentiation, and derivatives of any of these agents.

Technology

This invention provides compositions, pharmaceutical compositions, and methods for stimulating/increasing cell differentiation, and is particularly related to the treatment of tumors which have increased notch-1 expression. A polyclonal and/or monoclonal antibody generated against human Notch-1 Epidermal Growth Factor ("EGF") that recognizes an extracellular epitope of notch-1 and that stimulates target cell differentiation in the presence of an effect amount of differentiation inducing agent is disclosed as is the hybridoma which produces these antibodies. At a time during which differentiation has been promoted, and the cell is susceptible to interference with the anti-apoptosis effect of notch, the function of the notch protein is disrupted. Disruption of notch function can be achieved, for example, by the expression of antisense oligonucleotides that specifically interfere with expression of the notch protein on the cell, or by monoclonal antibodies that specifically bind to notch and inactivate it. This technology represents a novel method to induce apoptosis in tumor cells.

The above mentioned Invention is available, including any available foreign intellectual property rights, for licensing.

Dated: November 24, 1999.

Jack Spiegel,
Director, Division of Technology Development & Transfer, Office of Technology Transfer.

[FR Doc. 99–31343 Filed 12–2–99; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; 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 Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel. ZDK1 GRB–C J3 P.

Date: December 6–8, 1999.

Time: 7:00 p.m. to 12:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Radisson Hotel at Gateway, 651 Huron Road, Cleveland, OH 44115.


BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Disease; 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 contract proposals and the discussions could disclose
confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel. ZDK1 GRB–D (C4).

Date: November 29, 1999.

Time: 3:30 PM to 5:30 PM.

Agenda: To review and evaluate contract proposals.

Place: National Institutes of Health, Natcher Bldg., 45 Center Drive, Room 6AS–37, Bethesda, MD 20892. (Telephone Conference Call).


This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle. (Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: November 24, 1999.

LaVerne Y. Stringfield, Director, Office of Federal Advisory Committee Policy.

[FR Doc. 99–31341 Filed 12–2–99; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–4444–N–10]

Notice of Proposed Information Collection: Evaluation of Low-Level Lead Hazard Intervention in the CLEARCorps Program

AGENCY: Office of Lead Hazard Control, HUD.

ACTION: Notice.

SUMMARY: The proposed information collection requirement described below will be submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.

DATES: Comments Due Date: February 1, 2000.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to: Gail N. Ward, Reports Liaison Officer, Department of Housing and Urban Development, 451 7th Street, SW., Room P3206, Washington, DC 20410.

FOR FURTHER INFORMATION CONTACT: Mr. Eugene Pinzer, (202) 755–1785 ext. 120 (this is not a toll-free number) for available documents regarding this proposal.

SUPPLEMENTARY INFORMATION: This Notice is soliciting comments from members of the public and affected agencies concerning the proposed collection of information to: (1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) Evaluate the accuracy of the Department’s estimate of the burden of the proposed collection of information; (3) Enhance the quality, utility, and clarity of the information to be collected; and (4) Minimize the burden of the collection of information on those who are to respond; including through the use of appropriate automated collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

This Notice also lists the following information:

Title of the Proposal: Evaluation of Low-Level Lead Hazard Intervention in the CLEARCorps Program.

OMB Control Number: To be assigned.

Need For the Information and Proposed Use: Various means of treating residential lead-based paint hazards have been developed to reduce or eliminate the potential that occupants could be overexposed to lead. CLEARCorps, a division of AmeriCorps, has been funded by Congress, through HUD, to perform “low-level lead hazard interventions.” Plans include CLEARCorps operation in four cities: Baltimore, Detroit, Pittsburgh, and Portland, OR. Low level interventions are designed to reduce dust levels and prevent ingestion of lead-containing dust by infants and young children. Low-level interventions do not typically include lead-based paint removal. The CLEARCorps program for low-level interventions will be evaluated by the National Center for Lead Safe Housing and by Quantech, both funded by HUD. The HUD Guidelines or the Evaluation and Control of Lead-Based Paint Hazards in Housing (“Guidelines”) recommend that, “unless precluded by regulation, inert controls are most easily implemented when most surfaces with lead-based paint are intact and structurally sound and lead exposure comes primarily from deteriorating paint and excessive levels of lead in household dust and/or soil. Interim controls are also appropriate if the Housing unit is slated for demolition or renovation within a few years. In many cases resources will not be available to finance permanent abatement, making interim controls the only feasible approach.” There is considerable interest regarding the use of this potentially cost-effective treatment.

This information collection will involve telephone interviews and visits to CLEARCorps sites in the selected cities, as well as telephone interviews and visits to homes where the low-level interventions will be performed. If appropriate, the results of this information collection will be used to improve existing HUD guidance on the use of low-level lead-based paint interventions; findings may also be used to determine the need for and to design a study of the short and long term effectiveness of low-level lead-based paint interventions in controlling lead-based paint hazards.

Agency Form Numbers: None.

Members of Affected Public: Owners and occupants of units where low-level interventions will be performed.

Total Burden Estimate (First Year): Number of respondents: 180

Frequency of response: 19

Total Hours of response: 652

Status of the proposed information collection: New collection.


David E. Jacobs, Director, Office of Lead Hazard Control.

[FR Doc. 99–31441 Filed 12–2–99; 8:45 am]

BILLING CODE 4210–01–M

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–4432–N–48]

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.

EFFECTIVE DATE: December 3, 1999.

FOR FURTHER INFORMATION CONTACT: Clifford Taffet, 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 number 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: November 24, 1999.
Fred Karnas, Jr.,
Deputy Assistant Secretary for Special Needs Assistance Programs.

[FR Doc. 99–31075 Filed 12–2–99; 8:45 am]
BILLING CODE 4210–29–M

DEPARTMENT OF THE INTERIOR

DEPARTMENT OF COMMERCE

United States Coral Reef Task Force; Notice of Availability of Documents for Public Review and Comment

AGENCY: United States Coral Reef Task Force.

ACTION: Availability of documents.


ADDRESSES: Submit electronic comments on any or all of these documents to Patricia_Kennedy@ios.doi.gov. Alternatively, submit written comments to the United States Coral Reef Task Force, c/o Ms. Patricia Kennedy, Office of the Assistant Secretary for Fish and Wildlife and Parks, U.S. Department of the Interior, 1849 C Street, N.W., Mail Stop 3156, Washington, D.C. 20240, to request a copy of any or all of the documents.

FOR FURTHER INFORMATION CONTACT: Ms. Patricia Kennedy, 202–208–5378, concerning how to submit your comments. Contact Ms. Molly N. Ross, 202–208–5378, or Mr. Roger B. Griffis, 202–482–5034, concerning all other matters.

SUPPLEMENTARY INFORMATION: The world’s coral reefs are in serious jeopardy, threatened by a growing barrage of over-exploitation, pollution, habitat destruction, diseases, invasive species, bleaching and climate change. The rapid decline of these ancient and productive marine ecosystems has significant social, economic and environmental impacts on coastal cultures and on the nation as a whole.

In response to this global environmental crisis, President Clinton issued Executive Order 13089, 63 FR 32702 (June 16, 1998). The executive order established the United States Coral Reef Task Force (CRTF), to be chaired by the Secretary of the Interior and the Secretary of Commerce, through the Administrator of the National Oceanic and Atmospheric Administration. The executive order assigned the CRTF specific duties for coral reef protection, including coordination of a comprehensive program to map and monitor U.S. coral reefs; development and implementation of research aimed at identifying the major causes and consequences of degradation of coral reef ecosystems; development, recommendation, and implementation of measures necessary to reduce and mitigate coral reef ecosystem degradation and to restore damaged coral reefs; and assessment of the U.S. role in international trade and protection of coral reef species and implementation of appropriate strategies and actions to promote conservation and sustainable use of coral reef resources worldwide.

At its third meeting on November 2–3, 1999, in St. Croix, U.S. Virgin Islands, the CRTF endorsed or adopted three documents in furtherance of its duties under Executive Order 13089. The CRTF decided to provide an opportunity for public comment on each of these documents, as follows:

(1) The CRTF endorsed the “Draft National Action Plan to Conserve Coral Reefs” for the purpose of securing public comment on the draft plan and then revising it as necessary before adoption at a future meeting. This draft plan is a detailed, long-term strategy for implementing Executive Order 13089. It was prepared through careful deliberations of a large and diverse group of experts in coral reef science, management, policy and education, drawn from federal, state and territorial governments, academia and the private sector. The CRTF welcomes public review, discussion, and comment on the draft plan.

(2) The CRTF adopted the document entitled “Coral Reef Protected Areas: A Guide for Management,” subject to technical amendments. The purpose of this document is to assist those involved in planning and managing programs for coral reef protected areas. It is intended for use in developing management plans for new protected areas and for reviewing plans at established areas. The CRTF invites comment on this document.

(3) The CRTF adopted the document entitled “Oversight of Agency Actions Affecting Coral Reef Protection,” subject to revision in light of public comment. This document establishes the procedures necessary to carry out the CRTF’s duty under the Executive Order “to oversee implementation of the policy and Federal agency responsibilities set forth in this order.” The oversight procedures require CRTF members to develop by June 11, 2000, plans for implementing the executive order, and to provide annual reports summarizing the agency’s implementation each June. The oversight procedures also describe how a person who believes that an agency has taken action inconsistent with the Executive Order may register his or her concern and receive a response from the agency.
Dated: November 26, 1999.

Stephen C. Saunders,
Acting Assistant Secretary for Fish and Wildlife and Parks, Department of the Interior.

Sally Yozell,
Deputy Assistant Secretary for Oceans and Atmosphere, Department of Commerce.

SUMMARY: This order withdraws approximately 9,175 acres of National Forest System lands from location and entry under the United States mining laws, for a 20-year period, for the Bureau of Reclamation to protect the Roosevelt Lake expansion area. The lands have been and will remain open to mineral leasing.

EFFECTIVE DATE: December 3, 1999.


By virtue of the authority vested in the Secretary of the Interior by Section 204 of the Federal Land Policy and Management Act of 1976, 43 U.S.C. 1714 (1994), it is ordered as follows:

1. Subject to valid existing rights, the following described National Forest System lands are hereby withdrawn from location and entry under the United States mining laws (30 U.S.C. Ch. 2 (1994)), but not from leasing under the mineral leasing laws, to protect the Bureau of Reclamation’s Roosevelt Lake expansion area:

Gila and Salt River Meridian

Tonto National Forest

T. 5 N., R. 10 E., Sec. 1, NE\1/4NE\4.

T. 4 N., R. 11 E., Sec. 2, lot 4, SW\1/4NW\4, NW\1/4SW\4, and SE\4SW\4;

Sec. 3, lots 1 and 2, and S\1/2NE\4;

Sec. 11, NW\1/4NE\4 and SE\4NE\4;

Sec. 12, SE\4SW\4;

Sec. 13, N\1/2NE\4;

T. 5 N., R. 11 E., Sec. 5, SW\1/4NE\4, SE\4NW\4, NE\4SW\4, NW\4SE\4, and SE\4SE\4;

Sec. 6, lots 3, 4, and 5, SW\4NE\4, SE\4NW\4, NE\4SW\4, NW\4SE\4, and SE\4;

Sec. 7, NE\4 and N\1/2SE\4;

Sec. 8, E\1/2E\4, NW\4NE\4, and W\1/2NW\4;

Sec. 14, S\1/2SW\4 and SW\4SE\4;

Sec. 15, SW\4SW\4;

Sec. 16, SW\4NE\4, SW\4, and S\1/2SE\4;

Sec. 17, E\1/2NE\4 and NE\4SE\4;

Sec. 22, N\1/2NE\4;

Sec. 23, W\1/4NE\4, N\1/2NW\4, NW\4SE\4, and SE\4SE\4;

Sec. 24, S\1/2SW\4;

Sec. 25, W\1/2NE\4, NE\4NW\4, and N\1/2SE\4;

Sec. 28, SW\4NW\4 and SE\4SE\4;

Sec. 34, NW\4NW\4 and SE\4NW\4.

T. 6 N., R. 11 E., Sec. 11, lots 4 and 9, W\1/2SE\4SW\4, and E\1/2SE\4SE\4;

Sec. 32, SW\4SW\4;

T. 4 N., R. 12 E., Sec. 2, S\1/2 and S\1/2N\1/2;

Sec. 3;

Sec. 4, W\1/2SW\4;

Sec. 5, lot 1, and SE\4NE\4;

Sec. 9, N\1/2NE\4;

Sec. 10, N\1/2NW\4;

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[AZA 30355]

Public Land Order No. 7420;
Withdrawal of National Forest System Lands for Roosevelt Lake Expansion Area; Arizona

AGENCY: Bureau of Land Management, Interior.

ACTION: Public Land Order.
Public Land Order No. 7418; Partial Revocation of Public Land Order No.1479; Idaho

AGENCY: Bureau of Land Management, Interior.

ACTION: Public land order.

SUMMARY: This order revokes a public land order insofar as it affects 1.90 acres of National Forest System land withdrawn for the Forest Service’s Priest Lake Recreation Area. The land is no longer needed for this purpose, and the revocation is needed to make the land available for a land exchange. This action will open the land to such forms of disposition as may be made of National Forest System land. The land is temporarily closed to surface entry and mining due to the pending Forest Service exchange proposal. The land has been and will remain open to mineral leasing.

EFFECTIVE DATE: December 3, 1999.


By virtue of the authority vested in the Secretary of the Interior by Section 204 of the Federal Land Policy and Management Act of 1976, 43 U.S.C. 1714 (1994), it is ordered as follows:

1. Public Land Order No. 1479, which withdrew National Forest System land for recreation areas, and administrative and public service sites, is hereby revoked insofar as it affects the following described land:

Boise Meridian
Kaniksu National Forest
Priest Lake Recreation Area
T. 61 N., R. 4 W., Sec. 20, lot 1.

The area described contains 1.90 acres in Shoshone County.

2. At 9 a.m. on December 3, 1999, the land shall be opened to such forms of disposition as may by law be made of National Forest System land, subject to valid existing rights, the provisions of existing withdrawals, other segregations of record, and the requirements of applicable law.

Dated: November 17, 1999.

John Berry,
Assistant Secretary of the Interior.

Notice of Realty Re-designation of Public Domain (PD) land to O&C Status, Clackamas County, Oregon (OR–55235)

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice.

SUMMARY: The following public domain land in Clackamas County, Oregon has been examined and found suitable for re-designation and conversion to O&C status for management under the provisions of the O&C Act of August 28, 1937, 50 Stat. 874:

T. 7 S., R. 3 E., Willamette Meridian
Section 2, all,
Section 10, all,
Section 22, all,
Section 26, SW½NW¼,
Section 28, NW¼.

The abovementioned lands total 2.091.86 acres, more or less.

Title IV, Sec. 401(g) of the Oregon Resource Conservation Act of 1996, contained in Division B of the Omnibus Consolidated Appropriations Act of 1997, Public Law 104–208, mandated BLM to exchange certain land and manage the acquired land and other BLM lands within view of the Mt. Hood Loop Highway (U.S. Highway 26) primarily for the protection and enhancement of scenic qualities, “The Longview Fibre Exchange” (OR–55235). The legislation also required re-designation of sufficient public domain to O&C status so as to maintain the current flow of revenue to the O&C counties. Other than the proposed change in status, re-designated lands will continue to be managed in accordance with the Salem District Resource Management Plan completed in May, 1995.

Detailed information regarding this action is available for review at the office of the Salem District, Bureau of Land Management, 1717 Fabry Road S.E., Salem, Oregon 97306.

For a period of 45 days from the publication of this notice in the Federal Register, interested parties may submit comments regarding the proposed re-designation of the land to the Manager, Cascades Resource Area, 1717 Fabry Road S.E., Salem, Oregon 97306.

Comments received on the re-designation will become effective 60 days after the date of publication of this notice in the Federal Register.

Dated: November 22, 1999.

Richard C. Prather,
Manager, Cascades Resource Area.

[FR Doc. 99–31328 Filed 12–2–99; 8:45 am]

BILLING CODE 4310–33–P

DEPARTMENT OF THE INTERIOR

Minerals Management Service

Agency Information Collection Activities: Submitted for Office of Management and Budget Review, Comment Request

AGENCY: Minerals Management Service (MMS), Interior.

ACTION: Notice of information collection.

SUMMARY: Under the Paperwork Reduction Act of 1995, we are soliciting comments on an information collection titled Delegation of Authority to States, OMB Control Number 1010–0088, which expires on June 30, 2000.

DATES: Written comments should be received on or before February 1, 2000.

ADDRESSES: The mailing address for written comments regarding this information collection is David S. Guzy, Chief, Rules and Publications Staff, Minerals Management Service, Royalty Management Program, P.O. Box 25165, MS 3021, Denver, Colorado 80225. Courier address is Building 85, Room A–613, Denver Federal Center, Denver, Colorado 80225. Email address is RMP.comments@mms.gov.

PUBLIC COMMENT PROCEDURE: If you wish to comment, you may submit your comments by any one of several methods. You may mail comments to David S. Guzy, Chief, Rules and Publications Staff, Minerals Management Service, Royalty Management Program, P.O. Box 25165, MS 3021, Denver, CO 80225–0165. Courier or overnight delivery address is Building 85, Room A–613, Denver Federal Center, Denver, Colorado 80225. You may also comment via the Internet to RMP.comments@mms.gov.
submit Internet comments as an ASCII file avoiding the use of special characters and any form of encryption. Please also include Attn: Delegation of Authority to States, OMB Control Number 1010–0088, and your name and return address in your Internet message. If you do not receive a confirmation from the system that we have received your Internet message, contact David S. Guzy directly at (303) 231–3432.

We will post public comments after the comment period closes on the Internet at http://www.rmp.mms.gov. You may arrange to view paper copies of the comments by contacting David S. Guzy, Chief, Rules and Publications Staff, telephone (303) 231–3432, FAX (303) 231–3385. Our practice is to make comments, including names and addresses of respondents, available for public review on the Internet and during regular business hours at our offices in Lakewood, Colorado. Individual respondents may request that we withhold their home address from the rulemaking record, which we will honor to the extent allowable by law. There also may be circumstances in which we would withhold from the rulemaking record a respondent’s identity, as allowable by law. If you wish us to withhold your name and/or address, you must state this prominently at the beginning of your comment. However, we will not consider anonymous comments. We will make all submissions from organizations or businesses, and from individuals identifying themselves as representatives or officials of organizations or businesses, available for public inspection in their entirety.

FOR FURTHER INFORMATION CONTACT:
Dennis C. Jones, Rules and Publications Staff, phone (303) 231–3046, FAX (303) 231–3385, email Dennis.C.Jones@mms.gov.

SUPPLEMENTARY INFORMATION: Section 3506(c)(2)(A) of the Paperwork Reduction Act requires each agency “to provide notice * * * and otherwise consult with members of the public and affected agencies concerning each proposed collection of information * * *. Agencies must specifically solicit comments to: (a) Evaluate whether the proposed collection of information is necessary for the agency to perform its duties, including whether the information is useful; (b) Evaluate the accuracy of the agency’s estimate of the burden of the proposed collection of information; (c) Enhance the quality, usefulness, and clarity of the information; and (d) Minimize the burden on the respondents, including the use of automated collection techniques or other forms of information technology.

The Department of the Interior (DOI) is the department within the Federal Government responsible for matters relevant to mineral resource development on Federal and Indian Lands and the Other Continental Shelf (OCS). The Secretary of the Interior (Secretary) is responsible for managing the production of minerals from Federal and Indian Lands and the OCS; for collecting royalties from lessees who produce minerals; and for distributing the funds collected in accordance with applicable laws. MMS performs the royalty management functions for the Secretary.

We amended our regulations to authorize the delegation of certain Federal royalty management functions to states. On August 13, 1996, Congress enacted the Federal Oil and Gas Royalty Simplification and Fairness Act of 1996, Pub. L. 104–185, as corrected by Pub. L. 104–200 (RSFA). RSFA amended portions of the Federal Oil and Gas Royalty Management Act of 1982 (FOGRMA), 30 U.S.C. 1701 et seq. Prior to enactment, section 205 of FOGRMA, 30 U.S.C. 1735, provided for the delegation of only audits, inspections, and investigations to the States. RSFA amendments to section 205 now provide that MMS may delegate other Federal royalty management functions to requesting States:

(1) Conducting audits, and investigations;
(2) Receiving and processing production and royalty reports;
(3) Correcting erroneous report data;
(4) Performing automated verification; and
(5) Issuing demands, subpoenas (except for solid mineral and geothermal leases), orders to perform restructuring accounting, and related tolling agreements and notices to lessors or their designees.

We estimate that the annual burden to states participating in these delegated functions is 10,400 hours. We estimate that the annual burden for industry will be 200,000 hours for payors and reporters providing royalty and production reports to MMS.

Dated: November 24, 1999.
Lucy Querques Denett,
Associate Director for Royalty Management.
[FR Doc. 99–31336 Filed 12–2–99; 8:45 am]
BILLING CODE 4310–MR–M

DEPARTMENT OF THE INTERIOR
Minerals Management Service

Agency Information Collection Activities: Submitted for Office of Management and Budget Review, Comment Request

AGENCY: Minerals Management Service (MMS), Interior.

ACTION: Notice of information collection.

SUMMARY: Under the Paperwork Reduction Act of 1995, we are soliciting comments on an information collection titled Cooperative Agreements, OMB Control Number 1010–0087, which expires on July 31, 2000.

DATES: Written comments should be received on or before February 1, 2000.

ADDRESSES: The mailing address for written comments regarding this information collection is David S. Guzy, Chief, Rules and Publications Staff, Minerals Management Service, Royalty Management Program, P.O. Box 25165, MS 3021, Denver, Colorado 80225. Courier address is Building 85, Room A–613, Denver Federal Center, Denver, Colorado 80225. Email address is RMP.comments@mms.gov.

PUBLIC COMMENT PROCEDURE: If you wish to comment, you may submit your comments by any one of several methods. You may mail comments to David S. Guzy, Chief, Rules and Publications Staff, Minerals Management Service, Royalty Management Program, P.O. Box 25165, MS 3021, Denver, CO 80225–0165. Courier or overnight delivery address is Building 85, Room A–613, Denver Federal Center, Denver, Colorado 80225. You may also comment via the Internet to RMP.comments@mms.gov. Please submit Internet comments as an ASCII file avoiding the use of special characters and any form of encryption. Please also include Attn: Cooperative Agreements, OMB 1010–0087, and your name and return address in your Internet message. If you do not receive a confirmation from the system that we have received your Internet message, contact David S. Guzy directly at (303) 231–3432.

We will post public comments after the comment period closes on the Internet at http://www.rmp.mms.gov. You may arrange to view paper copies of the comments by contacting David S. Guzy, Chief, Rules and Publications Staff, telephone (303) 231–3432, FAX (303) 231–3385. Our practice is to make comments, including names and addresses of respondents, available for public review on the Internet and during regular business hours at our
DEPARTMENT OF THE INTERIOR

Notice of Inventory Completion for Native American Human Remains in the Possession of the Carnegie Museum of Natural History, Pittsburgh, PA

AGENCY: National Park Service, Interior.

ACTION: Notice.

Notice is hereby given in accordance with provisions of the Native American Graves Protection and Repatriation Act (NAGPRA), 43 CFR 10.9, of the completion of an inventory of human remains in the possession of the Carnegie Museum of Natural History, Pittsburgh, PA.

A detailed assessment of the human remains was made by Carnegie Museum of Natural History professional staff in consultation with representatives of the Pawnee Indian Tribe of Oklahoma.

In 1899, human remains representing one individual were sold by Thomas Howell Richards of Bunker Hill, IL to the Carnegie Museum of Natural History. No known individual was identified.

No associated funerary objects are present.

During the 1890s, Mr. Richards visited several reservations "in Dakota," and purchased a large collection of primarily Sioux materials during that time, of which these human remains are a part. Mr. Richard's information identifies these human remains (a scalp lock) as "Scalp lock taken by Running Bull (Sioux) from Pawnee Indian (sic) in the last battle between those nations."

Consultation with representatives of the Pawnee Indian Tribe of Oklahoma indicates this battle was probably at Massacre Canyon near Trenton, NE. No evidence exists to contradict this information.

Based on the above mentioned information, officials of the Carnegie Museum of Natural History have determined that, pursuant to 43 CFR 10.2(d)(1), the human remains listed above represent the physical remains of one individual of Native American ancestry. Officials of the Carnegie Museum of Natural History have also determined that, pursuant to 43 CFR 10.2(e), there is a relationship of shared group identity which can be reasonably traced between these Native American human remains and the Pawnee Indian Tribe of Oklahoma.

This notice has been sent to officials of the Pawnee Indian Tribe of Oklahoma, the Cheyenne River Sioux Tribe of the Cheyenne River Reservation, the Crow Creek Sioux Tribe of the Crow Creek Reservation, the Lower Brule Sioux Tribe of the Lower Brule Reservation, the Oglala Sioux Tribe of the Pine Ridge Reservation, the Standing Rock Sioux Tribe of North and South Dakota, and the Yankton Sioux Tribe of South Dakota. Representatives of any other Indian tribe that believes itself to be culturally affiliated with these human remains should contact Dr. James B. Richardson, Curator, Carnegie Museum of Natural History, 5800 Baum Blvd., Pittsburgh, PA 15206-3706; telephone: (412) 663-2601, before January 3, 2000. Repatriation of the human remains to the Pawnee Indian Tribe of Oklahoma may begin after that date if no additional claimsant come forward.

Dated: November 24, 1999.

Francis P. McManamon,
Departmental Consulting Archeologist, Manager, Archeology and Ethnography Program.

DEPARTMENT OF THE INTERIOR

National Park Service

Notice of Intent to Repatriate Cultural Items from Warren, RI in the Possession of the Museum of the City of New York, New York, NY

AGENCY: National Park Service, Interior.

ACTION: Notice.

Notice of intent to repatriate cultural items from Warren, RI in the possession of the Museum of the City of New York, New York, NY.

DEPARTMENT OF THE INTERIOR

National Park Service

Notice of Intent to Repatriate Cultural Items from Warren, RI in the Possession of the Museum of the City of New York, New York, NY

AGENCY: National Park Service, Interior.

ACTION: Notice.

Notice of Intent to Repatriate Cultural Items from Warren, RI in the possession of the Museum of the City of New York, New York, NY.

DEPARTMENT OF THE INTERIOR

Notice of Intent to Repatriate Cultural Items from Warren, RI in the Possession of the Museum of the City of New York, New York, NY

AGENCY: National Park Service, Interior.

ACTION: Notice.

Notice of Intent to Repatriate Cultural Items from Warren, RI in the possession of the Museum of the City of New York, New York, NY.
Notice is hereby given under the Native American Graves Protection and Repatriation Act, 43 CFR 10.10 (a)(3), of the intent to repatriate cultural items in the possession of the Museum of the City of New York, New York, NY which meet the definition of "unassociated funerary object" under Section 2 of the Act.

The 19 cultural items consist of two flushloop-varity, medium sized bells with broken attachment loops, a narrow hoe with a distinctive handle, a brass kettle (bottom missing) with rolled rim and riveted ears, three chain links (linked), a finger ring, five cylindrical blue glass trade beads, and five glass star trade beads.

In 1965, these cultural items were acquired by the Museum of the City of New York from the Heye Museum of the American Indian. These items were acquired earlier by the Heye Museum of the American Indian as part of the Carr collection from the Burr's Hill burial site in Warren, RI. Burr's Hill is believed to be located on the southern border of Sowams, a Wampanoag village. Sowams is identified in historical documents of the 16th and 17th centuries as a Wampanoag village, and was ceded to the English in 1653 by Massasoit and his eldest son Wamsutta (Alexander). Based on the condition and type, these cultural items have been dated to the contact period (1500-1690 A.D.).

Consultation evidence provided by representatives of the Wampanoag Repatriation Confederation representing the Gay Head Wampanoag Tribe of Massachusetts and the non-Federally recognized Indian groups the Mashpee Wampanoag Tribe, the Assonet Band of the Wampanoag, and the Narragansett Indian Tribe of Rhode Island, and representatives of any other Indian tribe that believes itself to be culturally affiliated with these objects, should contact Wendy Rogers, Museum of the City of New York, 1220 Fifth Avenue, New York, NY 10029; telephone: (212) 534-1672, ext. 221 before January 3, 2000. Repatriation of these objects to the Wampanoag Repatriation Confederation on behalf of the Gay Head Wampanoag Tribe of Massachusetts and the non-Federally recognized Indian groups the Mashpee Wampanoag Tribe, the Assonet Band of the Wampanoag, and the Narragansett Indian Tribe of Rhode Island may begin after that date if no additional claimants come forward.

Dated: November 24, 1999.
Francis P. McManamon,
Departmental Consulting Archeologist,
Manager, Archeology and Ethnography Program.

BILLING CODE 4310-70-F

DEPARTMENT OF THE INTERIOR
National Park Service

Notice of Inventory Completion for Native American Human Remains in the Possession of the University of Pennsylvania Museum of Archaeology and Anthropology, Philadelphia, PA

AGENCY: National Park Service, Interior.

ACTION: Notice.

Notice is hereby given in accordance with provisions of the Native American Graves Protection and Repatriation Act (NAGPRA), 43 CFR 10.9, of the completion of an inventory of human remains in the possession of the University of Pennsylvania Museum of Archaeology and Anthropology, Philadelphia, PA.

A detailed assessment of the human remains was made by University of Pennsylvania Museum of Archaeology and Anthropology professional staff in consultation with representatives of the Sac and Fox Nation, Oklahoma; the Sac and Fox Tribe of the Mississippi in Iowa; the Sac and Fox Nation of Missouri in Kansas and Nebraska; the Winnebago Tribe of Nebraska; the Kickapoo Tribe of Indians of the Kickapoo Reservation in Kansas, and the Citizen Potawatomi Nation, Oklahoma. The Forest County Potawatami Community of Wisconsin Potawatomi Indians, Wisconsin; Huron Potawatomi, Inc., Michigan; the Pokagan Band of Potawatomi Indians of Michigan; the Prairie Band of Potawatomi Indians, Kansas; the Hannakville Indian Community of Wisconsin Potawatomi Indians of Michigan; the Kickapoo Traditional Tribe of Texas; and the Kickapoo Tribe of Oklahoma were invited to consult, but did not participate.

At an unknown date, human remains representing one individual were removed from an unknown location by person(s) unknown. Prior to 1915, these human remains were received by the University of Pennsylvania Museum, transferred to the Wistar Institute, Philadelphia, PA in 1915, and transferred back to the University of Pennsylvania Museum in 1961. No known individual was identified. No associated funerary objects are present.

Accession information from the Wistar Institute identifies this individual as "Native American shot in the Black Hawk War, 1905." No further documentation is present to identify the recovery location, the collector, or the cultural affiliation of this individual. While many Sac and Fox people were killed during the Black Hawk War, groups of Potawatomi, Winnebago, and Kickapoo allied themselves with the Sac and Fox during this four-month conflict. No evidence exists to the contrary of the Wistar Institute’s accession information.

Based on the above mentioned information, officials of the University of Pennsylvania Museum have determined that, pursuant to 43 CFR 10.2 (d)(t), the human remains listed above represent the physical remains of one individual of Native American ancestry. Officials of the University of Pennsylvania Museum have determined that, pursuant to 43 CFR 10.2 (e), there is a relationship of shared group identity which can be reasonably traced between these Native American human remains and the Sac and Fox Nation, Oklahoma; the Sac and Fox Tribe of the Mississippi in Iowa; the Sac and Fox Nation in Kansas and Nebraska; the Winnebago Tribe of Nebraska; the Kickapoo Tribe of Indians of the Kickapoo Reservation in Kansas, the Citizen Potawatomi Nation, Oklahoma; the Forest County Potawatami Community of Wisconsin Potawatomi Indians, Wisconsin; Huron Potawatomi, Inc., Michigan; the Pokagan Band of Potawatomi Indians of Michigan; the
Prairie Band of Potawatomi Indians, Kansas; the Hannahville Indian Community of Wisconsin Potawatomi Indians of Michigan; the Kickapoo Traditional Tribe of Texas; and the Kickapoo Tribe of Oklahoma.

This notice has been sent to officials of the Sac and Fox Nation, Oklahoma; the Sac and Fox Tribe of the Mississippi in Iowa; the Sac and Fox Nation of Missouri in Kansas and Nebraska; the Winnebago Tribe of Nebraska; the Kickapoo Tribe of Indians of the Kickapoo Reservation in Kansas, the Citizen Potawatomi Nation, Oklahoma; the Forest County Potawatomi Community of Wisconsin Potawatomi Indians, Wisconsin; Huron Potawatomi, Inc., Michigan; the Pokagan Band of Potawatomi Indians of Michigan; the Prairie Band of Potawatomi Indians, Kansas; the Hannahville Indian Community of Wisconsin Potawatomi Indians of Michigan; the Kickapoo Traditional Tribe of Texas; the Kickapoo Tribe of Oklahoma, and the Ho-Chunk Nation of Wisconsin. Representatives of any other Indian tribe that believes itself to be culturally affiliated with these human remains should contact Dr. Jeremy Sabloff, the Williams Director, University of Pennsylvania Museum of Archaeology and Anthropology, 33rd and Spruce Streets, Philadelphia, PA 19104-6324; telephone: (215) 898-4051, fax (215) 898-0657, before January 3, 2000. Repatriation of the human remains to the Sac and Fox Nation, Oklahoma; the Sac and Fox Tribe of the Mississippi in Iowa; the Sac and Fox Nation of Kansas and Nebraska; the Winnebago Tribe of Nebraska; the Kickapoo Tribe of Indians of the Kickapoo Reservation in Kansas, the Citizen Potawatomi Nation, Oklahoma; the Forest County Potawatomi Community of Wisconsin Potawatomi Indians, Wisconsin; Huron Potawatomi, Inc., Michigan; the Pokagan Band of Potawatomi Indians of Michigan; the Prairie Band of Potawatomi Indians, Kansas; the Hannahville Indian Community of Wisconsin Potawatomi Indians of Michigan; the Kickapoo Traditional Tribe of Texas; and the Kickapoo Tribe of Oklahoma may begin after that date if no additional claimants come forward.

Dated: November 24, 1999.

Francis P. McManamon,
Departmental Consulting Archaeologist, Manager, Archeology and Ethnography Program.

BILLING CODE 4310-70-F

OVERSEAS PRIVATE INVESTMENT CORPORATION

Sunshine Act Meeting

TIME AND DATE: Tuesday, December 14, 1999, 1:00 pm (OPEN Portion) 1:30 pm (CLOSED Portion)

PLACE: Offices of the Corporation, Twelfth Floor Board Room, 1100 New York Avenue, N.W., Washington, D.C.

STATUS: Meeting OPEN to the Public from 1:00 pm to 1:30 pm; Closed portion will commence at 1:30 pm (approx.)

MATTERS TO BE CONSIDERED:

1. President’s Report
2. Testimonial
3. Approval of September 21, 1999 Minutes (Open Portion)

FURTHER MATTERS TO BE CONSIDERED:

1. Approval of September 21, 1999 Minutes (Closed Portion)
2. Update on Indonesia
4. Approval of September 21, 1999 Minutes (Open Portion)
5. Pending Major Projects
6. Finance Project in Turkey
7. Finance Project in Turkey
8. Finance Project in Jamaica
9. Update on Indonesia

CONTACT PERSON FOR INFORMATION:

Connie M. Downs, OPIC Corporate Secretary.

EFFECTIVE DATE: November 22, 1999.

FOR FURTHER INFORMATION CONTACT:

SUPPLEMENTARY INFORMATION:

Background

These investigations are being instituted in response to a petition filed on November 22, 1999, by BASF Corporation, Mount Olive, NJ; Huntsman Expandable Polymers Company LC, Salt Lake City, UT; Nova Chemicals, Inc., Moon Township, PA; and StyroChem U.S., Ltd., Radnor, PA.

Participation in the Investigations and Public Service List

Persons (other than petitioners) wishing to participate in the investigations as participants must file an entry of appearance with the Secretary to the Commission, as provided in sections 201.11 and 207.10 of the
Commission’s rules, not later than seven days after publication of this notice in the Federal Register. Industrial users and (if the merchandise under investigation is sold at the retail level) representative consumer organizations have the right to appear as parties in Commission antidumping investigations. The Secretary will prepare a public service list containing the names and addresses of all persons, or their representatives, who are parties to these investigations upon the expiration of the period for filing entries of appearance.

**Limited Disclosure of Business Proprietary Information (BPI) Under an Administrative Protective Order (APO) and BPI Service List**

Pursuant to section 207.7(a) of the Commission’s rules, the Secretary will make BPI gathered in these investigations available to authorized applicants representing interested parties (as defined in 19 U.S.C. 1677(9)) who are parties to the investigations under the APO issued in the investigation, provided that the application is made not later than seven days after the publication of this notice in the Federal Register. A separate service list will be maintained by the Secretary for those parties authorized to receive BPI under the APO.

**Conference**

The Commission’s Director of Operations has scheduled a conference in connection with these investigations for 9:30 a.m. on December 13, 1999, at the U.S. International Trade Commission Building, 500 E Street S.W., Washington, DC. Parties wishing to participate in the conference should contact Jonathan Seiger (202–205–3183) not later than December 9, 1999, to arrange for their appearance. Parties in support of the imposition of antidumping duties in these investigations and parties in opposition to the imposition of such duties will each be collectively allocated one hour within which to make an oral presentation at the conference. A nonparty who has testimony that may aid the Commission’s deliberations may request permission to present a short statement at the conference.

**Written Submissions**

As provided in sections 201.8 and 207.15 of the Commission’s rules, any person may submit to the Commission on or before December 16, 1999, a written brief containing information and arguments pertinent to the subject matter of the investigations. Parties may file written testimony in connection with their presentation at the conference no later than three days before the conference. If briefs or written testimony contain BPI, they must conform with the requirements of sections 201.6, 207.3, and 207.7 of the Commission’s rules. The Commission’s rules do not authorize filing of submissions with the Secretary by facsimile or electronic means. In accordance with sections 201.16(c) and 207.3 of the rules, each document filed by a party to the investigations must be served on all other parties to the investigations (as identified by either the public or BPI service list), and a certificate of service must be timely filed. The Secretary will not accept a document for filing without a certificate of service.

**Authority:** These investigations are being conducted under authority of title VII of the Tariff Act of 1930; this notice is published pursuant to section 207.12 of the Commission’s rules.


By order of the Commission.

Donna R. Koehnke, Secretary.

**Written Submissions**

As provided in sections 201.8 and 207.15 of the Commission’s rules, any person may submit to the Commission on or before December 16, 1999, a written brief containing information and arguments pertinent to the subject matter of the investigations. Parties may file written testimony in connection with their presentation at the conference no later than three days before the conference. If briefs or written testimony contain BPI, they must conform with the requirements of sections 201.6, 207.3, and 207.7 of the Commission’s rules. The Commission’s rules do not authorize filing of submissions with the Secretary by facsimile or electronic means. In accordance with sections 201.16(c) and 207.3 of the rules, each document filed by a party to the investigations must be served on all other parties to the investigations (as identified by either the public or BPI service list), and a certificate of service must be timely filed. The Secretary will not accept a document for filing without a certificate of service.

**Authority:** These investigations are being conducted under authority of title VII of the Tariff Act of 1930; this notice is published pursuant to section 207.12 of the Commission’s rules.


By order of the Commission.

Donna R. Koehnke, Secretary.

**INTERNATIONAL TRADE COMMISSION**

**Sunshine Act Meeting**

**AGENCY HOLDING THE MEETING:** United States International Trade Commission.

**TIME AND DATE:** December 8, 1999 at 10:00 a.m.

**PLACE:** Room 101, 500 E Street S.W., Washington, DC 20436, Telephone: (202) 205–2000.

**STATUS:** Open to the public.

**MATTERS TO BE CONSIDERED:**
1. Agenda for future meeting: none.
2. Minutes.
3. Ratification List.
4. Inv. Nos. AA1921–124 and 731–TA–546–547 (Review) (Steel Wire Rope from Japan, Korea, and Mexico)—briefing and vote. (The Commission will transmit its determination to the Secretary of Commerce on December 15, 1999.)
5. Inv. Nos. 731–TA–385–386 (Review) (Granular PTFE Resin from Italy and Japan)—briefing and vote. (The Commission will transmit its determination to the Secretary of Commerce on December 21, 1999.)
6. Inv. No. TA–201–70 (Remedy Phase) (Circular Welded Carbon Quality Line Pipe)—briefing and vote. (The Commission will transmit its recommendations to the President on December 17, 1999.)
7. Outstanding action jackets:
   (2) Document No. ID–99–021: Approval of transition report and proposal for a study focus on “Integration of Manufacturing in North America and Selected Regions.”

In accordance with Commission policy, subject matter listed above, not disposed of at the scheduled meeting, may be carried over to the agenda of the following meeting.

Issued: December 1, 1999.

By order of the Commission.

Donna R. Koehnke, Secretary.
DEPARTMENT OF JUSTICE
Drug Enforcement Administration

Notice of Hearing

This Notice of Administrative Hearing, Summary of Comments and Objections

Notice of Hearing

This Notice of Administrative Hearing, Summary of Comments and Objections, regarding the application of Johnson Matthey, Inc., for registration as an importer of raw opium and concentrate of poppy straw, Schedule II controlled substances, is published pursuant to 21 CFR 1301.34. On April 9, 1999, DEA published a notice in the Federal Register, 64 FR 17,415 (DEA 1999), stating that Johnson Matthey has applied to be registered as an importer of raw opium and concentrate of poppy straw.

Both Noramco of Delaware, Inc., and Mallinckrodt, Inc., timely requested a hearing in this matter. On September 20, 1999, all parties filed prehearing statements. Notice is hereby given that a hearing will be conducted pursuant to the provisions of 21 U.S.C. 952(a), 958; 21 CFR 1301.34.

Hearing Date

The hearing will begin at 9:30 a.m. on January 5, 2000, and will be held at the Drug Enforcement Administration Headquarters, 600 Army Navy Drive, Hearing Room, Room E–2103, Arlington, Virginia. The hearing will be closed to the public, except (a) to the parties, and (b) to those persons who have a right to participate and have requested a hearing or entered a notice of appearance pursuant to 21 CFR 1301.34.

Notice of Appearance

Any person entitled to participate in this hearing pursuant to 21 CFR 1301.34, and desiring to do so, may participate by filing a notice of intention to participate in accordance with 21 CFR 1301.43, in triplicate, with the Hearing Clerk, Office of Administrative Law Judges, Drug Enforcement Administration, Washington, DC 20537, within 30 days of publication of this notice in the Federal Register. Each notice of appearance must be in the form prescribed in 21 CFR 1316.48.

FOR FURTHER INFORMATION CONTACT:
Helen Farmer, Hearing Clerk, Drug Enforcement Administration, Washington, DC 20537; Telephone (202) 307–8188.

Summary of Comments and Objections

Mallinckrodt’s Comments

Mallinckrodt, a registered importer of raw opium and poppy straw concentrate, intends to show that Johnson Matthey lacks a sufficient commitment to comply with DEA regulations; Johnson Matthey’s registration will undermine the ability of U.S. importers to comply with the 80/20 sourcing rule; Johnson Matthey’s lack of technical expertise regarding the importation of narcotic raw materials (NRMs) and the use of NRMs during manufacturing could result in shortage of NRMs; Johnson Matthey’s processing inefficiencies could lead to increases in opium cultivation in violation of international policy; and as Johnson Matthey has no intention of using the registration, the potential registration constitutes an unnecessary administrative burden.

Noramco’s Comments

Noramco, a registered importer of NRMs, intends to show that Johnson Matthey’s capability to maintain effective controls required by an importer of NRMs is questionable given its past record in the area of controlled substances; Johnson Matthey’s registration is likely to weaken U.S. ability to contain the rapid increase in the price of NRMs; Johnson Matthey’s plans for importation may be inconsistent with DEA restrictions on sourcing or may place an unfair burden on existing suppliers; Johnson Matthey’s planned use of the NRMs will exacerbate a shortage of NRMs; and Johnson Matthey’s planned use of NRMs may adversely affect the industry’s total cost of production.
housing. Barriers to employment faced by these individuals include homelessness, addiction recovery, transportation, criminal records or reentry from prison or other justice-related or social service-related institutions.”

High-risk individuals are not always aware of services provided through the employment and training system. The work to be conducted under this solicitation seeks to further improve the array of services authorized by WIA to reach and serve individuals who may not otherwise have access to information regarding WIA services. This solicitation also seeks the provision of quality job training and related services including follow-up services tailored to the interests and aptitudes of the client population that facilitates at-risk youth and adults returning from various institutions to their communities.

Further, as WIA emphasizes the need to ensure that training services be directly linked to job opportunities in their local area or may be linked to jobs in another area to which the individual is willing to relocate, these grants will need to demonstrate that services under WIA are in fact linked to local employment opportunities. As a result, recipients of these grants will be expected to build connections to local workforce investment systems, such as linkages with Local Workforce Investment Boards (LWIBs)/Private Industry Councils (PICs), while demonstrating approaches that ensure that “high-risk” youth and adults are provided with quality workforce development services.

For the purpose of this solicitation, quality workforce investment services are defined as those services (including training) that can provide high risk individuals with improved long-term employability prospects and increased earnings. According to Winning the Skills Race (1998), a report compiled by the U.S. Council on Competitiveness, competition for low-skilled occupations has escalated as jobs today increasingly demand higher skill levels. Thus, any job training program to prepare new labor market entrants or reentrants for employment—even individuals with multiple barriers to employment—should emphasize the concept of high (or advanced) skills training. As a result, this solicitation will also seek to provide training for high risk youth and adults in new and growing occupations in information technology and related areas.

DATES: The closing date for receipt of applications is February 4, 2000.

Applications must be received by 4 p.m. eastern standard time. No exceptions to the mailing and hand-delivery conditions set forth in this notice will be granted. Applications that do not meet the conditions set forth in this notice will not be considered. Telefacsimile (FAX) applications will not be honored.

ADDRESSES: Applications must be mailed or hand-delivered to: U.S. Department of Labor, Employment and Training Administration, Division of Federal Assistance, Attention: Denise Roach, Reference: SGA/DFA–101; 200 Constitution Avenue, NW., Room S–4203; Washington, DC 20210. Your application must specify on the cover sheet (See Appendix “A”) which project areas you are applying as outlined in this solicitation. Failure to clearly identify this information on the cover sheet may be grounds for rendering your application non-responsive.

Hand Delivered Proposals: If proposals are hand delivered, they must be delivered at the designated place by 4 p.m., Eastern Time, February 4, 2000. All overnight mail will be considered to be hand delivered and must be received at the designated place by specified closing date and time. Telegraphed and/or faxed proposals will not be honored. Failure to adhere to the above instructions will be a basis for a determination of nonresponsiveness.

Late Proposals: A proposal received at the designated office after the exact time specified for receipt will not be considered unless it is received before the award is made and it:

- Was sent by registered or certified mail not later than the fifth calendar day before the date specified for receipt of applications (e.g., an offer submitted in response to a solicitation requiring receipt of applications by the 20th of the month must be mailed by the 15th);
- Was sent by U.S. Postal Service Express Mail Next Day Service, Post Office to addressee, not later than 5 p.m. at the place of mailing two working days prior to the date specified for the proposals. The term “working days” excludes weekends and U.S. Federal holidays.

The only acceptable evidence that an application was in accordance with these requirements is a printed, stamped, or otherwise place impression (exclusive of a postage meter machine impression) that is readily identifiable without further action as having been supplied or affixed on the date of the mailing by employees of the U.S. Postal Service.

Withdrawal of Proposals: A grant application may be withdrawn by written notice or telegram (including mailgram) received at any time before the awarding of a grant. An application may be withdrawn in person by the grant applicant, or by an authorized representative of the grant applicant if the representative’s identity is made known and the representative signs a receipt for the proposal.

FOR FURTHER INFORMATION CONTACT: Questions should be faxed to Denise Roach, Grants Management Specialist, Division of Federal Assistance at (202) 219–8739 (this is not a toll-free number). All inquiries should include the SGA/DFA–101 and a contact name, fax and phone number. This solicitation will also be published on the Internet, on the Employment and Training Administration (ETA) Home Page at http://www.doleta.gov. Award notifications will also be published on the ETA Home Page.

SUPPLEMENTARY INFORMATION: Funding for these awards is authorized under the Job Training Partnership Act (JTPA), Title IV, Pilots and Demonstrations Programs. This is the last year of funding under JTPA prior to the transition to the new programs authorized by the Workforce Investment Act (WIA) of 1998. For this reason, grants will be awarded on a one time only basis, for a period of 24 months. No option years are included as part of this solicitation. Grantees will be expected to leverage grant funds with other resources available through supplemental public or private in-kind or cash commitments. In addition to a roughly one-for-one leveraging requirement during the grant period, grantees will be expected to strive to sustain the projects beyond the Federal funding phase of the grant. The projects are intended to help expand the reach of the new workforce investment system, particularly in their local communities, and therefore, every effort should be made by grantees to coordinate and link project activities with local WIIBs established under WIA.

This announcement consists of three sections: **

(A) Capacity building grants to develop models for use by States and local boards on how to increase the capacity to serve “high-risk” individuals in their state or local areas.

(B) Direct service grants to demonstrate how local, state, or national organizations can provide services specifically targeting the high-risk youth population to ensure that the workforce development system provides services to this population in their state or local area.
(C.) Direct service grants to demonstrate how local, state, or national organizations can provide services specifically targeting the high-risk adult population to ensure that the workforce development system provides services to this population in their state or local area.

**Note:** Applicants are only allowed to compete for one of the three sections of this solicitation. Thus, an applicant can only submit a proposal for either section A, section B, or section C. Applicants who submit proposals for more than one section under this solicitation will not be eligible to receive funding under this SGA.

**Proposal Submission**

Applicants must submit four (4) copies of their proposal, with original signatures. The proposal must consist of two (2) distinct parts, Part I and Part II. Part I of the proposal shall contain the Standard Form SF 424, “Application for Federal Assistance” (appendix B) and a “Budget Information Sheet” (appendix C). All copies of the SF 424 MUST have original signatures of the legal entity applying for grant funding. Applicants shall indicate on the (SF) 424 the organization’s IRS status, if applicable. According to the Lobbying Disclosure Act of 1995, section 18, an organization described in section 501 (c) (4) of the Internal Revenue Code of 1986 which engages in lobbying activities shall not be eligible for the receipt of federal funds constituting an award, grant, or loan.

The applicant’s financial proposal shall contain Standard Form 424, “Application for Federal Assistance” (Appendix B) and the “Budget Information Sheet (Appendix C) for the 24 month initial grant period. Both of these forms are attached. The budget shall include on a separate page a detailed breakout of each proposed budget line item, including the cost or estimated cost for the outside evaluator selected. For each budget line item that includes funds or in-kind contributions from a source other than grant funds, identify the source, the amount, and any restrictions that may apply to these funds. The Federal Domestic Assistance Catalogue Number is 17.249.

Part II must contain a technical proposal that demonstrates the applicant’s capabilities in accordance with the Statement of Work contained in this document. A grant application is limited to twenty-five (25) double-spaced, single side, 8.5-inch x 11-inch pages with 1-inch margins. Text type will be 12 points or larger. Applications that do not meet the requirements will not be considered. Each application must include a Timeline outlining project activities and an Executive Summary not to exceed two pages. The Timeline and the Executive Summary do not count against the 25-page limit. The 25-page limitation does include attachments. No cost data or reference to price should be included in the technical proposal.

All applicants must include a certification prepared within the last six months, attesting to the adequacy of the entity’s fiscal management and accounting systems to account for and safeguard Federal funds properly. The Certification must be signed by a Certified Public Accountant.

**Funding/Period of Performance**

Approximately $9 million will be available for funding demonstration projects under this solicitation. This SGA consists of three distinct sections: (A.) Grants for capacity building to develop models for serving “high risk” adults and youth. (B.) grants for the provision of direct services to “high-risk” youth and (C.) grants to provide direct services to “high-risk” adults. We anticipate funding up to three (3) capacity building grants, not to exceed $500,000 per grant and up to nine (9) direct services grants, not to exceed $1 million per grant and within the limit of the available $9 million. Within the direct services component of this SGA, we anticipate awarding up to five (5) grants for projects serving youth and up to four (4) grants for projects serving adults. The period of performance for these grants will be for 24 months from the date the grant is awarded. Because the Department views these grants as initial start-up funding, it is anticipated that these awards will be one-time grants with no provision of an option year.

**Reporting and Evaluation**

During the demonstration project, an outside evaluator selected by the grantee and approved by DOL will be required to conduct an analysis of the implementation of the project and to assess the processes utilized at each site. For direct service grants only, the outside evaluator will also be required to evaluate each site using the following criteria: participant outcome levels in terms of their entry in employment, job retention rate, earnings, and level of educational and/or skill attainment from the time the participant entered the project until the completion of the demonstration. For both capacity building and direct services grants, each outside evaluator will also be responsible for the preparation of a report which includes lessons learned and best practices based upon the operational experiences of the particular project. Grantees will be required to submit quarterly and final status reports and ensure that a final report is reviewed by DOL not later than 30 days prior to the termination date of the grant.

**Statement of Work for High-Risk Youth and Adults**

**Background**

The Conference Agreement for Fiscal Year 1999 appropriation for Title IV of JTPA set aside $9 million for a competition to “provide training and related services aimed at high-risk youth and adults.” This set-aside is also intended to provide support for a wide-range of organizations, working in collaboration with the WIA system, to plan and implement services that address the needs of “high-risk” populations.

Nationally, the overall unemployment rate is at its lowest level in almost 30 years, but in the midst of this broad prosperity, there continue to be communities that suffer high levels of unemployment, poverty, and related economic and social problems. “High risk” adults and youth living in inner-city and rural areas of high poverty, crime, drug abuse, and school dropout rates including communities that are isolated (e.g., Appalachia, American Indian reservations and migrant and farm laborers) face considerable barriers to succeeding in life.

High-risk individuals may be described as those who have multiple environmental, social and/or educational barriers to becoming employed. This population includes individuals who are homeless, recovering addicts, those who generally reside in communities of high poverty and unemployment, or who are involved in gangs or the criminal justice system. In the Conference Agreement for the Fiscal Year 1999 Appropriation for Title IV of JTPA, “high-risk” individuals are those described as: “including displaced homemakers and older workers, and those adults or youth who are under the supervision of the criminal justice or penal systems, or who are living in foster care, homeless facilities, and public or assisted housing. Barriers to employment faced by these individuals include homelessness, addiction recovery, transportation, criminal records or reentry from prison or other justice-related or social service-related institutions.” When individuals with multiple barriers to employment and/or returning to school sought assistance through the
local employment and training system under the “old” employment and training, they easily became discouraged when faced with the often time consuming but necessary administrative tasks that needed to be accomplished before any services could be provided, if the services were even available. The local employment and training programs under this system often did not work for these individuals. As a result, many unemployed and/or disadvantaged individuals have become clearly at-risk of becoming (or have become) permanently lost to the legitimate economy. However, the “new” workforce development system established under WIA will include a greater focus on meeting the specific needs of individual customers with strong accountability requirements to gauge how well it is reaching the needs of the community at the local level.

The purpose of this demonstration project is twofold. First, the capacity building grants under this procurement are to develop and establish “models” for use by States and local boards on how to increase in their local area the capacity to provide relevant services to serve “high risk” youth and adults through their workforce development systems. Second, direct service grants under this procurement are to demonstrate how local, state, or national organizations can provide services to the “high-risk” individuals to ensure that they receive quality workforce development services including skills training in the growing technology fields and other supports necessary through the workforce development system.

Eligible Applicants

For Capacity Building Grants

Capacity building grants under this solicitation will be limited to State or local public agencies, and public and private non-profit organizations demonstrating an ability to develop models or interventions that can provide technical assistance to other public entities to increase their capacity to serve high risk individuals under WIA. In situations where individuals or organizations may be unincorporated, prospective bidders should gain the endorsement of the local WIB, local PIC, or the chief elected official (LEO) regarding project coordination and management/oversight of Federal grant funds.

To show the ability to work with “high-risk” youth, an eligible applicant for a direct service grant must outline previous experience working with high-risk youth which may include providing residential treatment programs for youth involved in the criminal justice system, creating job opportunities for youth or are out of school and at-risk, etc.

To show the ability to work with “high-risk” adults, an eligible applicant for this section must outline previous experience working with high-risk adults which may include providing workforce development services that are directly linked to job opportunities in their local area, including apprenticeships, on-the-job training (OJT), and other work-based interventions, preparing displayed homeworkers or seniors for jobs in information technology, etc.

Project Summary

Section A: Capacity Building Grants

I. Purpose of Capacity Building Grants

ETA anticipates awarding approximately three (3) capacity building grants under this SGA. The total estimated cost of each grant should not exceed $500,000.

These grants are to develop models for use by States and local boards that will provide interventions to increase assistance to high risk individuals who face multiple barriers to employment in their local areas. The primary purpose in awarding these grants is to build service capacity into the workforce investment system that will expand the range and quality of services available to prepare more “high risk” youth and adults for “high-quality” employment; i.e., employment where there are career development ladders that enable a worker to obtain livable wages.

Entities applying under this component of the solicitation must demonstrate a strong focus on developing models for use by States and local boards on how to increase the capacity to serve “high-risk” youth and adults within the WIA system.

II. Rating Criteria for Awards/Selection Process for Capacity-Building Grants

A careful review of applications will be made by a technical panel who will evaluate the applications against the criteria listed below. The panel results are advisory in nature and not binding on the Grant Officer. The Government may elect to award the grant with or without discussions with the offeror. In situations without discussions, an award will be based on the offeror’s signature on the (SF) 424, which constitutes a binding offer. The Government also reserves the right to make awards under this section of the solicitation in a manner that ensures geographical balance. The Grant Officer will make final award decisions based upon what is in the best interest of the Government.

1. What Are the Needs in the Geographic Area To Be Assisted? (15 Pts.)

The applicant should provide a general description of the unit of government which the project will assist. Most important, the applicant should provide the estimated size of the “high-risk” population based on available data taken from the 1990 Census, school records, penal or criminal justice system records, social services records of homeless, assisted housing, or foster care. The applicant should also describe the local labor market and the types of jobs that are in demand, the types of training available that address the demand in the area and other services available to the unit to be assisted by their proposed project.

2. How Will the Proposed Capacity Building Be Used To Enhance the Capacity To Provide Workforce Investment Act Services for This Population? (45 Pts.)

The applicant should describe in detail how their assistance will enhance the capacity of the system design authorized under the Workforce Investment Act to increase the employment rate of one or more groups...
within the high-risk population as defined in the Statement of Work. The framework for the proposed capacity building model should provide for (as applicable) individual needs assessment; individual service strategies; preparation for employment; job placement; long-term follow-up services; linkages with the workforce development system, human services, education, and/or transportation services. It is highly encouraged that developed models focus on interventions that provide training in new and growing occupations in technological fields including information technology, telecommunications, and other fields in which technology skills are critical parts of the jobs emerging in the regional labor market. Training models may also include basic skills and pre-apprenticeship training (as appropriate). Individual assessment and capacity for strategies. The applicant should discuss how they plan to develop in their models various strategies to actively recruit the high-risk population rather than waiting for them to apply. If applicable, individual service strategies should allow for flexibility in meeting the needs of each individual participant. Most importantly the applicant should discuss the length of time they will test a model before deciding if it does or does not provide appropriate technical assistance and implementing; if necessary, another strategy which will then be tested for success.

Program elements. The applicant should show how it plans to enhance the capacity of the WIA system to serve high-risk youth and adults. It should include innovative strategies of services that have been or are being developed to address the barriers to employment for this population and the flexibility of services to meet the needs, interests and aptitudes of the client population and facilitate high-risk youth and adults moving from dependency to independent living in their communities.

Follow-up services. As required by WIA, the applicant should discuss in its proposal the capacity to provide for longer term follow-up services in their models. The applicant should discuss longer-term activities that can be sustained once the funding under this solicitation is no longer available, and how these activities will be sustained.

3. How Will This Project Be Managed To Ensure That Quality Strategies Are Developed and Positive Outcomes Are Achieved? (25 Pts.)

The applicant’s proposal should address here the management structure of the project, including the lead agency; core staff; how other agencies and service providers will be involved; and staff expertise. In particular, the applicant should discuss the following issues in their proposal:

Core staff. The project should have a project director who is dedicated full time to the project and who has a background in providing technical assistance to meet the needs of high-risk population, and developing strategies for addressing its needs. Core staff should also include individuals who have experience with assisting entities working with high risk youth and adults and familiarity with the local employment and training system under the Job Training Partnership Act programs and changes to the system under the WIA.

Role of local Workforce Investment Board and Youth Council. How engaged will the local Board be in this project? Will it provide both programmatic and/or fiduciary oversight of the project? Will the project director be an employee of the Board or of some other lead agency? Will the Board or some other lead agency be ultimately responsible for the success or failure of the project? Will there be a role for the new Youth Council required by the WIA?

4. Evaluation / Measuring Results (15 Pts.)

The applicant should explain what mechanisms are in place for reporting progress on a quarterly basis and for capturing and reporting on the results of project interventions. (Quarterly reports, an annual report and final report summarizing progress, are required for projects under this SGA.) The applicant should describe the specific evaluation reports and other deliverables it plans to provide ETA as documentation of progress and results in terms of improved outcomes for the entity being assisted.

As the applicant is responsible for hiring an outside independent evaluator for their project, the applicant should also discuss how they 23 plan to choose an evaluator to conduct a thorough evaluation of its demonstration project and provide (if known), the name of the organization that will conduct the project evaluation along with a description of that organization’s evaluation capabilities and their previous experience in conducting similar evaluations.

Section B: Direct Services Grants for Youth

I. Purpose of Direct Services Grants for Youth

Youth demonstration direct service projects will be expected to link with and build on resources available in the community, including human, educational, workforce development (through collaboration with local WIBs/PCIs) and transportation services. These projects should prepare high-risk youth for high quality employment utilizing core and intensive services under WIA in addition to training services, as appropriate.

As high-risk youth face special barriers to employment, they typically require support services such as counseling, as well as training education opportunities which may facilitate their reintegration into the community and improve their prospects for making contributions to society as productive citizens. Youth eligible to participate in this demonstration project range between the ages of 14 and 21.

The youth direct service demonstration project grants must utilize existing community resources in order to attain their specific goals, including the achievement of training, education, and employment objectives; the transition of youth to independent living within the community; and a reduction in recidivism.

The service strategies for “high-risk” youth projects should focus on providing assistance to promote staying in school, returning to school, training for a job in a “demand” occupation, employment or providing assistance to establish successful independent living. The youth projects should experiment with various services and systems, different levels and types of outreach, flexible but high quality support services, training and educational instruction, linkages with other service providing institutions including the WIA system, and support for employers and/or educational institutions to address the needs of the “high risk” youth population.

The following are some illustrative concepts for projects that could be awarded under this subsection. However, the Department does not guarantee funding any of the concepts outlined below, and other possible strategies and approaches for serving at-risk youth will be given full consideration.

- Concept A—Projects could assist in the assimilation and adjustment process into society of youth and young adults involved with the criminal justice or penal systems. These high-risk youth
face special barriers to employment and training and may require support services such as counseling and education opportunities which may facilitate their reintroduction and improve their prospects for making contributions to society as productive citizens. These grants could be for the development, refinement, or expansion of youth day treatment centers which can offer an alternative to residential programs and demonstrate a cost-effective way to provide supportive services to juveniles without removing them from their communities. These projects should utilize existing community resources in order to attain their specific goals, including the achievement of training, education, and employment objectives; the transition of youth to independent living within the community; and a reduction in recidivism.

- Concept B—Projects could provide services for youth who are transitioning to independent living within the community from either foster care, homeless centers, or the criminal justice and penal systems. These projects would be intended to aid the adjustment of participants returning to their communities to enable them to have the necessary supports to improve their prospects for employment and education opportunities. Job training and placement and other support services such as counseling might be a part of the services provided. These might include education, training, employment, social and health services, counseling, mentoring, training in budgeting resources and time, making decisions/choices, being responsible, paying bills on time, relationships with faith based organizations in the community, contributing to the community through volunteer work, etc.

- Concept C—Projects could address the needs of out-of-school and high-risk youth who reside in a community of high crime, poverty, and high levels of drug abuse. The community would have to be small, say less than 10,000 residents as indicated in the 1990 Census. This project might be designed to increase the academic achievements, community services activities, elimination in crime and drug activities, and increase in employment. It may also include life skills, job behavior training, and proper tutoring and counseling, including family counseling (if needed). The concept might establish partnerships and linkages with other youth service providers of the community including the local school, faith-based organizations, State, local, and other Federally-funded youth initiatives. Referrals might be made when needed to local health facilities, drug treatment centers and similar organizations. Job training could relate to the available employment in the local labor market and have full employer participation in the development of curriculum and job opportunities for participants. This concept may provide exposure to colleges, arts, crafts, culture, sports and recreation, and other supportive youth development activities. Bonds could also be made available through the Federal Bonding Program for youth with criminal records.

- Concept D—Projects could provide long-term (up to 2 years) training in technological fields. The training curriculum (module) could be supported by several high-tech industries that are seeking employees in the fields in which participants are to be trained. The training could be provided to youth and young adults who have had little or no opportunity to be involved in this type of training. This program might develop relationships with employers who would contribute to this program through matching funds or in-kind by providing instructors, lecturers, on-the-job training opportunities, and job shadowing opportunities to all participants and certifying the training and instructors. In this concept, the project could also provide instructions in life skills and job skills behavior, mentoring, tutoring, and other case management services. The success of this project might be measured by the number of high-tech industries involved and the placement of the participants in unsubsidized jobs.

Grants awarded under this section (both youth and adult direct service grants) may also focus more specifically on providing training in Information Technology

(ITT) occupations or training in other new and/or growing occupations in technological areas that are critical parts of jobs emerging in the grantees’ labor market. For youth, a project focusing on training in IT or other new/growing occupations awarded under this grant should train no less than 50 participants for entry into long-term, sustainable occupations where there are career development ladders, not jobs lacking the need for even basic skills. Thus, the preparation should focus on occupational areas such as information technology, health services, or other occupations (requiring high skills levels) in demand in their local labor market. As WIA emphasizes the need to ensure that training services be directly linked to job opportunities in their local area, the objective of these grants should be to ensure that services are in fact linked to local employment opportunities. As a result, these grants will be expected to build connections to local WIBs/PICs, while examining approaches that demonstrate how
“high-risk” adults can be provided with quality workforce development services tailored to their unique individual needs.

For high-risk adults, service strategies should focus on increasing these individuals’ employment and earnings through work-based learning interventions such as on-the-job-training (OJT), apprenticeships, or job readiness training, along with occupational skills training and other necessary services based upon the development of an individual employment plan (which itself is an intensive service under WIA). Providing “high-risk” adults with training that is directly linked to local employment opportunities is important because it provides low-skilled individuals with a “real world” context for learning “real world” skills. Each grant providing a direct service to adults will provide an opportunity to examine how different combinations of services can best help prepare “high-risk” individuals to obtain high-quality employment.

Grants awarded under this section (both youth and adult direct service grants) may also focus more specifically on providing training in Information Technology (IT) occupations or training in other new and/or growing occupations in technological areas that are critical parts of jobs emerging in the grantees’ labor market. For youth, a project focusing on training in IT or other new/growing occupations awarded under this grant should train no less than 50 participants who are either high school dropouts or high school graduates between the ages of 18–21. For adults, a project focusing on training in IT or other new/growing occupations under this grant should also train no less than 50 participants from such populations as welfare recipients, low income seniors, displaced homemakers, etc. to fill identified IT skills shortages.

II. Rating Criteria for Awards/Selection Process for Direct Service Grants (Youth and Adults)

A careful evaluation of applications will be made by a technical review panel who will evaluate the applications against the criteria listed below. The panel results are advisory in nature and not binding on the Grant Officer. The Government may elect to award grants with or without discussions with the offerers. In situations without discussions, an award will be based on the offeror’s signature on the Standard Form (SF) 424, which is a binding offer. The Government reserves the right to make awards under this section of the solicitation to ensure geographical balance. The Grant Officer will make final award decisions based upon what is in the best interests of the Government.

1. Statement of Need (10 Pts.)

The applicant should include a brief overview that documents the need for such a project and justifies the approach to be taken, including empirical evidence and appropriate anecdotal experience. The applicant should present the goals of the project and related objectives, and how these are to be achieved through the proposed project. Are the goals and objectives presented observable and measurable, and do they reflect the intended purpose of the project?

Finally, the applicant should clearly define the population to be served in terms of its characteristics, including the age and number of participants to be served. The applicant should explain how the population is representative of the target population identified in this SGA. Further, the applicant should detail how the target population will benefit from the services they plan to provide under this demonstration.

2. Service Delivery Approach (40 Pts.)

The applicant should discuss their overall approach to the delivery of workforce investment services to the population to be served specified in the Statement of Need. The applicant should demonstrate how they plan to partner with WIBs/PICs in ensuring that the training provided will be for jobs available in their local area. Thus, there should be a discussion of how the applicant plans to ensure that training provided will be for jobs that are in demand in the local labor market. The applicant should outline how it will obtain information on job opportunities in the local labor market area. The applicant should devise a strategy to make sure the training will target occupations which need to be filled by local area employers.

The objective of direct service grants is to prepare “high-risk” youth and adults for high-quality jobs. Thus, the applicant should emphasize preparing participants for entry into occupations where there are career development ladders, not low-skilled, short-term jobs (e.g. dishwashers, hamburger cooks, etc.). They should discuss in which high-quality occupational areas (such as the growing information technology or health care fields) they plan to train their program participants, and how the training they provide will prepare participants for jobs in these occupations.

Individual assessment and services strategies. The applicant’s proposal should discuss how they will use various strategies to actively assess “high-risk” individuals and develop service strategies for each individual. Individual service strategies should allow for flexibility in meeting the needs of each project participant.

Program elements. The applicant should utilize innovative strategies to address the barriers to employment for this population and demonstrate the flexibility of services to meet the needs, interests and aptitudes of the population specified in the Statement of Need, and facilitate high-risk youth and adults moving from dependency to independent living in their communities. In addition, the applicant should spell out what exact services they plan to utilize that will help prepare “high-risk” youth and adults for “high quality” employment over the long run. The applicant should discuss specific training activities built into their program including OJT or other work-based training and classroom training that will be established for program participants.

Follow-up services. As required by the WIA, longer-term follow-up services must be provided to the participants with projects funded under this SGA. The applicant should discuss what services will be provided to participants during the follow-up period, and how long the follow-up period will typically be. In the proposal, the applicant should describe complementary strategies for long-term follow-up activities. Such a strategy may include “soft-skills” training, i.e., job behavior and life-skills training, conflict resolution, parenting classes, exposure to post-secondary education opportunities, service learning projects including peer mentoring and tutoring, organizational and teamwork training, training in decision-making including determining priorities, citizenship training, budgeting of resources, and regular contact with participants’ employers, including assistance in addressing work-related peer support groups.

Other Considerations. If applicable, the applicant’s proposal should also discuss linkages to vocational training available in a range of occupations that are in demand locally. The applicant’s proposal should discuss opportunities for which they plan to develop new training opportunities; also the reasons why they selected these occupations, and how employers will be involved in designing the training to meet their needs and in providing on-the-job training and job opportunities for project participants. Finally, the
applicant should discuss using bonding when needed and how bonding will be integrated into the overall service strategy. If the applicant plans to use the Federal Bonding Program to assist in placing participants in private sector jobs, the applicant should discuss how they will integrate bonding into their program strategy.

3. Linkages With Key Actors and Sustainability (20 Pts.)

The applicant should explain whether or not they have experience working with any component of their local workforce development system, including One Stops and/or WIBs/PICs. If so, they should explain the extent of the linkages and whether this relationship is expected to be strengthened under this grant.

The applicant should discuss here how they will use Workforce Investment Act adult and youth formula funds to complement these grant funds, including, as appropriate, establishing satellite one-stop centers which will make services more accessible to “high-risk” youth and adults. The applicant should discuss the roles of the following organizations as appropriate for youth or adult projects: The juvenile or adult judiciary systems, parole officers, police departments, courts, social service agencies, health service agencies, local foundations, Boys and Girls Clubs, YWCAs and WMCAs, faith-based organizations, community development corporations, and State and locally funded programs and educational agencies. The applicant should also show any linkages with other agencies that serve “high-risk” youth and adults that are community-based, (e.g. U.S. Department of Housing and Urban Development programs) and local transportation initiatives.

In addition, the applicant should explain how they will leverage and align with other funds or other resources that will contribute to building the foundation for permanent partnerships to continue providing services to “high-risk” adults or youth (respectively) after funding for this grant expires.

4. Institutional and Staff Capacity (15 Pts.)

The applicant should thoroughly describe the proposed management structure of the project, including the lead agency, core staff, and the experience of the lead agency and core staff in working with the target population for that project. They should also demonstrate their ability to provide quality job training to “high-risk” youth and adults, showing clearly the capability to work with individuals who have multiple environmental, social, and/or educational barriers to employment.

Core staff. The project should have a project director who is dedicated full-time to the project, and who has experience in serving the needs of the high-risk population, and developing strategies for addressing their needs. Core staff for the project should also include individuals who have experience working with the eligible youth and/or adult population and the local employment and training system under the Job Training Partnership Act programs which preceded the WIA.

Staff development activities. The applicant should discuss how they will provide initial training and offer development opportunities to staff who will provide the services to project participants. They should describe the innovative strategies, that will be used in the project, including educational opportunities at local community colleges, on-the-job training, seminars, workshops, etc.

Service Delivery Experience. The applicant should discuss if they currently are using or have used interventions that address one or more barriers that help “high-risk” individuals transition into jobs, and what significant improvements to these interventions will be made under this grant opportunity. The applicant should also discuss if they have any past experience in training individuals for high-quality jobs (e.g., occupations such as health care, information technology (IT) specialities).

5. Evaluation/Measuring Results (15 Pts.)

The applicant should explain what mechanisms are in place for reporting progress on a quarterly basis and for capturing and reporting on the results of project interventions. (Quarterly reports, an annual report and final report summarizing progress are required for projects funded under this SGA).

As the applicant is responsible for hiring an outside independent evaluator, the applicant should also discuss how it plans to choose an evaluator to conduct a thorough evaluation of its demonstration project and (if known), provide the name of the organization that will conduct the project evaluation along with a description of that organization’s evaluation capabilities and their previous experience in conducting similar evaluations. The applicant should describe the specific evaluation reports and other deliverables it plans to provide ETA as documentation of the demonstration’s progress and results in terms of improved outcomes for demonstration participants.

Signed in Washington, DC, this 30th day of November, 1999.

Laura Cesario,
Grant Officer.

4Appendix “A” Cover Sheet
Appendix “B” SF 424
Appendix “C” Budget Information Sheet

BILLING CODE 4510-30-P
COVER SHEET

Application for funding under SGA/DFA - 101
"High-Risk Youth and Adults"

Name of Applicant: ____________________________________________

Contact Person: _____________________________________________

Phone Number: _____________________________________________

SECTION: (MUST CHECK ONE)

___ Section A - Capacity Building Grants

___ Section B - Direct Services Grants for Youth

___ Section C - Direct Services Grants for Adults
<table>
<thead>
<tr>
<th>1. TYPE OF SUBMISSION:</th>
<th>FEDERAL ASSISTANCE</th>
<th>2. DATE SUBMITTED</th>
<th>Applicant Identifier</th>
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<tr>
<td>□ Non-Construction</td>
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<td></td>
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<tr>
<td>□ Construction</td>
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<tr>
<td>□ Non-Construction</td>
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<th>3. DATE RECEIVED BY STATE</th>
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<tr>
<th>4. DATE RECEIVED BY FEDERAL AGENCY</th>
<th>Federal Identifier</th>
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<th>5. APPLICANT INFORMATION</th>
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<td>Legal Name:</td>
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<th>6. EMPLOYER IDENTIFICATION NUMBER (EIN):</th>
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<tr>
<th>7. TYPE OF APPLICANT: (enter appropriate letter in box)</th>
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<tbody>
<tr>
<td>□ A. State</td>
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<tr>
<td>B. County</td>
</tr>
<tr>
<td>C. Municipia</td>
</tr>
<tr>
<td>D. Township</td>
</tr>
<tr>
<td>E. Interstate</td>
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<tr>
<td>F. Intermunicipal</td>
</tr>
<tr>
<td>G. Special District</td>
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<th>8. TYPE OF APPLICATION:</th>
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<tr>
<td>□ New</td>
</tr>
<tr>
<td>□ Continuation</td>
</tr>
<tr>
<td>□ Revision</td>
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</tbody>
</table>

<table>
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<tr>
<th>If Revision, enter appropriate letter(s) in box(s):</th>
</tr>
</thead>
<tbody>
<tr>
<td>□ A. Increase Award</td>
</tr>
<tr>
<td>B. Decrease Award</td>
</tr>
<tr>
<td>C. Increase Duration</td>
</tr>
<tr>
<td>D. Decrease Duration</td>
</tr>
<tr>
<td>Other (specify):</td>
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<tr>
<th>9. NAME OF FEDERAL AGENCY:</th>
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<tr>
<th>10. CATALOG OF FEDERAL DOMESTIC ASSISTANCE NUMBER:</th>
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<tr>
<th>11. DESCRIPTIVE TITLE OF APPLICANT'S PROJECT:</th>
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<tr>
<th>12. AREAS AFFECTED BY PROJECT (cities, counties, States, etc.):</th>
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</table>

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<tr>
<th>13. PROPOSED PROJECT:</th>
<th>14. CONGRESSIONAL DISTRICTS OF:</th>
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</thead>
<tbody>
<tr>
<td>Start Date</td>
<td>Ending Date</td>
</tr>
<tr>
<td>a. Applicant</td>
<td>b. Project</td>
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<tr>
<th>15. ESTIMATED FUNDING:</th>
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<tbody>
<tr>
<td>a. Federal $ .00</td>
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<tr>
<td>b. Applicant $ .00</td>
</tr>
<tr>
<td>c. State $ .00</td>
</tr>
<tr>
<td>d. Local $ .00</td>
</tr>
<tr>
<td>e. Other $ .00</td>
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</tbody>
</table>

| f. Program Income $ .00 |
| g. TOTAL $ .00          |

<table>
<thead>
<tr>
<th>16. IS APPLICATION SUBJECT TO REVIEW BY STATE EXECUTIVE ORDER 12372 PROCESS?</th>
</tr>
</thead>
<tbody>
<tr>
<td>a. YES, THIS PREAPPLICATION/APPLICATION WAS MADE AVAILABLE TO THE STATE EXECUTIVE ORDER 12372 PROCESS FOR REVIEW ON</td>
</tr>
<tr>
<td>DATE ___________________________</td>
</tr>
<tr>
<td>b. NO. □ PROGRAM IS NOT COVERED BY E.O. 12372</td>
</tr>
<tr>
<td>□ OR PROGRAM HAS NOT BEEN SELECTED BY STATE FOR REVIEW</td>
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<tr>
<th>17. IS THE APPLICANT DELINQUENT ON ANY FEDERAL DEBT?</th>
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<tbody>
<tr>
<td>□ Yes If &quot;Yes,&quot; attach an explanation. □ No</td>
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<tr>
<th>18. TO THE BEST OF MY KNOWLEDGE AND BELIEF, ALL DATA IN THIS APPLICATION/PREAPPLICATION ARE TRUE AND CORRECT. THE DOCUMENT HAS BEEN DULY AUTHORIZED BY THE GOVERNING BODY OF THE APPLICANT AND THE APPLICANT WILL COMPLY WITH THE ATTACHED ASSURANCES IF THE ASSISTANCE IS AWARDED.</th>
</tr>
</thead>
<tbody>
<tr>
<td>a. Typed Name of Authorized Representative</td>
</tr>
<tr>
<td>d. Signature of Authorized Representative</td>
</tr>
</tbody>
</table>

Authorized for Local Reproduction
INSTRUCTIONS FOR THE SF 424

This is a standard form used by applicants as a required facesheet for preapplications and applications submitted for Federal assistance. It will be used by Federal agencies to obtain applicant certification that States which have established a review and comment procedure in response to Executive Order 12372 and have selected the program to be included in their process, have been given an opportunity to review the applicant’s submission.

<table>
<thead>
<tr>
<th>Item:</th>
<th>Entry:</th>
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</thead>
<tbody>
<tr>
<td>1.</td>
<td>Self-explanatory.</td>
</tr>
<tr>
<td>2.</td>
<td>Date application submitted to Federal agency (or State if applicable) &amp; applicant's control number (if applicable).</td>
</tr>
<tr>
<td>3.</td>
<td>State use only (if applicable)</td>
</tr>
<tr>
<td>4.</td>
<td>If this application is to continue or revise an existing award, enter present Federal identifier number. If for a new project, leave blank.</td>
</tr>
<tr>
<td>5.</td>
<td>Legal name of applicant, name of primary organizational unit which will undertake this assistance activity, complete address of the applicant, and name and telephone number of the person to contact on matters related to this application.</td>
</tr>
<tr>
<td>6.</td>
<td>Enter Employer Identification Number (EIN) as assigned by the Internal Revenue Service.</td>
</tr>
<tr>
<td>7.</td>
<td>Enter the appropriate letter in the space provided.</td>
</tr>
</tbody>
</table>
| 8.    | Check appropriate box and enter appropriate letter(s) in the space(s) provided.  
- "New" means a new assistance award.  
- "Continuation" means an extension for an additional funding/budget period for a project with a projected completion date.  
- "Revision" means any change in the Federal Government's financial obligation or contingent liability from an existing obligation. |
| 9.    | Name of Federal agency from which assistance is being requested with this application. |
| 10.   | Use the Catalog of Federal Domestic Assistance number and title of the program under which assistance is required. |
| 11.   | Enter a brief descriptive title of the project. If more than one program is involved, you should append an explanation on a separate sheet. If appropriate (e.g., construction or real property projects), attach a map showing project location. For preapplications, use a separate sheet to provide a summary description of the project. |
| 12.   | List only the largest political entities affected (e.g., State, counties, cities). |
| 14.   | List the applicant’s Congressional District and any District(s) affected by the program or project. |
| 15.   | Amount requested or to be contributed during the first funding/budget period by each contributor. Value of in-kind contributions should be included on appropriate lines as applicable. If the action will result in a dollar change to an existing award, indicate only the amount of the change. For decreases, enclose the amounts in parentheses. If both basic and supplemental amounts are included, show breakdown on an attached sheet. For multiple program funding, use totals and show breakdown using same categories as item 15. |
| 16.   | Applicants should contact the State Single Point of Contact (SPOC) for Federal Executive Order 12372 to determine whether the application is subject to the State intergovernmental review process. |
| 17.   | This question applies to the applicant organization, not the person who signs as the authorized representative. Categories of debt include delinquent audit disallowances, loans and taxes. |
| 18.   | To be signed by the authorized representative of the applicant. A copy of the governing body's authorization for you to sign this application as official representative must be on file in the applicant's office. (Certain Federal agencies may require that this authorization be submitted as part of the application.) |
**APPENDIX C**

**PART II - BUDGET INFORMATION**

**SECTION A - Budget Summary by Categories**

<table>
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<tr>
<th></th>
<th>(A)</th>
<th>(B)</th>
<th>(C)</th>
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<tbody>
<tr>
<td>1. Personnel</td>
<td>$</td>
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<tr>
<td>2. Fringe Benefits (Rate%)</td>
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<tr>
<td>3. Travel</td>
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<td>4. Equipment</td>
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<td>5. Supplies</td>
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<td>6. Contractual</td>
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<td>7. Other</td>
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<tr>
<td>8. Total, Direct Cost (Lines 1 through 7)</td>
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<td>9. Indirect Cost (Rate%)</td>
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<tr>
<td>10. Training Cost/Stipends</td>
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<tr>
<td>11. TOTAL Funds Requested (Lines 8 through 10)</td>
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**SECTION B - Cost Sharing/Match Summary (if appropriate)**

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<tr>
<th></th>
<th>(A)</th>
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<tbody>
<tr>
<td>1. Cash Contribution</td>
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<tr>
<td>2. In-Kind Contribution</td>
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<td></td>
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<tr>
<td>3. TOTAL Cost Sharing/Match (Rate %)</td>
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</tbody>
</table>

**NOTE:** Use Column A to record funds requested for the initial period of performance (i.e. 12 months, 18 months, etc.); Column B to record changes to Column A (i.e. requests for additional funds or line item changes; and Column C to record the totals (A plus B).
INSTRUCTIONS FOR PART II - BUDGET INFORMATION

SECTION A - Budget Summary by Categories

1. **Personnel:** Show salaries to be paid for project personnel which you are required to provide with W2 forms.

2. **Fringe Benefits:** Indicate the rate and amount of fringe benefits.

3. **Travel:** Indicate the amount requested for staff travel. Include funds to cover at least one trip to Washington, DC for project director or designee.

4. **Equipment:** Indicate the cost of non-expendable personal property that has a useful life of more than one year with a per unit cost of $5,000 or more. Also include a detailed description of equipment to be purchased including price information.

5. **Supplies:** Include the cost of consumable supplies and materials to be used during the project period.

6. **Contractual:** Show the amount to be used for (1) procurement contracts (except those which belong on other lines such as supplies and equipment); and (2) sub-contracts/grants.

7. **Other:** Indicate all direct costs not clearly covered by lines 1 through 6 above, including consultants.

8. **Total, Direct Costs:** Add lines 1 through 7.

9. **Indirect Costs:** Indicate the rate and amount of indirect costs. Please include a copy of your negotiated Indirect Cost Agreement.

10. **Training/Stipend Cost:** (If allowable)

11. **Total Federal funds Requested:** Show total of lines 8 through 10.

SECTION B - Cost Sharing/Matching Summary

Indicate the actual rate and amount of cost sharing/matching when there is a cost sharing/matching requirement. Also include percentage of total project cost and indicate source of cost sharing/matching funds, i.e. other Federal source or other Non-Federal source.

**NOTE:** PLEASE INCLUDE A DETAILED COST ANALYSIS OF EACH LINE ITEM.
DEPARTMENT OF LABOR

Employment Standards Administration; Wage and Hour Division

Minimum Wages for Federal and Federally Assisted Construction; General Wage Determination Decisions

General wage determination decisions of the Secretary of Labor are issued in accordance with applicable law and are based on the information obtained by the Department of Labor from its study of local wage conditions and data made available from other sources. They specify the basic hourly wage rates and fringe benefits which are determined to be prevailing for the described classes of laborers and mechanics employed on construction projects of a similar character and in the localities specified therein.

The determinations in these decisions of prevailing rates and fringe benefits have been made in accordance with 29 CFR Part 1, by authority of the Secretary of Labor pursuant to the provisions of the Davis-Bacon Act of March 3, 1931, as amended (46 Stat. 1494, as amended, 40 U.S.C. 276a) and of other Federal statutes referred to in 29 CFR Part 1, Appendix, as well as such additional statutes as may from time to time be enacted containing provisions for the payment of wages determined to be prevailing by the Secretary of Labor in accordance with the Davis-Bacon Act. The prevailing rates and fringe benefits determined in these decisions shall, in accordance with the provisions of the foregoing statutes, constitute the minimum wages payable on Federal and federally assisted construction projects to laborers and mechanics of the specified classes engaged on contract work of the character and in the localities described therein.

Good cause is hereby found for not utilizing notice and public comment procedure thereon prior to the issuance of these determinations as prescribed in 5 U.S.C. 553 and not providing for delay in the effective date as prescribed in that section, because the necessity to issue current construction industry wage determinations frequently and in large volume causes procedures to be impractical and contrary to the public interest.

General wage determination decisions, and modifications and supersedes decisions thereto, contain no expiration dates and are effective from their date of notice in the Federal Register, or on the date written notice is received by the agency, whichever is earlier. These decisions are to be used in accordance with the provisions of 29 CFR Parts 1 and 5. Accordingly, the applicable decision, together with any modifications issued, must be made a part of every contract for performance of the described work within the geographic area indicated as required by an applicable Federal prevailing wage law and 29 CFR Part 5. The wage rates and fringe benefits, notice of which is published herein, and which are contained in the Government Printing Office (GPO) document entitled “General Wage Determinations Issued Under The Davis-Bacon And Related Acts,” shall be the minimum paid by contractors and subcontractors to laborers and mechanics.

Any person, organization, or governmental agency having an interest in the rates determined as prevailing is encouraged to submit wage rate and fringe benefit information for consideration by the Department. Further information and self-explanatory forms for the purpose of submitting this data may be obtained by writing to the U.S. Department of Labor, Employment Standards Administration, Wage and Hour Division, Division of Wage Determinations, 200 Constitution Avenue, N.W., Room S–3014, Washington, D.C. 20210.

Modifications to General Wage Determination Decisions

The number of decisions listed in the Government Printing Office document entitled “General Wage Determinations Issued Under the Davis-Bacon and Related Acts” being modified are listed by Volume and State. Dates of publication in the Federal Register are in parentheses following the decisions being modified.

Volume I

None

Volume II

District of Columbia
DC990001 (Mar. 12, 1999)
DC990003 (Mar. 12, 1999)

Maryland
MD990001 (Mar. 12, 1999)
MD990002 (Mar. 12, 1999)
MD990015 (Mar. 12, 1999)
MD990021 (Mar. 12, 1999)
MD990023 (Mar. 12, 1999)
MD990026 (Mar. 12, 1999)
MD990031 (Mar. 12, 1999)
MD990034 (Mar. 12, 1999)
MD990036 (Mar. 12, 1999)
MD990037 (Mar. 12, 1999)
MD990042 (Mar. 12, 1999)
MD990046 (Mar. 12, 1999)
MD990048 (Mar. 12, 1999)
MD990055 (Mar. 12, 1999)
MD990056 (Mar. 12, 1999)
MD990057 (Mar. 12, 1999)
MD990058 (Mar. 12, 1999)

Pennsylvania
PA990004 (Mar. 12, 1999)

Virginia
VA990006 (Mar. 12, 1999)
VA990018 (Mar. 12, 1999)
VA990022 (Mar. 12, 1999)
VA990025 (Mar. 12, 1999)
VA990035 (Mar. 12, 1999)
VA990039 (Mar. 12, 1999)
VA990048 (Mar. 12, 1999)
VA990050 (Mar. 12, 1999)
VA990055 (Mar. 12, 1999)
VA990058 (Mar. 12, 1999)
VA990069 (Mar. 12, 1999)
VA990078 (Mar. 12, 1999)
VA990079 (Mar. 12, 1999)
VA990084 (Mar. 12, 1999)
VA990085 (Mar. 12, 1999)
VA990092 (Mar. 12, 1999)
VA990099 (Mar. 12, 1999)

Volume III

None

Volume IV

None

Volume V

Arkansas
AR990001 (Mar. 12, 1999)
AR990008 (Mar. 12, 1999)
AR990023 (Mar. 12, 1999)

Missouri
MO990001 (Mar. 12, 1999)
MO990002 (Mar. 12, 1999)
MO990006 (Mar. 12, 1999)
MO990007 (Mar. 12, 1999)
MO990009 (Mar. 12, 1999)
MO990011 (Mar. 12, 1999)
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MO990042 (Mar. 12, 1999)
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MO990052 (Mar. 12, 1999)
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MO990057 (Mar. 12, 1999)
MO990058 (Mar. 12, 1999)
MO990062 (Mar. 12, 1999)
MO990064 (Mar. 12, 1999)
MO990065 (Mar. 12, 1999)
MO990067 (Mar. 12, 1999)
MO990068 (Mar. 12, 1999)
MO990070 (Mar. 12, 1999)
MO990072 (Mar. 12, 1999)

Volume VI

NONE

Volume VII

California
CA990001 (Mar. 12, 1999)
CA990002 (Mar. 12, 1999)
CA990009 (Mar. 12, 1999)
CA990028 (Mar. 12, 1999)
CA990029 (Mar. 12, 1999)
CA990030 (Mar. 12, 1999)

Virginia
VA990018 (Mar. 12, 1999)
VA990022 (Mar. 12, 1999)
VA990025 (Mar. 12, 1999)
VA990035 (Mar. 12, 1999)
VA990039 (Mar. 12, 1999)
VA990048 (Mar. 12, 1999)
VA990050 (Mar. 12, 1999)
VA990055 (Mar. 12, 1999)
VA990058 (Mar. 12, 1999)
VA990069 (Mar. 12, 1999)
VA990078 (Mar. 12, 1999)
VA990079 (Mar. 12, 1999)
VA990084 (Mar. 12, 1999)
VA990085 (Mar. 12, 1999)
VA990092 (Mar. 12, 1999)
VA990099 (Mar. 12, 1999)
NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Notice (99–148)]

Notice of Agency Report Forms Under OMB Review

SUMMARY: The National Aeronautics and Space Administration, 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 (Pub. L. 104–13: 44 U.S.C. 3506(c)(2)(A)). This information is used to determine whether the requested license should be granted.

DATES: Written comments and recommendations on the proposal for the collection of information should be received on or before February 1, 2000.

ADDRESSES: All comments should be addressed to Mr. Karl Beisel, Code HC, National Aeronautics and Space Administration, Washington, DC 20546. All comments will become a matter of public record and will be summarized in NASA’s request for OMB approval.

FOR FURTHER INFORMATION CONTACT: Ms. Carmela Simonson, Office of the Chief Information Officer, (202) 358–1223.

Reports:

Title: Security Requirements for Unclassified Information Technology Resources.

OMB Number: 2700.

Type of Review: New.

Need and Uses: NASA must safeguard its unclassified Information Technology hardware, software and data. The clause requires NASA contractors and subcontractors to comply with NASA IT security directives and guides.

Affected Public: Business or other for-profit.

Number of Respondents: 200.

Responses Per Respondent: 2.

Annual Responses: 400.

Hours Per Request: 470 hrs.

Annual Burden Hours: 188,000.

Frequency of Report: Semi-annually.

David B. Nelson,
Deputy Chief Information Officer, Office of the Administrator.

NATIONAL ARCHIVES AND RECORDS ADMINISTRATION

Records Schedules for Electronic Copies Previously Covered by General Records Schedule 20; Availability and Request for Comments

AGENCY: National Archives and Records Administration, Office of Records Services—Washington, DC.

ACTION: Notice of availability of proposed records schedules; request for comments.

SUMMARY: The National Archives and Records Administration (NARA) publishes notice at least once monthly of certain Federal agency requests for records disposition authority (records schedules). Once approved by NARA, records schedules provide mandatory instructions on what happens to records when no longer needed for current Government business. They authorize the preservation of records of continuing value in the National Archives of the United States and the destruction, after a specified period, of records lacking administrative, legal, research, or other value. Notice is published for records schedules in which agencies propose to destroy records not previously authorized for disposal or reduce the retention period of records already authorized for disposal.

This request for comments pertains solely to schedules for electronic copies of records created using word processing and electronic mail where the recordkeeping copies are already scheduled. (Electronic copies are records created using word processing or electronic mail software that remain in storage on the computer system after the recordkeeping copies are produced.)

These records were previously approved for disposal under General Records Schedule 20, Items 13 and 14. Pursuant to NARA Bulletin 99–04, agencies must submit schedules for the electronic copies associated with program records and administrative records not covered by the General Records Schedules. NARA invites public comments on such records schedules, as required by 44 U.S.C. 3303a(a). To facilitate review of these schedules, their availability for comment is announced in Federal Register notices separate from those used for other records disposition schedules.

DATES: Requests for copies must be received in writing on or before January 18, 2000. On request, NARA will send a copy of the schedule. NARA staff usually prepare appraisal.
memorandums concerning a proposed schedule. These, too, may be requested. Requesters will be given 30 days to submit comments. Some schedules submitted in accordance with NARA Bulletin 99–04 group records by program, function, or organizational element. These schedules do not include descriptions at the file series level, but, instead, provide citations to previously approved schedules or agency records disposition manuals (see SUPPLEMENTARY INFORMATION section of this notice). To facilitate review of such disposition requests, previously approved schedules or manuals that are cited may be requested in addition to schedules for the electronic copies. NARA will provide the first 100 pages at no cost. NARA may charge $.20 per page for additional copies. These materials also may be examined at no cost at the National Archives at College Park (8601 Adelphi Road, College Park, MD).

ADDRESSES: To request a copy of any records schedule identified in this notice, write to the Life Cycle Management Division (NWML), National Archives and Records Administration (NARA), 8601 Adelphi Road, College Park, MD 20740–6001. Requests also may be transmitted by FAX to 301–713–6852 or by e-mail to records.mgt@arch2.nara.gov.

Requesters must cite the control number, which appears in parentheses after the name of the agency which submitted the schedule, and must provide a mailing address. Those who desire appraisal reports and/or copies of previously approved schedules or manuals should so indicate in their request.

FOR FURTHER INFORMATION CONTACT:
Marie Allen, Director, Life Cycle Management Division (NWML), National Archives and Records Administration (NARA), 8601 Adelphi Road, College Park, MD 20740–6001. Telephone: (301) 713–7110. E-mail: records.mgt@arch2.nara.gov.

SUPPLEMENTARY INFORMATION: Each year Federal agencies create billions of records on paper, film, magnetic tape, and other media. To control this accumulation, agency records managers prepare schedules proposing retention periods for records and submit these schedules for NARA approval, using the Standard Form (SF) 115, Request for Records Disposition Authority. These schedules provide for the timely transfer into the National Archives of historically valuable records and authorize the disposal of all other records after the agency no longer needs the records to conduct its business. Routine administrative records common to most agencies are approved for disposal in the General Records Schedules (GRS), which are disposition schedules issued by NARA that apply Government-wide.

In the past, NARA approved the disposal of electronic copies of records created using electronic mail and word processing via General Records Schedule 20, Items 13 (word processing documents) and 14 (electronic mail). However, NARA has determined that a different approach to the disposition of electronic copies is needed. In 1998, the Archivist of the United States established an interagency Electronic Records Work Group to address this issue and pursuant to its recommendations, decided that agencies must submit schedules for the electronic copies of program records and administrative records not covered by the GRS. On March 23, 1999, the Archivist issued NARA Bulletin 99–04, which tells agencies what they must do to schedule electronic copies associated with previously scheduled program records and certain administrative records that were previously scheduled under GRS 20, Items 13 and 14.

Schedules submitted in accordance with NARA Bulletin 99–04 only cover the electronic copies associated with previously scheduled series. Agencies that wish to schedule hitherto unscheduled series must submit separate SF 115s that cover both recordkeeping copies and electronic copies used to create them. In developing SF 115s for the electronic copies of scheduled records, agencies may use either of two scheduling models. They may add an appropriate disposition for the electronic copies formerly covered by GRS 20, Items 13 and 14, to every item in their manuals or records schedules where the recordkeeping copy has been created with a word processing or electronic mail application. This approach is described as Model 1 in Bulletin 99–04. Alternatively, agencies may group records by program, function, or organizational component and propose disposition instructions for the electronic copies associated with each grouping. This approach is described as Model 2 in the Bulletin. Schedules that follow Model 2 do not describe records at the series level. For each schedule covered by this notice the following information is provided: name of the Federal agency and any subdivisions requesting disposition authority; the organizational unit(s) accumulating the records or a statement that the schedule has agency-wide applicability in the case of schedules that cover records that may be accumulated throughout an agency; the control number assigned to each schedule; the total number of schedule items; the number of temporary items (the record series proposed for destruction); a brief description of the temporary electronic copies; and citations to previously approved SF 115s or printed disposition manuals that scheduled the recordkeeping copies associated with the electronic copies covered by the pending schedule. If a cited manual or schedule is available from the Government Printing Office or has been posted to a publicly available Web site, this too is noted.

Further information about the disposition process is available on request.

Schedules Pending

1. Department of Commerce, National Institute of Standards and Technology (N9–167–00–01, 2 items, 2 temporary items). Electronic copies of records created using electronic mail and word processing that are associated with temporary records included in the NIST comprehensive schedule. Also included are electronic copies associated with temporary records included in schedules that pertain to the Malcolm Baldrige National Quality Award Program, Demonstration Project Payout Files, the Manufacturing Extension Partnership Program, and the National Voluntary Laboratory Accreditation Program. Electronic copies are associated with such file series as award applications, applicant files, score books, examiners’ files, duplicate copies of publications, unpublished manuscripts, working papers and background materials accumulated in preparing administrative issuances, reading files, administrative correspondence maintained at the division level or lower, test fee records, test folders, temporary research notebooks, technical standards and specification reference files, patent records, accreditation case files, and laboratory status records. This schedule follows Model 2 as described in the SUPPLEMENTARY INFORMATION section of this notice. Recordkeeping copies of these files are included in Disposition Job Nos. N1–167–91–2, N1–167–92–2, N1–167–97–1, N1–167–98–1, and N1–167–98–3.

2. Department of Commerce, National Institute of Standards and Technology (N9–167–00–02, 1 item, 1 temporary item). Electronic copies of records created using electronic mail and word processing that are associated with permanent records included in the NIST comprehensive schedule. Also included
are electronic copies associated with permanent records included in
schedules that pertain to the Malcolm Baldrige National Quality Award
Program, Demonstration Project Payout Schedules, the Manufacturing Extension
Partnership Program, and the National Voluntary Laboratory Accreditation
Program. Electronic copies are associated with such file series as
annual reports to overseers, reports to Congress, official sets of publications,
oficial sets of administrative issuances, audiovisual records, administrative
correspondence maintained at the operating unit level, minutes of
committees and conferences, director's subject files, selected project case files,
selected research notebooks, and
components, delegations of authority,
organization and functions of agency
subjects as legislation, policy
management. Included are electronic
copies of records pertaining to such
subjects as legislation, policy
formulation, program planning, the
organization and functions of agency
components, delegations of authority, committee management, inventions and
patents, health and safety matters,
personnel management, grants and
awards, and research contracts. This
schedule follows Model 2 as described in the
SUPPLEMENTARY INFORMATION section of
this notice. Recordkeeping copies of
these files are included in Disposition
Job Nos. N1–167–92–1, N1–167–92–2,
N1–167–97–1, N1–167–98–1, and N1–
3. Department of Health and Human
Services, National Institutes of Health
(N9–443–00–01, 27 items, 27 temporary
items). Electronic copies of records
created using electronic mail and word
processing that relate to agency
operations and administrative
management. Included are electronic
copies of records pertaining to such
subjects as legislation, policy
formulation, program planning, the
organization and functions of agency
components, delegations of authority, committee management, inventions and
patents, health and safety matters,
personnel management, grants and
awards, and research contracts. This
schedule follows Model 2 as described in the
SUPPLEMENTARY INFORMATION section of
this notice. Recordkeeping copies of
these files are included in Disposition
Job Nos. N1–443–98–2, N1–
443–97–1, N1–443–94–1, NCI–443–84–
1, NCI–90–83–4, NCI–90–82–6, NCI–
90–79–7, NCI–90–78–9, NCI–90–78–12,
and NCI–90–77–2.
4. Department of Labor, Pension and
Welfare Benefits Administration (N9–
317–00–01, 4 items, 4 temporary items).
Electronic copies of records created
using word processing accumulated by
the Office of the Assistant Secretary for
Pension and Welfare Benefits.
Electronic copies relate to such matters
as the activities of the Advisory Council
Committee, the development and
implementation of policies and
procedures, and other routine office
administrative matters, and
internal memorandums signed by or on
behalf of the Secretary of Labor and the
Deputy Secretary. This schedule follows
Model 1 as described in the
SUPPLEMENTARY INFORMATION section of
this notice. Recordkeeping copies of
these files are included in Disposition
5. Department of Labor, Pension and
Welfare Benefits Administration (N9–
317–00–2, 2 items, 2 temporary items).
Electronic copies of records created
using word processing that relate to
investigative case files opened by the
Office of Enforcement in connection
with its responsibility for enforcing
provisions of the Employee Retirement
Income Security Act. This schedule
follows Model 1 as described in the
SUPPLEMENTARY INFORMATION section of
this notice. Recordkeeping copies of
these files are included in Disposition
6. Department of Labor, Pension and
Welfare Benefits Administration (N9–
317–00–3, 1 item, 1 temporary item).
Electronic copies of records created
using word processing that relate to
petitions received by the Office of
Exemption Determination for exemption
from the prohibited transactions
provisions of the Employee Retirement
Income Security Act and/or the Internal
Revenue Code. This schedule follows
Model 1 as described in the
SUPPLEMENTARY INFORMATION section of
this notice. Recordkeeping copies of
these files are included in Disposition
Dated: November 24, 1999.
Michael J. Kurtz,
Assistant Archivist for Record Services—
Washington, DC.
[FR Doc. 99–31383 Filed 12–2–99; 8:45 am]
BILLING CODE 7515–01–P

NUCLEAR REGULATORY COMMISSION

Decommissioning Criteria for the West Valley Demonstration Project (M–32) and West Valley Site; Draft Policy Statement and Notice of Public Meeting

AGENCY: Nuclear Regulatory Commission.

ACTION: Draft policy statement and notice of public meeting.

SUMMARY: By memorandum from the Secretary of the Commission to the staff, dated June 3, 1999, the Commission approved the application of the U.S. Nuclear Regulatory Commission’s (NRC’s) License Termination Rule (LTR), as the decommissioning criteria for the West Valley Demonstration Project and the West Valley site. NRC is issuing this draft policy statement on the decommissioning criteria for public comment. It also is issuing a notice of public hearing to solicit public comment on the draft.

DATES: Comments on this draft policy statement should be submitted by February 1, 2000. Comments received after this date will be considered if it is practical to do so, but the Commission is able to assure consideration only for comments received on or before this date.

ADDRESSES: Submit written comments to: Jack D. Parrott, Project Scientist, Office of Nuclear Material Safety and Safeguards, Mail Stop T–8F37, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001. Hand-deliver comments to: 11555 Rockville Pike, Rockville, Maryland, between 7:30 a.m. and 4:15 p.m., Federal workdays. Copies of comments received may be examined at the NRC Public Document Room, 2120 L Street, NW (Lower Level), Washington, DC.

FOR FURTHER INFORMATION CONTACT: Jack D. Parrott, Project Scientist, Office of Nuclear Material Safety and Safeguards, Mail Stop T–8F37, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone 301–415–6700; e-mail: jdp1@nrc.gov.

SUPPLEMENTARY INFORMATION:

Background

From 1966 to 1972, under an Atomic Energy Commission (AEC) license, Nuclear Fuel Services (NFS) reprocessed 640 metric tons of spent fuel at its West Valley, New York, facility—the only commercial spent fuel reprocessing plant in the U.S. The facility shut down in 1972 for modifications to increase its seismic stability and to expand capacity. In 1976, without restarting the operation, NFS withdrew from the reprocessing business and returned control of the facilities to the site owner, the New York State Energy Research and Development Authority (NYSERDA). The reprocessing activities resulted in 2,300,000 liters (600,000 gallons) of liquid high-level radioactive waste (HLW), stored below ground in HLW tanks, and other radioactive wastes and residual radioactive contamination.

The West Valley site was licensed by AEC, and then NRC, until 1981, when the license was suspended to execute the 1980 West Valley Demonstration Project (WVDP) Act, Pub. L. 96–368. The WVDP Act authorized the U. S. Department of Energy (DOE), in cooperation with NYSERDA, the owner of the site and the holder of the suspended NRC license, to: (1) carry out...
a liquid-HLW management demonstration project; (2) solidify, transport, and dispose of the HLW at the site; (3) dispose of low-level waste (LLW) and transuranic waste produced by the WVDP, in accordance with applicable licensing requirements; and (4) decontaminate and decommission facilities used for the WVDP, in accordance with requirements prescribed by NRC. NYSERDA is responsible for all site facilities and areas outside the scope of the WVDP Act. Although NRC suspended the license covering the site until completion of the WVDP, NRC has certain responsibilities under the WVDP Act, that include prescribing decontamination and decommissioning criteria.

The WVDP is currently removing liquid HLW from underground HLW tanks at the site, vitrifying it, and storing it onsite for eventual offsite disposal in the Federal repository. The vitrification operations are nearing completion. In addition to the vitrified HLW, the WVDP operations have also produced large quantities of LLW and transuranic waste which, under the Act, must be disposed of in accordance with applicable licensing requirements. Besides the HLW at the site, the historical spent-fuel reprocessing and waste disposal operations resulted in large quantities of a full range of buried radioactive wastes and structural and environmental contamination at the site.

In 1989, DOE and NYSERDA began to develop a joint Environmental Impact Statement (EIS) for project completion and site closure, and to evaluate waste disposal and decommissioning alternatives. Because the WVDP Act requires NRC to prescribe decommissioning criteria for the project, NRC and DOE agreed on NRC's participation as a cooperating agency on the EIS, with DOE and NYSERDA, to aid NRC in its decision on decommissioning requirements. The draft EIS was published in 1996.

After public review of the draft EIS, the WVDP convened the West Valley Citizen Task Force (CTF) in early 1997 to obtain stakeholder input on the EIS. The CTF recommendations for the preferred alternative in the EIS were completed in July 1998. The CTF generally does not believe the West Valley site is suitable for long-term isolation of waste and, therefore, favors disposal of the waste offsite at suitable and safe disposal facilities. In the latter half of 1997 (during the period that the CTF was working on their recommendations), the NRC's LTR was published (62 FR 39058; July 21, 1997). Because NRC is authorized to prescribe decommissioning criteria for the WVDP by the WVDP Act, the NRC staff proposed decommissioning criteria for West Valley to the Commission in a Commission Paper entitled “Decommissioning Criteria for West Valley” dated October 30, 1998 (SECY–98–251). The Commission requested a public meeting on SECY–98–251 to obtain input from interested parties. Based on the results from this meeting, which was held January 12, 1999, the Commission issued a Staff Requirements Memorandum (SRM) on January 26, 1999, requesting additional information on the staff's proposed decommissioning criteria for West Valley. In response to the January 26, 1999, SRM the staff provided SECY–99–057, to the Commission, entitled “Supplement to SECY–98–251, ‘Decommissioning Criteria for West Valley.’” Based on the contents of SECY–98–251, SECY–99–057, and written and oral comments from interested parties, the Commission issued an SRM on June 3, 1999, detailing its decisions on the decommissioning criteria for West Valley. This draft policy statement is based on the contents of that SRM.

**Statement of Policy**

**Decommissioning Criteria for the WVDP**

Under the authority of the WVDP Act, the Commission is prescribing NRC's LTR as the decontamination and decommissioning criteria for the WVDP. These criteria shall apply to the decontamination and decommissioning of: (1) the HLW tanks and other facilities in which HLW, solidified under the project, was stored; (2) the facilities used in the solidification of the waste; and (3) any material and hardware used in connection with the WVDP. The LTR does not apply a single public dose criterion. Rather, it provides for a range of criteria. For unrestricted release, the LTR specifies a dose criterion of 25 millirem (mrem)/year to the average member of the critical group plus as low as reasonably achievable (ALARA) considerations (10 CFR 20.1402). For restricted release, the LTR specifies an individual dose criterion of 25 mrem/year plus ALARA considerations utilizing legally enforceable institutional controls established after a public participatory process (10 CFR 20.1403). Even if institutional controls fail, individual doses should generally not exceed 100 mrem/year. If it is demonstrated that the general 100 mrem/year criterion in the event of failure of institutional controls is technically unachievable or prohibitively expensive, the individual dose criterion in the event of failure of institutional controls may be as high as 500 mrem/year. However, in this circumstance this site would be rechecked by a responsible government entity no less frequently than every five years and resources would have to be set aside to provide for any necessary control and maintenance of the institutional controls. Finally, the LTR permits alternate individual dose criteria of up to 100 mrem/year plus ALARA considerations for restricted release with institutional controls established after a public participatory process (10 CFR 20.1404). Use of alternate criteria must be approved by the Commission itself after coordination with the Environmental Protection Agency and after consideration of the NRC staff's recommendations and all public comments. The Commission's application of the LTR to the WVDP is a two-step process: (1) The NRC is now prescribing the application of the LTR; and (2) following the completion of DOE/NYSERDA's Environmental Impact Statement (EIS) and selection of its preferred alternative, the NRC will verify that the specific criteria identified by DOE is within the LTR and will prescribe the use of this specific criteria for the WVDP.

**Decommissioning Criteria for the NDA and SDA**

NRC will apply the criteria in the LTR to the NRC-licensed radioactive waste disposal area (NDA) within the WVDP site boundary since the NDA is under NRC jurisdiction. NRC will not apply the criteria in the LTR to the State-licensed radioactive waste disposal area (SDA) adjacent to the WVDP site boundary since the SDA is not under NRC jurisdiction.

**Decommissioning Criteria for License CSF–1**

The criteria in the LTR will also apply to the termination of NYSERDA's NRC license on the West Valley site once that license is reactivated.

**Policy Implications**

The policy of applying NRC's existing LTR to the decommissioning of the WVDP and West Valley site is consistent with the decommissioning requirements for all NRC licensees. Therefore, no policy implications are foreseen with the application of the LTR to the decommissioning of the WVDP and West Valley site.
Environmental Analysis

The environmental impact of applying the LTR to NRC licensees was evaluated in a Generic Environmental Impact Statement (GEIS, NUREG-1496) that supports the LTR. When the particular criteria permitted by the LTR are selected, the environmental impacts from the application of the criteria will be considered. The NRC intends to rely on the DOE/NYSERDA’s EIS for this purpose. The DOE is considered for NEPA purposes as the lead federal agency. DOE is developing a decommissioning plan and is responsible for its preparation and implementation. The NRC, in view of its responsibilities under the WVDP Act, is considered a cooperating agency for this EIS and is participating in the development of the DOE/NYSERDA EIS. The NRC does not anticipate the need to prepare its own duplicative EIS as the NRC can consider the environmental impacts described in the DOE/NYSERDA EIS in approving the particular decommissioning criteria for the WVDP under the LTR. Under this arrangement, the DOE/NYSERDA EIS will fulfill the NEPA responsibilities for the NRC.

Availability of Documents

The NRC’s draft policy statement on decommissioning criteria for West Valley is also available at NRC’s Public Electronic Reading Room (http://www.nrc.gov/NRC/ADAMS/index.html) on the NRC’s home page (http://www.nrc.gov). Copies of documents cited in this section are available for inspection and/or reproduction for a fee in the NRC Public Document Room, 2120 L Street, NW (Lower Level), Washington, DC 20003. The NRC Public Document Room is open from 7:45 a.m. to 4:15 p.m., Monday through Friday, except on Federal holidays. Reference service and access to documents may also be requested by telephone (202–634–3273 or 800–397–4209), between 8:30 a.m. and 4:15 p.m.; or by e-mail (PDR@nrc.gov); fax (202–634–3343); or a letter (NRC Public Document Room, LL–6, Washington, DC 20555–0001). In addition, copies of: (1) SECY–98–251, “Decommissioning Criteria for West Valley”; (2) the transcript of the public meeting held January 12, 1999; (3) the Commission’s SRM of January 26, 1999, concerning the January 12, 1999, public meeting on SECY–98–251; (4) SECY–99–057, “Supplement to SECY–98–251, ‘Decommissioning Criteria for West Valley’”; (5) the Commission’s vote sheets on SECY–98–251 and SECY–99–057; and (6) the Commission’s SRM of June 3, 1999, on SECY–98–251 and SECY–99–057, can be obtained electronically on NRC’s home page at the Commission’s Activities link (http://www.nrc.gov/NRC/COMMISSION/activities.html).

Public Meeting

NRC will conduct a public meeting at the Ashford Office Complex, 9030 Route 219, West Valley, New York, conference room C1, on January 5, 2000, to discuss the draft policy statement for the decommissioning criteria for West Valley with interested members of the public. The meeting is scheduled for 7:00–9:00 p.m., and will be facilitated by Francis X. Cameron, Special Counsel for Public Liaison, NRC. There will be an opportunity for members of the public to ask questions of NRC staff and make comments related to the West Valley decommissioning criteria. The meeting will be transcribed. For more information on the public meeting, please contact Jack D. Parrott, Project Scientist, Office of Nuclear Material Safety and Safeguards, Mail Stop T–8F37, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; 301–415–6700; e-mail: jdtp1@nrc.gov.

Dated at Rockville, Maryland, this 29th day of November, 1999.

For the Nuclear Regulatory Commission.

Annette L. Vietti-Cook,
Secretary of the Commission.

[FR Doc. 99–31375 Filed 12–2–99; 8:45 am]
BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

Notice of Public Meeting of the Sewage Sludge Subcommittee of the Interagency Steering Committee on Radiation Standards

AGENCIES: Nuclear Regulatory Commission, Environmental Protection Agency, and Department of Energy.

ACTION: Notice of public meeting.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) will host a meeting of the Sewage Sludge Subcommittee of the Interagency Steering Committee on Radiation Standards (ISCORS) on December 13, 1999, in Rockville, Maryland to discuss the sampling and analysis of sludge and ash from Publicly Operated Treatment Works (POTW) to screen for radiation hazards. The parent committee, ISCORS, fosters early resolution and coordination of regulatory issues associated with radiation standards. Agencies represented on the ISCORS Sewage Sludge Subcommittee include the U.S. Nuclear Regulatory Commission, U.S. Environmental Protection Agency, U.S. Department of Energy, U.S. Department of Defense, in addition to State and Local representatives.

The objectives of the ISCORS Sewage Sludge Subcommittee are to: (1) Conduct a survey of selected POTWs; (2) prepare a guidance document for use by the POTWs in collecting samples of sludge and ash for analysis; and (3) prepare a model for estimating dose from use and disposal of sewage sludge and ash.

This ISCORS Sewage Sludge Subcommittee meeting will consist of presentations by members of the sewage sludge subcommittee and statements by members of the public. Subcommittee meetings normally involve pre-decisional intra-governmental discussions and, as such, are normally not open for observation by members of the public or media. Minutes of subcommittee meetings are available through the NRC’s Public Document Room, 2120 L Street, NW (Lower Level), Washington, DC 20555; telephone 202–634–3273; fax 202–634–3343.

DATES: The meeting will be held from 9 a.m. to 11 a.m. on Monday, December 13, 1999.

ADDRESSES: The meeting will be held in the NRC auditorium, at Two White Flint North, 11545 Rockville Pike, Rockville, Maryland 20852.

FOR FURTHER INFORMATION CONTACT: Mary L. Thomas, Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission, Washington, DC 20555, telephone 301–415–6230; fax 301–415–5385; E-mail mlth@NRC.GOV; or Duane Schmidt, Office of Nuclear Material Safety and Safeguards, telephone 301–415–6919; fax 301–415–5398; E-mail dws2@NRC.GOV, U.S. Nuclear Regulatory Commission, Washington, DC 20555.

SUPPLEMENTARY INFORMATION: Visitor parking around the NRC building is limited; however, the workshop site is located adjacent to the White Flint Metro Station on the Red Line. Seating for the public will be on a first-come, first-served basis.

Dated at Rockville, MD, this 29th day of November 1999.

For the Nuclear Regulatory Commission.

Cheryl A. Trotter,

[FR Doc. 99–31376 Filed 12–2–99; 8:45 am]
BILLING CODE 7590–01–P
**NUCLEAR REGULATORY COMMISSION**

**NRC To Hold Public Meetings on Spent Fuel Shipping Cask Accident Studies**

**AGENCY:** Nuclear Regulatory Commission.

**ACTION:** Notice of public meeting on spent nuclear fuel transportation studies and update to previous notice of public meeting (64 FR 56525).

**SUMMARY:** The U.S. Nuclear Regulatory Commission is initiating a study on spent nuclear fuel cask responses to severe transportation accidents. NRC previously studied this issue in the 1980s (see NUREG/CR–4829 and NUREG/BR–0111, called the “modal study”). The modal study looked at possible rail and highway accidents and concluded that spent nuclear fuel cask designs would survive nearly all transportation accidents without releasing radioactive material to the environment. Risk insights obtained using modern analysis techniques, physical testing, and through interaction with stakeholders and the public, will support NRC’s ongoing efforts to assure that its regulatory actions are risk-informed and effective. Ongoing public interactions throughout this project will help ensure that public concerns are effectively identified and understood, and that the study design considers these issues.

NRC will conduct a public meeting on this topic in Henderson, Nevada, on December 8, 1999. This meeting was noticed at 64 FR 56525 along with a November 17, 1999, meeting in Bethesda, Maryland. Based on the lessons learned in Bethesda and discussions with stakeholders, the agenda for Henderson has been revised and an additional seminar session (similar to the Henderson evening seminar) has been scheduled for December 9, 1999, in Pahrump, Nevada.

Francis X. Cameron, Special Counsel for Public Liaison, in the Commission’s Office of the General Counsel, will be the convener and facilitator for the meetings.

**DATES:** The meeting will be: (1) in Henderson, NV, on December 8, 1999, from 8:00 a.m. to 4:30 p.m.; followed by (2) an evening seminar in the same room from 7:00 p.m. to 9:30 p.m.; and (3) a seminar in Pahrump, NV, on December 9, 1999, from 10:00 a.m. to 12:00 noon.

**ADDRESSES:** On December 8, all meetings will be in the Grand Ballroom at the Henderson Convention Center, 200 Water Street, Henderson, NV. On December 9, the meeting will be held at the Mountain View Casino and Bowl, 1750 Pahrump Valley Road, Pahrump, NV.

**INFORMATION:** Contact Francis X. Cameron, Special Counsel for Public Liaison, Office of the General Counsel, Nuclear Regulatory Commission, Washington, DC, 20555–0001, Telephone: 301–415–1642.

**SUPPLEMENTARY INFORMATION:** The risks from accidents while transporting highly radioactive spent nuclear fuel from nuclear power plants to a centralized storage facility or to an underground repository is an issue that has recently received increased NRC and public attention because of the increase in the number of shipments that will occur if and when such facilities begin operating. Risk to the public from transportation accidents depends on accident rates, number of shipments, and the likely consequences and severity of the accidents. About 1300 shipments of spent nuclear fuel have been made in NRC-certified packages, with an exceptional safety record of no releases from accidents. Despite the previous studies and safety record, some stakeholders may have questions or concerns regarding spent nuclear fuel transport package safety. Several groups have criticized NRC’s cask standards and the modal study as being insufficient to adequately demonstrate safety during severe transportation accidents.

During the morning and afternoon of December 8 in Henderson, representatives of the interests affected by the study will discuss their views on the issues in a “roundtable” format. In order to have a manageable discussion, the number of participants around the table will, of necessity, be limited. The Commission, through the facilitator for the meeting, will attempt to ensure participation by the broad spectrum of interests at the meetings, including citizen and environmental groups, nuclear industry interests, state, tribal, and local governments, experts from academia, or other agencies. Other members of the public are welcome to attend, and the public will have the opportunity to comment on each of the agenda items slated for discussion by the roundtable participants. Questions about participation may be directed to the facilitator, Francis X. Cameron.

On December 8 in Henderson, and on December 9 in Pahrump, seminars will be conducted. At these seminars, the NRC staff will briefly present the NRC’s role in ensuring transportation safety and its views regarding the upcoming study. A moderated discussion will then be held to discuss the study’s proposed content or approach with those in the audience. The NRC staff will then be available to further discuss issues or public concerns regarding transportation safety.

The meeting and seminars will have a pre-defined scope and agenda focused on the major technical issues in regard to spent nuclear fuel cask performance during transportation accidents. However, the meeting format will be sufficiently flexible to allow for the introduction of additional related issues that the participants may wish to raise. The purpose of the meetings and seminars is to hear the views of the participants on the issues and options to resolve the issues for the forthcoming study. The agenda is set forth below.

**Roundtable Meeting, December 8, 8:00 a.m. to 4:30 p.m., Henderson, NV**

**Introductions and Ground Rules**

**Welcome and Overview**

**NRC Spent Fuel Transportation Studies**

**Use of Physical Testing and Computer Simulation**

**Roundtable Discussion; Audience Comments**

**Highway and Railway Accidents Likelihoods**

**Roundtable Discussion; Audience Comments**

**Container Performance During Collisions and Fires**

**Roundtable Discussion; Audience Comments**

**Spent Nuclear Fuel Assembly Behavior in Accidents**

**Roundtable Discussion; Audience Comments**

**Other Transportation Safety Issues**

**Roundtable Discussion; Audience Comments**

**Wrap-up and Adjourn**

**Seminars, December 8, 7:00 p.m. to 9:30 p.m., Henderson, NV and December 9, 10:00 a.m. to 12:00 noon, Pahrump, NV**

**Welcome and Overview**

**NRC Role and Regulatory Framework**

**NRC Spent Fuel Transportation Studies Overview of Upcoming Study Discussion Forum**

**Wrap-up and Adjourn**

**Dated at Rockville, Maryland, this 26th day of November 1999.**

For the Nuclear Regulatory Commission.

M. Wayne Hodges,
NUCLEAR REGULATORY COMMISSION
[Docket No. 50–220]

Niagara Mohawk Power Corporation, Nine Mile Point Nuclear Station, Unit No. 1; Issuance of Final Director's Decision Under 10 CFR 2.206

Notice is hereby given that the Director, Office of Nuclear Reactor Regulation, has taken action with regard to a letter dated May 24, 1999, as supplemented by letter dated August 10, 1999, (Petition) filed by Tim Judson (Petitioner) of the Syracuse Peace Council, on behalf of himself and others, pursuant to Section 2.206 of Title 10 of the Code of Federal Regulations (10 CFR 2.206). The Petitioner requested that the U.S. Nuclear Regulatory Commission (Commission or NRC) suspend the operating license issued to Niagara Mohawk Power Corporation (NMPC or Licensee) for Nine Mile Point Nuclear Station, Unit 1 (NMP1) until (1) NMPC releases the most recent inspection data on the plant's core shroud; (2) a public meeting can be held in Oswego County, New York, to review this inspection data and the repair design to core shroud vertical welds V9 and V10; and (3) an adequate public review of the safety of the plant's continued operation is accomplished.

In a letter dated June 11, 1999, the Director of the Office of Nuclear Reactor Regulation acknowledged receipt of the Petition of May 24, 1999, and addressed the actions under 10 CFR 2.206 that Petitioner requested to be taken before restart of NMP1 from its 1999 refueling outage (RFO–15). In the letter of June 11, 1999, the staff explained that the issues and concerns addressed in the Petition do not warrant deferring restart of NMP1 and that a meeting to provide for public review of the shroud reinspection results need not be held before restart.

In the supplemental letter dated August 10, 1999, Petitioner reiterated the request for the meeting to provide for public review of the shroud reinspection data and repair, even though the meeting would take place after restart. Petitioner stated that the need for the meeting had increased because cracks were identified in the main drain line and control rod stub tubes during the hydrostatic testing of the reactor vessel during RFO–15. Petitioner stated that these cracks from the hydrostatic tests raise two concerns: (1) That the NRC's "leak-before-break" model for safety of aging reactors is inadequate and (2) that the problem of cracking is not confined to the core shroud, but may be spreading throughout the reactor internals, pipes, and other systems, representing an unanalyzed condition that is only being identified piecemeal through certain incidental cases that, together, reveal a pattern of degradation of reactor components and systems and overall embrittlement of the reactor. Petitioner also expressed concern in the letter of August 10, 1999, that the core shroud inspection during RFO–15 indicated that shroud vertical weld V10 is growing at a rate in excess of the NRC's accepted crack growth rate limit of 22 microinch/hr (1.55 × 10–6 centimeter/second), whereas he believes the measured rate should be at least 2 sigma below the limit.

The Director of the Office of Nuclear Reactor Regulation has concluded that the 1999 shroud reinspection results, reviewed by the NRC staff since receipt of the Petition, support NMPC's conclusion, reached before restart, that the structural integrity of the core shroud will be maintained during at least the current operating cycle in its present configuration. The additional issues raised by Petitioner in the supplement to the Petition were previously known and addressed by the NRC. These issues were resolved consistent with approved Boiling Water Reactor Vessel Internals Project programs, codes and standards, plant technical specifications, and the Commission's regulations. The crack growth rate for shroud vertical weld V10 did not exceed the NRC staff's accepted limit and its repair has diminished concern for its current and future behavior. Some of the issues of concern to the Petitioner were discussed during the Plant Performance Meeting at the NMP site on October 22, 1999, and the NRC staff remained in the area after the meeting to discuss issues of interest with the public and the local press. For these reasons, the NRC staff concludes the additional meeting requested by the Petitioner is not warranted. The Director of the Office of Nuclear Reactor Regulation has concluded that the issues raised in the Petition do not represent a significant safety issue and do not warrant any NRC staff action to modify, suspend, or revoke operation of NMP1 for the reasons that are explained in the "Final Director's Decision Pursuant to 10 CFR 2.206" (DD–99–14). Therefore, the Petition is not granted.

The complete text of the Final Director's Decision follows this notice and is available for public inspection at the Commission's Public Document Rooms located in the Gelman Building, 2120 L Street, NW., Washington, DC, and accessible electronically through the ADAMS Public Electronic Reading Room link at the NRC Web site (http://www.nrc.gov).

A copy of the Decision will be filed with the Secretary of the Commission for the Commission's review in accordance with 10 CFR 2.206(c) of the Commission's regulations. As provided for by this regulation, the Decision will constitute the final action of the Commission 25 days after the date of issuance of the Decision unless the Commission, on its own motion, institutes a review of the Decision within that time.

Dated at Rockville, Maryland, this 29th day of November 1999.

For the Nuclear Regulatory Commission.

Brian W. Sheron,
Acting Director, Office of Nuclear Reactor Regulation.

SECURITIES AND EXCHANGE COMMISSION

Request For Public Comment

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of Filings and Information Services, Washington, DC 20549

Extension:
Rule 24b–1, SEC File No. 270–205, OMB Control No. 3235–0194

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 24b–1 (17 CFR 240.24b–1) requires a national securities exchange to keep and make available for public inspection a copy of its registration statement and exhibits filed with the Commission, along with any amendments thereto.

There are eight national securities exchanges that spend approximately one half hour each complying with this rule, for an aggregate total compliance burden of four hours per year. The staff estimates that the average cost per respondent is $57.66 per year, calculated as the costs of copying ($12.36) plus storage ($45.32), resulting in a total cost of compliance for the respondents of $461.44.
Written 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 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. Consideration will be given to comments and suggestions submitted in writing within 60 days of this publication.

Direct your written comments to Michael E. Bartell, Associate Executive Director, Office of Information Technology, Securities and Exchange Commission, 450 5th Street, NW, Washington, DC 20549.


Jonathan G. Katz, Secretary.

[FR Doc. 99-31389 Filed 12-2-99; 8:45 am]

BILLING CODE 8010-01-M

SECURITIES AND EXCHANGE COMMISSION

[Rel No. IC–24178; File No. 812–11686]

American General Annuity Insurance Company, et al.; Notice of Application

November 29, 1999.

AGENCY: Securities and Exchange Commission (“SEC” or “Commission”).

ACTION: Notice of application for an order under Sections 26(b) and 17(b) of the Investment Company Act of 1940 (the “1940 Act” or “Act”).

SUMMARY OF APPLICATION: Applicants seek an order under Section 26(b) of the 1940 Act approving the proposed substitution of shares of certain series of American General Series Portfolio Company, OCC Accumulation Trust (“OCCAT”), and Van Kampen Life Investment Trust (“LIT”) for shares of comparable series of A.G. Series Trust held by A.G. Separate Account A to fund certain individual fixed and variable deferred annuity contracts issued by American General Annuity Insurance Company. Applicants also seek an order under Section 17(b) of the 1940 Act granting exemptions from Section 17(a) to permit certain in-kind redemption and purchase transactions in connection with the substitutions.


FILING DATE: The application was filed on July 7, 1999.

HEARING OR NOTIFICATION OF HEARING: An order granting the application will be issued unless the Commission orders a hearing. Interested persons may request a hearing on the application by writing to the Secretary of the SEC and serving the Applicants with a copy of the request, in person or by mail. Hearing requests must be received by the Commission by 5:30 p.m., on December 20, 1999, and must be accompanied by proof of service on the Applicants in the form of an affidavit or, for lawyers, a certificate of service. Hearing requests should state the nature of the writer’s interest, the reason for the request and the issues contested. Persons who wish to be notified of a hearing may request notification by writing to the Secretary of the SEC.

ADDRESSES: Secretary, Securities and Exchange Commission, 450 Fifth Street, NW, Washington, DC 20549–0609.

Applicants, c/o Huey P. Falgout, Jr., 2929 Allen Parkway, Houston, Texas 77019.

FOR FURTHER INFORMATION CONTACT: Joyce Merrick Pickholz, Senior Counsel, or Susan M. Olson, Branch Chief, Office of Insurance Products, Division of Investment Management, at (202) 942–0670.

SUPPLEMENTARY INFORMATION: The following is a summary of the application. The complete application is available for a fee from the SEC’s Public Reference Branch, 450 Fifth Street, NW, Washington, DC 20549–0102 (tel. (202) 942–8090).

Applicants’ Representations

1. AGAIC is a stock life insurance company incorporated in Texas. AGAIC is wholly owned by Western National Corporation which is a wholly owned subsidiary of ACG Life Insurance Company, a subsidiary of American General Corporation.

2. The Account was established by AGAIC under Texas law. The Account is registered under the 1940 Act as a unit investment trust and serves as funding vehicles for certain individual flexible premium fixed and variable deferred annuity contracts issued by AGAIC (the “Contracts”). The Account is currently divided into fifteen sub-accounts.

3. Under the Contracts, a Contract owner may select between seven of the Account’s sub-accounts each of which invests in a corresponding series of the Trust and two fixed account options. An owner of any Contract may make transfers between these options subject to the following limits: (a) the minimum transfer is $250 or the value of the account, if less; (b) only one transfer per day is permitted between the variable options; and (d) transfer from the dollar cost averaging fixed account option to the variable account options is limited to 20% of the dollar cost averaging account value.

4. The Trust, an unincorporated business trust established under Massachusetts law, is registered under the 1940 Act as an open-end management investment company. Shares of the Trust’s seven portfolios are sold exclusively to the Account to fund benefits under the Contracts. AGAIC Advisory Services, Inc (“AGAIS”), an indirect subsidiary of Western National Corporation, is the investment advisor to the Trust.

5. Shares of AGSPC are sold exclusively to separate accounts to fund benefits under variable annuity contracts and variable life insurance policies sponsored by The Variable Annuity Life Insurance Company (“VALIC”), its affiliates or employer thrift plans maintained by VALIC or American General Corporation. VALIC is an indirect wholly owned subsidiary of American General Corporation.

6. AGSPC is a Maryland corporation registered under the 1940 Act as an open-end management investment company.VALIC serves as AGSPC’s investment advisor. Bankers Trust Company serves as sub-advisor to the AGSPC’s Stock Index Fund.

6. OCCAT is a Massachusetts business trust registered under the 1940 Act as an open-end management investment company. Shares of OCCAT are sold only to variable accounts of life insurance companies as an investment vehicle for variable annuity and variable life insurance contracts and to qualified pension and retirement plans. OpCap Advisors serves as investment advisor for OCCAT.
7. Shares of LIT, a Delaware business trust registered under the 1940 Act as an open-end management investment company, are sold only to variable accounts of life insurance companies as an investment vehicle for their variable annuity and variable life insurance contracts. Van Kampen Management Inc. serves as LIT's investment advisor.

8. AGAIC proposes to substitute:
(a) shares of AGSPC's Government Securities Fund for shares of the Trust's American General U.S. Government Securities Portfolio;
(b) shares of AGSPC’s Growth & Income Fund for shares of the Trust’s Credit Suisse Growth and Income Portfolio;
(c) shares of AGSPC’s International Equities Fund for shares of the Trust’s Credit Suisse International Equities Portfolio;
(d) shares of OCCAT’s Managed Portfolio for shares of the Trust’s Elite Value Portfolio;
(e) shares of AGSPC’s Stock Index Fund for shares of the Trust’s State Street Global Advisors Growth Equity Portfolio;
(f) shares of AGSPC’s Money Market Fund for shares of the Trust’s State Street Global Advisors Money Market Portfolio; and
(g) shares of LIT’s Emerging Growth Portfolio for shares of the Trust’s Van Kampen Emerging Growth Portfolio.


10. The Trust’s Credit Suisse Growth and Income Portfolio seeks long-term growth of capital, current income and growth of income, consistent with reasonable investment risk through investments primarily in equity securities, fixed income securities and cash instruments. AGSPC’s Growth and Income Fund seeks to provide long-term growth of capital and, secondarily, income through investment in common stocks and equity-related securities.

11. The Trust’s Credit Suisse International Equity Portfolio seeks long-term capital appreciation by investing in equity and equity-related securities of companies located in at least five foreign countries, excluding the United States. AGSPC’s International Equities Fund has as its investment objective the long-term growth of capital through investments in a diversified portfolio of equity and equity-related securities of foreign issuers that, as a group, are expected to provide investment results closely corresponding to the performance of the EAFE Index.

12. The investment objective of both the Trust’s Elite Value Portfolio and OCCAT’s Managed Portfolio is growth of capital over time through investment in a portfolio consisting of common stocks and cash equivalents.

13. The Trust’s State Street Global Advisors Growth Equity Portfolio has as its investment objective to provide total returns that exceed, over time, the S&P Index through investment in equity securities. AGSPC’s Stock Index Fund seeks long-term capital growth through investment in common stocks that as a group, are expected to provide results closely corresponding to the performance of the S&P Index.

14. The Trust’s State Street Global Advisors Growth Equity Portfolio has as its investment objective to provide total returns that exceed, over time, the S&P Index through investment in equity securities. AGSPC’s Stock Index Fund seeks long-term capital growth through investment in common stocks that as a group, are expected to provide results closely corresponding to the performance of the S&P Index.

15. The Trust’s Van Kampen Emerging Growth Portfolio’s investment objective is capital appreciation and any ordinary income from portfolio securities is entirely incidental. The investment objective of LIT’s Emerging Growth Portfolio is capital appreciation by investing in a portfolio of securities consisting principally of common stocks of small and medium sized companies considered by the portfolio’s investment advisor to be emerging growth companies.

16. Applicants submit that the substitutions are expected to result in enhanced administrative efficiency. Applicants state that the portfolios of the Trust have remained relatively small and their expense ratios have, therefore, remained relatively high because the costs of administering the portfolios is spread over a relatively small asset base. To maintain expense ratios at competitive levels, AGAIC has subsidized the portfolios’ expenses and until May 1, 1998, the portfolios’ investment advisor, AGAIC, was also waiving in part its investment advisory fee. Since the Trust’s inception, AGAIC has subsidized other expenses of the Trust, limiting such expense to .12%. Without those fee waivers and subsidies, total portfolio expenses would have ranged from 1.41% for the Elite Portfolio to 3.78% for the Credit Suisse International Equity Portfolio. AGAIC is unwilling to continue fee reimbursements indefinitely because of the cost to AGAIC. For 1998, fee waivers and reimbursements amounted to approximately $876,000. The AGSPC funds, OCCAT Managed Portfolio, and LIT Emerging Growth Portfolio are much larger and, therefore, enjoy economies of scale that the Trust’s portfolios do not.

17. Applicants state that for all substitutions, the gross total expense ratios for the Trust’s portfolios are substantially higher than those of the much larger AGSPC funds, OCCAT Managed Portfolio, and LIT Emerging Growth Portfolio that would replace them. On a net basis (after waivers or reimbursements), the proposed substitutions of AGSPC’s Government Securities Fund for the Trust’s American General U.S. Government Securities Portfolio, AGSPC’s Money Market Fund for the Trust’s State Street Global Advisors Money Market Portfolio, OCCAT’s Managed Portfolio for the Trust’s Elite Value Portfolio, and LIT’s Emerging Growth Portfolio for the Trust’s Van Kampen Emerging Growth Portfolio results in increases in total expense ratios of .01%, .05%, .13% and .05%, respectively. Applicants state that those differences are, however, at least partly attributable to the waiver by AGAIS of its investment advisory fees for part of 1998. Applicants state that since those waivers have already been discontinued, it is likely that the expense ratios of the Trust’s portfolios would be higher than their proposed replacements.

18. Applicants expect that the substitution of AGSPC’s Stock Index Fund for the Trust’s State Street Global Advisors Growth Equity Portfolio, AGSPC’s Money Market Fund for the Trust’s State Street Global Advisors Money Market Portfolio, and OCCAT’s Managed Portfolio for the Trust’s Elite Value Portfolio will result in increases in advisory fees of .25%, .05% and .13%, respectively, but the gross total expense ratios are expected to decline .35%, 1.9%, and .59%, respectively. The chart below shows for each proposed substitution the total net assets, management fee (with and without waiver in the case of the Trust’s portfolios), and total expense ratios (with and without reimbursement in the case of the Trust’s portfolios) for the year ended December 31, 1998.
### Substituting funds

<table>
<thead>
<tr>
<th>Substituting funds</th>
<th>Eliminated fund assets (000's)</th>
<th>Eliminated fund mgmt fee w/o reimburs</th>
<th>Eliminated fund mgmt fee w/ reimburs</th>
<th>Eliminated fund total exp. w/o reimb.</th>
<th>Eliminated fund total exp. w/ reimb.</th>
<th>Replacement fund assets (000's)</th>
<th>Replacement fund mgmt fee</th>
<th>Replacement fund total exp.</th>
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</thead>
<tbody>
<tr>
<td>AGSPC Growth &amp; Income for Credit Suisse Growth &amp; Income</td>
<td>$16,713</td>
<td>0.75</td>
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<td>AGSPC International Equities for Credit Suisse International Equity</td>
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<td>AGSPC Gov't Securities for American General U.S. Gov't Securities Portfolios</td>
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<td>AGSPC Stock Index for State Street Global Advisors Growth Equity</td>
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<td>0.61</td>
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<td>1.96</td>
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<td>LIT Emerging Growth with waivers (without) for Van Kampen Emerging Growth</td>
<td>9,253</td>
<td>0.45</td>
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<td>0.71</td>
<td>777,087</td>
<td>0.78</td>
<td>0.84</td>
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</tbody>
</table>

1 Effective fee rate based on the following schedule: 0.80% on the first $400 Million, 0.75% on the next $400 Million, and 0.70% on the excess over $800 Million.

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20. Below is a chart showing the total returns for each of the funds involved in the proposed substitutions for the past one, three, and five fiscal years (if available) or since inception (if less than five years), as the case may be. Applicants state the performance of the proposed replacement AGSPC funds, OCCAT Management Portfolio, and LIT Emerging Growth Portfolio for comparable periods exceeds the performance of the substituted Trust portfolios in all but one case. For the proposed substitution of AGSPC’s Money Market Fund for the Trust’s State Street Global Advisors Money Market Portfolio, the replaced portfolio’s performance for the one- and three-year period exceeds that of the AGSPC fund. However, Applicants submit that performance was accomplished with substantially subsidized total expenses. Without those subsidies the Trust’s portfolios would likely have significantly underperformed the AGSPC fund in the past and would likely continue to do so in the future owing to its substantially higher expenses. Applicants state that the State Street Global Advisors Money Market Portfolio out-performance of .08% to .20% would be eliminated by the 1.90% increase reflected in the gross total expense ratio.

<table>
<thead>
<tr>
<th>Substituting funds</th>
<th>Trust portfolios performance (percent)</th>
<th>Since Inception</th>
<th>Replacement funds performance (percent)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1 year</td>
<td>3 Year</td>
<td>1 Year</td>
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<tr>
<td>AGSPC Growth &amp; Income for Credit Suisse Growth and Income</td>
<td>14.16</td>
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<tr>
<td>AGSPC International Equities for Credit Suisse International Equity</td>
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<td>6.40</td>
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<tr>
<td>AGSPC Gov't Securities for American General U.S. Gov't Securities</td>
<td>7.49</td>
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<tr>
<td>AGSPC Stock Index for State Street Global Advisors Growth Equity</td>
<td>21.60</td>
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</tbody>
</table>
21. By supplements to the prospectus for the Contracts and the Account, AGAIC will notify all owners of the Contracts of its intention to take the necessary actions to substitute shares of the funds. The supplements will advise Contract owners that from the date of the supplement until the date of the proposed substitutions, owners are permitted to make transfers among the sub-accounts as usual, except that the limit on frequency of transfers from the variable account options to the non-dollar cost averaging fixed account option will be waived. The supplements will also inform Contract owners that AGAIC will not exercise any rights reserved under any Contract to impose additional restrictions on transfers until at least 30 days after the proposed substitutions.

22. The proposed substitutions will take place at relative net asset value with no change in the amount of any Contract owner’s Contract value, cash value or death benefit or in the dollar value of his or her investment in the Separate Account. Contract owners will not incur any fees or charges as a result of the proposed substitutions, nor will their rights or AGAIC’s obligations under the Contracts be altered in any way. All expenses incurred in connection with the proposed substitutions, including legal, accounting and other fees and expenses, will be paid by AGAIC. In addition, the proposed substitutions will not impose any tax liability on Contract owners. The proposed substitutions will not cause the Contract Fees and charges currently being paid by existing Contract owners to be greater after the proposed substitutions than before the proposed substitutions. The proposed substitutions will not be treated as a transfer for the purpose of assessing transfer charges or for determining the number of remaining permissible transfers in a Contract year.

23. In addition to the prospectus supplements distributed to Contract owners, within five days after the substitutions, contract owners will be sent a written notice informing them that the substitutions were carried out and that they may make open transfer of all contract value or cash value under a Contract invested in any one of the sub-accounts on the date of the notice to another sub-account available under their Contract without regard to the usual limit on the frequency of transfers from the variable account options to the non-dollar cost averaging fixed account option. The notice will also reiterate that AGAIC will not exercise any rights reserved by it under the Contracts to impose additional restrictions on transfers until at least 30 days after the proposed substitutions. Notices delivered in certain states may also explain that, under the insurance regulations in those states, affected contract owners may exchange their Contracts for other annuity contracts issued by AGAIC (or one of its affiliates) during the 60 days following the proposed substitutions. The notices will be accompanied by current prospectuses for the portfolios/funds involved.

Applicants' Legal Analysis

1. Section 26(b) of the 1940 Act provides, in pertinent part, that “[i]t shall be unlawful for any depositor or trustee of a registered unit investment trust holding the security of a single issuer to substitute another security for such security unless the Commission shall have approved such substitution.” The purpose of Section 26(b) is to protect the expectation of investors in a unit investment trust that the unit investment trust will accumulate the shares of a particular issuer and to prevent unscrutinized which might, in effect, force shareholders dissatisfied with the substituted security to redeem their shares, thereby possibly incurring either a loss of the sales load deducted from initial purchase payments, an additional sales load upon reinvestment of the redemption proceeds, or both. Section 26(b) affords this protection to investors by preventing a depositor or trustee of a unit investment trust holding the shares of one issuer from substituting for those shares the shares of another issuer, unless the Commission approves that substitution.

2. AGAIC and the Account (the “Section 26(b) Applicants”) request that the Commission issue an order pursuant to Section 26(b) of the Act approving the substitutions by AGAIC of shares held by corresponding sub-accounts of the Account as follows: (a) Shares of AGSPC’s Government Securities Fund for shares of the Trust’s American General U.S. Government Securities Portfolio; (b) shares of AGSPC’s Growth & Income Portfolio for shares of the Trust’s Credit Suisse Growth & Income Portfolio; (c) shares of AGSPC’s International Equities Fund for shares of the Trust’s Credit Suisse International Equities Portfolio; (d) shares of OCCAT’s Emerging Growth Portfolio for shares of the Trust’s Elantax Emerging Growth Portfolio; (e) shares of AGSPC’s Stock Index Fund for shares of the Trust’s Elantax Growth Equity Portfolio; (f) shares of AGSPC’s Money Market Fund for shares of the Trust’s Elantax Global Advisors Money Market Portfolio; and (g) shares of LIT’s Emerging Growth Portfolio for shares of the Trust’s Van Kampen Emerging Growth Portfolio.

3. The Contracts expressly reserve to AGAIC the right, subject to compliance with applicable law, to substitute shares of another open-end investment company for shares of an open-end management investment company held by a sub-account of the Account. The prospectuses for the Contracts contain appropriate disclosure of this right.

4. In the case of the proposed substitution of shares of OCCAT’s
Managed Portfolio and LIT’s Emerging Growth Portfolio for shares of the Trust’s Elite Value and Van Kampen Emerging Growth Portfolios, the Trust’s portfolios are being replaced by the funds after which they were modeled. However, Applicants state that the replacement funds have substantially lower expense ratios, on a gross basis (and within 0.13% on a net basis); superior historical performance and investment objectives that are essentially identical.

5. With respect to the substitution of shares of AGSPC’s Government Securities Fund for shares of the Trust’s American General U.S. Government Securities Portfolio, shares of AGSPC’s Growth & Income Fund for shares of the Trust’s Credit Suisse Growth and Income Portfolio, and shares of AGSPC’s Money Market Fund for the Trust’s State Street Global Advisors Money Market Portfolio, Applicants state that the replacement funds have substantially lower expense ratios, on a gross basis (and within 0.05% on a net basis); superior historical performances, and investment objectives that are substantially the same.

6. With respect to the substitution of shares of AGSPC’s International Equity Fund for shares of the Trust’s Credit Suisse International Equity Portfolio, and shares of AGSPC’s Stock Index Portfolio for shares of the Trust’s State Street Global Advisors Growth Equity Portfolio, Applicants state that the replacement funds have also lower expense ratios, on a subsidized and unsubsidized basis; superior historical performance, and sufficiently similar investment objectives to make them appropriate replacement candidates.

7. The Substitution Applicants anticipate that Contract owners will be at least as well off with the array of sub-accounts offered after the proposed substitutions as they have been with the array of sub-accounts offered prior to the substitutions. If the proposed substitutions are carried out, all Contract owners will be permitted to allocate purchase payments and transfer Contract values between and among the same number of sub-accounts as they could before the proposed substitutions.

8. Applicants submit that none of the proposed substitutions is the type of substitution that Section 26(b) was designed to prevent. Unlike traditional unit investment trusts where a depositor could only substitute an investment security in a manner that permanently affected all the investors in the trust, the Contracts provide each Contract owner with the right to exercise his or her own judgment and transfer contract values into other sub-accounts. Moreover, Contract owners will be offered the opportunity to transfer amounts out of the affected sub-accounts without cost or other disadvantage. The proposed substitutions, therefore, will not result in the type of costly forced redemption that Section 26(b) was designed to prevent. In addition, other factors that may have influenced a Contract owner to purchase a Contract, such as AGAIC’s size, financial condition, and reputation and the type of insurance coverage and benefits provided by the Contract, will remain the same.

9. The Section 26(b) Applicants request an order of the Commission pursuant to Section 26(b) of the Act approving the proposed substitutions by AGAIC. The Section 26(b) Applicants submit that, for all the reasons stated above, the proposed substitutions are inconsistent with the protection of investors and the purposes fairly intended by the policy and provisions of the Act.

10. AGAIC, the Account, AGSPC and the Trust ("Section 17(b) Applicants") request an order pursuant to Section 17(b) of the 1940 Act exempting them from the provisions of Section 17(a) of the Act to the extent necessary to permit them to carry out the following proposed substitutions of shares held by corresponding sub-accounts of the Account: (1) Shares of AGSPC’s Government Securities Fund for shares of the Trust’s American General U.S. Securities Portfolio; (2) shares of AGSPC’s Growth & Income Fund for shares of the Trust’s Credit Suisse Growth and Income Portfolio; (3) shares of AGSPC’s International Equity Fund for shares of the Trust’s Credit Suisse International Equity Portfolio; (4) shares of AGSPC’s Stock Index Fund for shares of the Trust’s State Street Global Advisors Growth and Equity Portfolio; and (5) shares of AGSPC’s Money Market Fund for shares of the Trust’s State Street Global Advisors Money Market Portfolio (the "In Kind Transactions").

11. Section 17(a)(1) of the 1940 Act, in relevant part, prohibits any affiliated person of a registered investment company, or any affiliated person of such a person, acting as principal, from knowingly selling any securities or other property to that company. Section 17(a)(2) of the Act generally prohibits the same persons, acting as principals, from knowingly purchasing any security or other property from the registered investment company.

12. Section 2(a)(3) of the 1940 Act defines the term “affiliated person of” to have the following part as: (A) Any person directly or indirectly owning, controlling, or holding with power to vote, 5 percent or more of the outstanding voting securities of such other person; (B) any person 5 percent or more of whose outstanding voting securities are directly or indirectly owned, controlled, or held with power to vote, by such other person; and (C) any person directly or indirectly controlling, controlled by, or under common control with, such other person.

13. Applicants submit that the Trust and AGSPC and the portfolios/funds of each may be affiliated persons of each other or affiliated persons of affiliated persons of each other. Each may also be an affiliate person of AGAIC. The proposed In Kind Transactions could be seen as the indirect purchase of shares of AGSPC funds with portfolio securities of the Trust’s portfolios and the indirect sale of portfolio securities of the Trust’s portfolios for shares of the AGSPC funds. Pursuant to this analysis, the proposed In Kind Transactions could also be viewed as a purchase or sale of such securities to funds of AGAIC by AGAIC acting as principal. If categorized in this manner, the proposed In Kind Transactions would contravene Section 17(a).

14. Section 17(b) of the Act provides that the Commission may, upon application, issue an order exempting any proposed transaction from the provisions of Section 17(a) if evidence establishes that: (1) The terms of the proposed transaction, including the consideration to be paid or received, are reasonable and fair and do not involve overreaching on the part of any person involved in the transaction; (2) the proposed transaction is consistent with the policy of each registered investment company concerned; (3) the proposed transaction is consistent with the general purposes of the Act.

15. Rule 17a–7 under the 1940 Act exempts from the prohibitions of Section 17(a), subject to certain enumerated conditions, a purchase or sale transaction between registered investment companies or separate series of registered investment companies, which are affiliated persons, or affiliated persons of affiliated persons, of each other, between separate series of a registered investment company, or between a registered investment company or a separate series of a registered investment company and a person which is an affiliated person of such registered investment company (or affiliated person of such person) solely by reason of common control, common investment advisor or investment advisors which are affiliated persons of...
each other, common directors, and/or common officers.

16. AGAIC, the Trust and AGSPC cannot, however, rely on Rule 17a–7 in connection with their participation as principals in the proposed In Kind Transaction because they are not affiliated persons of each other solely by reason of having a common investment advisor or affiliated investment advisors, common directors, and/or common officers. Moreover, one of the conditions enumerated in Rule 17a–7 requires that the transaction be a purchase or sale, for no consideration other than cash payment against prompt delivery of a security for which market quotations are readily available. The proposed purchase of AGSPS shares with the Trust’s securities, however, entails the purchase and sale of securities for securities.

17. The Section 17(b) Applicants submit that the terms of the proposed substitutions by AGAIC, including the consideration to be paid and received, are reasonable fair and do not involve overreaching on the part of any person concerned. The Section 17(b) Applicants also submit that the proposed In Kind Transactions are consistent with the policies of each of the investment companies involved as recited in the current registration statements and reports filed by the Trust filed under the 1940 Act.

18. The Section 17(b) Applicants maintain that the terms of the proposed transaction, including the consideration to be paid and received, are reasonable, fair and do not involve overreaching because (1) the transactions do not cause owner’s interests under a contract to be diluted and (2) the transactions will comply with the conditions set forth in Rule 17a–7, other than the requirement related to consideration. The In Kind Transaction will take place at relative net asset value with no change in amount of any Contract owner’s contract or cash value or death benefit or the dollar value of his or her investment in the account.

19. The Section 17 Applicants state that the board of trustees/directors of the Trust and AGSPC have adopted procedures, as required by paragraph (e)(1) of Rule 17a–7, pursuant to which the series of each may purchase and sell securities to and from their affiliates. The Section 17(b) Applicants represent that they will carry out the proposed substitutions in conformity with the conditions of Rule 17a–7 and each series’ procedures thereunder, except that the consideration paid for the securities purchased or sold will not be entirely in cash. The proposed transactions will be effected based upon the independent current market price of the portfolio securities valued as specified in paragraph (b) of Rule 17a–7 and the net asset value per share of each fund involved will be valued in accordance with the procedures disclosed in the Trust’s and AGSPC’s registration statements and as required by Rule 22c–1 under the Act. No brokerage commission, fee, or other remuneration will be paid to any party in connection with the proposed transactions. In addition, the boards of trustees/directors of each of the Trust and AGSPC will subsequently review the proposed substitutions and make determinations required by paragraph (e)(3) of Rule 17a–7.

20. Applicants assert that the proposed redemption of shares of the Trust is consistent with the investment policy of the Trust and each of its portfolios, provided that the shares are redeemed at their net asset value in conformity with Rule 22c–1 under the Act. Likewise, the sales of shares of the AGSPC funds for investment securities, as contemplated by the proposed substitutions, is consistent with the investment policies of each of its funds, as recited in AGSPC’s registration statement, provided that (a) the shares are sold at their net asset value and (b) the investment securities are of the type and quality that the respective funds would each have acquired with the proceeds from share sales had the shares been sold for cash. To assure that the second condition is met, VALIC will examine the portfolio securities being offered to each AGSPC fund and accept only those securities as consideration for shares that it would have acquired for such fund in a cash transaction.

21. The Section 17(b) Applicants submit that, for all the reasons stated above, the terms of the proposed In Kind Transactions, including the consideration to be paid and received, are reasonable and fair to: (1) AGSPC and its funds, (2) the Trust and its portfolios, and (3) Contract owners invested in AGSPC’s funds and the Trust portfolios; and do not involve overreaching on the part of any person concerned. Furthermore, the Section 17(b) Applicants represent that the proposed substitutions will be consistent with the policies of: (a) AGSPC and its funds and (b) the Trust and its portfolios, as is, or will be, stated in the registration statement and reports filed under the Act by each, and with the general purposes of the Act.

Conclusion

Applicants assert that, for the reasons and upon the facts set forth above, the requested orders meet the standards set forth in Sections 26(b) and 17(b) of the 1940 Act and should be granted.

For the Commission, by the Division of Investment Management, pursuant to delegated authority.

Jonathan G. Katz,
Secretary.

[FR Doc. 99–31390 Filed 12–2–99; 8:45 am]

BILLING CODE 8010–01–M

SECURITIES AND EXCHANGE COMMISSION

Sunshine Act Meeting

Notice is hereby given, pursuant to the provisions of the Government in the Sunshine Act, Pub. L. 94–409, that the Securities and Exchange Commission will hold the following meeting during the week of December 6, 1999.

An open meeting will be held on Wednesday, December 8, 1999 at 10:00 a.m.

The subject matter of the open meeting scheduled for Wednesday, December 8, 1999, at 10:00 a.m., will be:

Adopting an amendment to the Intermarket Trading Systems (ITS) Plan, expanding the ITS/Computer Assisted Execution System linkage to all listed securities. For further information, please contact Christine Richardson at (202) 942–0748.

Issuing a concept release on market information fees and the role of revenues generated by such fees in funding the operation and regulation of the markets. The release would describe the current arrangements for disseminating market information and invite public comment on ways in which the arrangements could be revised to further the Securities Exchange Act of 1934 (“Exchange Act”) national market system objectives. For further information, please contact Daniel M. Gray at (202) 942–4164.

Proposing an amendment to Rule 12f–2 under the Exchange Act which governs unlisted trading privileges in listed initial public offerings. For further information, please contact Kevin Ehrlich at (202) 942–0778.

The Commission will hear oral argument on an appeal by the Division of Enforcement from an administrative law judge’s initial decision imposing sanctions on Clarence Z. Wurts. The law judge found that Wurts failed reasonably to supervise Michael G. Cohen, a registered representative, with a view to preventing violations of the federal securities laws. For further information, please contact Diane V. White at (202) 942–0959.

At times, changes in Commission priorities require alternations in the
On August 6, 1999.2 No comment letters was published in the agreement approved by the Commission is substantially similar to the form of agreement with each of these entities (``ISCC''). According to EMCC, the form Securities Clearing Corporation (``GSCC''), and the International Securities Clearing Corporation (``NSCC''), the Government agency cross-guaranty agreements with the Government National Securities Clearing Corporation (``NSCC'').4 Generally, the limited cross-guaranty provided for by the clearing agency cross-guaranty agreements is invoked when a clearing entity ceases to act for a common member. This limited guaranty enables clearing agencies that have entered into limited cross-guaranty agreements to benefit from a defaulting member’s excess collateral at other clearing agencies in which the defaulting member was a participant. The guaranty provides that resources of the defaulting common member remaining after the defaulting common member’s obligations to the guaranteeing clearing agency have been satisfied may be used to satisfy any unsatisfied obligations to the other clearing agencies. The guaranty is limited to the extent of the resources relative to the defaulting common member remaining at the guaranteeing clearing agency. EMCC believes that the clearing agency cross-agency agreements should be beneficial because the funds that may be made available to it may provide resources that may make a pro rata charge against its clearing fund unnecessary or lesser in amount. The benefits accruing to EMCC from a clearing agency cross-guaranty agreement are illustrated by the following example:

Broker-dealer BD upon insolvency owes EMCC a net of $5 million. BD is owed a net of $3 million by Clearing Entity X. In the absence of a clearing agency cross-guaranty agreement, Clearing Entity X would be obligated to pay $3 million to BD’s bankruptcy estate, and EMCC would have a claim for $5 million against BD’s bankruptcy estate as a general creditor with no assurance as to the extent of recovery. Under an effective cross-guaranty agreement, however, Clearing Entity X would pay to EMCC the $3 million it owed to BD. As a result, EMCC’s net exposure to the defaulting common member BD would be reduced.

II. Discussion

Section 17A(b)(3)(F) of the Act requires that the rules of a clearing agency be designed to assure the safeguarding of securities in the custody or control of the clearing agency or for which it is responsible and to foster cooperation and coordination with persons engaged in the clearance and settlement of securities transactions. The Commission believes that the proposal is consistent with EMCC’s obligation to assure the safeguarding of securities and funds in the custody or control of the clearing agency for which it is responsible because cross-guarantee agreements among clearing entities are a method of reducing risk of loss due to a common member’s default. Furthermore, the Commission has encouraged the use of cross-guarantee agreements and other similar arrangements among clearing agencies.5 Consequently, cross-guarantee agreements should assist clearing agencies in assuring the safeguarding of securities and funds in their custody or control.

The Commission also believes the proposals are consistent with EMCC’s obligation to foster cooperation and coordination with persons engaged in the clearance and settlement of securities transactions. The Commission believes that by entering into such agreements, EMCC can mitigate the systematic risks posed to it and to the national clearance and settlement system as a result of a defaulting common member.

III. Conclusion

On the basis of the foregoing, the Commission finds that the proposals are consistent with the requirements of the Act, and in particular with the requirements of Section 17A of the Act and the rules and regulations thereunder.

It is Therefore Ordered, pursuant to Section 19(b)(2) of the Act, that the proposed rule change [File No. SR–EMCC–99–7] be, and hereby is, approved.

For the Commission by the Division of Market Regulation, pursuant to delegated authority.6

Jonathan G. Katz,
Secretary.

[FR Doc. 99–31391 Filed 12–2–99; 8:45 am]
BILLING CODE 8010–01–M

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3 Under EMCC’s Rule 1, “clearing agency cross-guaranty agreement” means an agreement between EMCC and another clearing entity relating to the guaranty by EMCC of certain obligations of a member to such clearing entity.
SECURITIES AND EXCHANGE
COMMISSION


Self-Regulatory Organizations; The Options Clearing Corporation; Notice of Filing and Order Granted
Accelerated Approval of a Proposed
Rule Change Relating to Closing Early

November 19, 1999.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"), notice is hereby given that on October 27, 1999, 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 by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's
Statement of the Terms of Substance of the
Proposed Rule Change

The proposed rule change would allow OCC the flexibility, with notice to its Clearing Members, to set earlier cut-off times in Rule 801 when OCC's participant exchanges close early.

II. Self-Regulatory Organization's
Statement of the Purpose of, and
Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The self-regulatory organization has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.1

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

The purpose of the proposed rule change is to provide OCC the flexibility to deviate, with notice to its Clearing Members, from the cut-off times designated in OCC's Rule 801 on those dates when OCC's participant exchanges announce an early close. For example, the rule change would apply to early market closes scheduled for November 26, 1999 and December 31, 1999.

Rule 801 designates specific cut-off times for the exercise of options on business days other than the business day preceding the expiration date. These times include the time by which exercise notices must be submitted and the time when they become irrevocable. In respect of most American option contracts, the time for both of these events is 7:00 p.m.2 OCC is unable to commence its processing until after that time, as the exercises made during a business day are an integral part of OCC's nightly processing. When the exchanges close early, OCC has to wait for hours before it can close the window for exercise notices and begin nightly processing. Likewise, Clearing Members have to wait for critical production reports from OCC. The flexibility to deviate from the designated time in Rule 801 when the participant exchanges close early would allow OCC to process early and generate critical reports to Clearing Members on a more timely basis. Thus, it would provide for a more prompt clearance and settlement process and benefit both OCC and its Clearing Members.

The ability to process early is even more critical for December 31, 1999. The participant exchanges have announced an early market close for that day. OCC would like to complete its processing that day by midnight in an effort to reduce any year 2000 related problems, including the potential for any issues caused by third party vendors. OCC's nightly processing for December 31, includes both its processing for that trading day and its year-end processing. Early processing would better ensure that timely reports will be provided to OCC's Clearing Members. It would also give OCC more time to address any problems that might arise. Thus, for that day, the flexibility to change the times under Rule 801 would provide both the prompt and accurate clearance and settlement of securities transactions.

To help achieve the goal of completing processing by midnight on December 31, the exchanges have agreed to transmit their matched and unmatched trade files to OCC early. However, as previously stated, to commence early processing, it is necessary to advance the cut-off time for exercises. OCC anticipates providing Clearing Members with the same amount of time to transmit post-trading activity and exercise notices to OCC as after a regular market close. However, as a result of this earlier processing by OCC, Clearing members would receive critical production reports earlier, allowing them to complete their own internal processing for December 31 on a more timely basis.

The exchanges have also announced an early market close for November 26, 1999, the day after Thanksgiving. On that day, OCC and the exchanges would like to process early as a test for the early processing scheduled for December 31. The rule change would allow OCC the flexibility to conduct this "test run."

The proposed rule change is consistent with Section 17A of the Act, because it promotes the prompt and accurate clearance and settlement of securities transactions by giving OCC flexibility to begin processing early.

B. Self-Regulatory Organization's Statement on Burden on Competition

OCC does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act, in the public interest, and for the protection of investors.

C. Self-Regulatory Organization's
Statement on Comments on the
Proposed Rule Change Received from
Members, Participants or Others

Written comments were not and are not intended to be solicited with respect to the proposed rule change and none have been received.

III. Date of Effectiveness of the
Proposed Rule Change and Timing for
Commission Action

OCC requests accelerated effectiveness of this filing pursuant to Section 19(b)(2) inasmuch as such treatment is necessary to enable OCC to provide adequate notice to its Members of the time changes for the November 25, 1999 and December 31, 1999 processing schedules so they can notify their customers.

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. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, NW, Washington, DC 20549-0609. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written

2 The Commission has modified the text of the summaries prepared by OCC.
3 All times herein are Central time.
communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission’s Public Reference Section, 450 Fifth Street, NW, Washington, DC 20549. Copies of such filing will also be available for inspection and copying at the principal office of the above-mentioned self-regulatory organization. All submissions should refer to the file number in the caption above and should be submitted by December 27, 1999.

It is Therefore ordered, pursuant to Section 19(b)(2) of the Act, that the proposed rule change (File No. SR–OCC–99–13) be, and hereby is, approved on an accelerated basis.

For the Commission by the Division of Market Regulation, pursuant to delegated authority.

Jonathan Katz, Secretary.
[FR Doc. 99–31392 Filed 12–2–99; 8:45 am]
BILLING CODE 8010–01–M

DEPARTMENT OF STATE
[Notice No. 3165]

Shipping Coordinating Committee, Subcommittee on Ship Design and Equipment; Meeting Notice

The Shipping Coordinating Committee will conduct an open meeting at 1:00 pm on Tuesday, December 7, 1999, in Room 6103, at U.S. Coast Guard Headquarters, 2100 2nd Street, SW, Washington, DC 20593–0001. The purpose of the meeting is to prepare for the forty-third session of the Subcommittee on Ship Design and Equipment of the International Maritime Organization (IMO) which is scheduled for April 10–14, 2000, at IMO Headquarters in London, England. Among other things, items of particular interest are: revision of the High Speed Craft Code; revision of resolutions MEPC.60(33) and A.586(14) regarding pollution prevention equipment; safety of passenger submersible craft; asbestos-related problems on board ships; casualty analysis; development of guidelines for ships operating in ice-covered waters; developments on requirements for wing-in-ground craft; low-powered radio homing devices for liferafts on ro-ro passenger ships; international approval procedures for life-saving appliances; improved thermal protection; amendments to resolution A.744(18) regarding guidelines on the enhanced program of inspections during surveys of bulk carriers and oil tankers; and guidelines under MARPOL Annex VI on prevention of air pollution from ships.

IMO works to develop international agreements, guidelines, and standards for the marine industry. In most cases, these form the basis for class society rules and national standards/regulations. Such an open meeting supports the U.S. Representative to the IMO Subcommittee in developing the U.S. position on those issues raised at the IMO Subcommittee meetings. This open meeting serves as an excellent forum for the public to express their ideas and participate in the international rulemaking process. All members of the public are encouraged to attend or send representatives to participate in the development of U.S. positions on those issues affecting your maritime industry and remain abreast of all activities ongoing within the IMO.

Members of the public may attend this meeting up to the seating capacity of the room. Interested persons may seek information by writing: Mr. Wayne Lundy, U.S. Coast Guard Headquarters, Commandant (G–MSE–3), 2100 2nd Street, SW, Washington, DC 20593–0001 or by calling: (202) 267–2206.

Dated: November 30, 1999.

Stephen M. Miller, Executive Secretary, Shipping Coordinating Committee.
[FR Doc. 99–31550 Filed 12–2–99; 8:45 am]
BILLING CODE 4710–07–U

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Antidrug and Alcohol Misuse Prevention Programs for Personnel Engaged in Specified Aviation Activities

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice.

SUMMARY: The FAA has determined that the minimum percentage rate for drug testing for the period January 1, 2000, through December 31, 2000, will remain at 25 percent of covered aviation employees for random drug testing and will remain at 10 percent of covered aviation employees for random alcohol testing.

FOR FURTHER INFORMATION CONTACT: Ms. Patrice M. Kelly, Office of Aviation Medicine, Drug Abatement Division, Program Analysis Branch (AAM–810), Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone (202) 267–8976.

SUPPLEMENTARY INFORMATION:

Administrator’s Determination of 1999 Random Drug and Alcohol Testing Rates

In final rules published in the Federal Register on February 15, and December 2, 1994 (59 FR 7380 and 62218, respectively), the FAA announced that it will set future minimum annual percentage rates for random alcohol and drug testing for aviation industry employers according to the results which the employers experience conducting random alcohol and drug testing during each calendar year. The rules set forth the formula for calculating an annual aviation industry “violation rate” for random alcohol testing and an annual aviation industry “positive rate” for random drug testing. The “violation rate” for random alcohol tests means the number of covered employees found during random tests given under 14 CFR part 121, appendix J to have an alcohol concentration of 0.04 or greater plus the number of employees who refused a random alcohol test, divided by the total reported number of employees given random alcohol tests plus the total reported number of employees who refused a random test. The “positive rate” means the number of positive results for random drug tests conducted under 14 CFR part 121, appendix I plus the number of refusals to take random drug tests, divided by the total number of random drug tests plus the number of refusals to take random drug tests. The violation rate and the positive rate are calculated using information required to be submitted to the FAA by specified aviation industry employers as part of an FAA Management Information System (MIS) and form the basis for maintaining or adjusting the minimum annual percentage rates for random alcohol and drug testing as indicated in the following paragraphs.

When the annual percentage rate for random alcohol testing is 25 percent or more, the FAA Administrator may lower the rate to 10 percent if data received under the MIS reporting requirements for two consecutive calendar years indicate that the violation rate is less than 5 percent.

When the minimum annual percentage rate for random alcohol testing is 50 percent, the FAA Administrator may lower the rate to 25 percent if data received under the MIS reporting requirements for two consecutive calendar years indicate that
the violation rate is less than 1.0 percent but equal to or greater than 0.5 percent.

When the minimum annual percentage rate for random alcohol testing is 10 percent, and the data received under the MIS reporting requirements for that calendar year indicate that the violation rate is equal to or greater than 0.5 percent but less than 1.0 percent, the FAA Administrator must increase the minimum annual percentage rate for random alcohol testing to 25 percent.

When the minimum annual percentage rate for random alcohol testing is 25 percent or less, and the data received under the MIS reporting requirements for that calendar year indicate that the violation rate is equal to or greater than 1.0 percent, the FAA Administrator will increase the minimum annual percentage rate for random alcohol testing to 50 percent.

When the minimum annual percentage rate for random drug testing is 25 percent, and the data received under the MIS reporting requirements for any calendar year indicate that the reported positive rate is equal to or greater than 1.0 percent, the Administrator will increase the minimum annual percentage rate for random drug testing to 50 percent.

There is a one year lag in the adjustment in the minimum annual percentage rates for random drug and alcohol testing because MIS data for a given calendar year is not reported to the FAA until the following calendar year. For example, MIS data for 1997 is not reported to the FAA until March 15, 1998, and any rate adjustments resulting from the 1997 data are not effective until January 1, 1999, following publication by the FAA of a notice in the Federal Register.

The minimum annual percentage rate for random alcohol testing was 10 percent for calendar year 1999. In this notice, the FAA announces that it has determined that the violation rate for calendar year 1998 is less than one percent positive, at approximately 0.14 percent. Since the data received for that calendar year do not indicate that the violation rate is equal to or greater than 0.5 percent but less than 1.0 percent, the minimum annual percentage rate for random alcohol testing for aviation industry employers for calendar year 2000 will remain at 10 percent.

The minimum annual percentage rate for random drug testing was 25 percent in calendar year 1999. Therefore, the FAA is also announcing that it has determined that the positive rate for calendar year 1998 is less than 1 percent, at approximately 0.68 percent, and that the minimum annual percentage rate for random drug testing for aviation industry employers for calendar year 2000 will remain at 25 percent.


Robert Poole,
Acting Federal Air Surgeon.

[FR Doc. 99–31405 Filed 12–2–99; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF THE TREASURY

Departmental Offices

Privacy Act of 1974, as Amended; System of Records

AGENCY: Departmental Offices, Treasury.

ACTION: Notice of alteration to Privacy Act System of Records.

SUMMARY: The Department is consolidating systems of records pertaining to the implementation of the Freedom of Information Act and Privacy Act programs into one Treasury-wide system of records. The system of records Treasury/DO .150—Disclosure Records will be renamed “Freedom of Information Act/Privacy Act Request Records.”

DATES: Comments must be received no later than January 3, 2000. The proposed alterations to the system of records will be effective January 12, 2000, unless the Department receives comments that would result in a contrary determination.

ADDRESSES: Comments should be sent to Departmental Disclosure Office, Room 1054 MT, Department of the Treasury, Washington, DC 20220.


SUPPLEMENTARY INFORMATION: The Department is consolidating systems of records pertaining to the implementation of the Freedom of Information and Privacy Act programs into one Treasury-wide system of records. The notices for the systems of records were last published in their entirety beginning at 63 FR 69716 on December 17, 1998. Each Treasury bureau (except the Internal Revenue Service) is listed under “System Location” and the disclosure official for each bureau is identified as a “System Manager.” The Internal Revenue Service will retain its own system of records Treasury/IRS 48.001—Disclosure Records since it pertains not only to requests for disclosure pursuant to the Freedom of Information Act and the Privacy Act, but also to the disclosure of returns and return information as provided by the Internal Revenue Code (26 U.S.C. 6103, 7801 and 7802).

The notice also revises existing routine uses, adds five new routine uses, and revises the policies and practices for storing, retrieving, accessing, retaining, and disposing of the records in the system.

The following systems of records notices will be deleted on January 12, 2000:

ATF .005—Freedom of Information Requests
CC .012—Freedom of Information Index and Log
CS .078—Disclosure of Information File
DEPARTMENT OF THE TREASURY

BEP .040—Freedom of Information and Privacy Act Requests
OTIS .010—Inquiry/Request Control

The altered system of records report, as required by 5 U.S.C. 552a(r) of the Privacy Act, has been submitted to the Committee on Government Reform and Oversight of the House of Representatives, the Committee on Government Affairs of the Senate, and the Office of Management and Budget, pursuant to Appendix I to OMB Circular A–130, Federal Agency Responsibilities for Maintaining Records About Individuals, dated February 8, 1996. This system of records, Treasury/DO .150—“Freedom of Information Act/Privacy Act Request Files” is published in its entirety below.


Shelia Y. McCann,
Deputy Assistant Secretary (Administration).

Treasury/DO .150

SYSTEM NAME: Freedom of Information Act/Privacy Act Request Records—Treasury/DO.

SYSTEM LOCATION:

Department of the Treasury, 1500 Pennsylvania Avenue, NW., Washington, DC 20220. The locations at which the system is maintained by Treasury components and their associated field offices are:

(a) Departmental Offices (DO), which includes the Financial Crimes Enforcement Network (FinCEN), and the Office of Inspector General (OIG);

(b) Bureau of Alcohol, Tobacco and Firearms (ATF);
THE PURPOSES OF SUCH USES:
these records may be used to:

- SYSTEM, INCLUDING CATEGORIES OF USERS AND ROUTINE USES OF RECORDS MAINTAINED IN THE
- and other Department management
- compliance with the FOIA/PA and to
- administratively control and/or process
- PURPOSE(S):
- The system is used by officials to
- to employees responsible for the
- system and/or employees of program offices who have

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:
Individuals who have: (1) Requested access to records pursuant to the Freedom of Information Act of 1974, as amended, 5 U.S.C. 552, (FOIA) or who have appealed initial denials of their requests; and/or (2) made a request for access, amendment or other action pursuant to the Privacy Act of 1974, 5 U.S.C. 552a (PA).

CATEGORIES OF RECORDS IN THE SYSTEM:
Requests for records or information pursuant to the FOIA and/or PA which includes the names of individuals making written requests for records under the FOIA or the PA, the mailing addresses of such individuals, and the dates of such requests and their receipt. Supporting records include the written correspondence received from requesters and responses made to such requests; internal processing documents and memoranda, referrals and copies of records provided or withheld, and may include legal memoranda and opinions. Comparable records are maintained in this system with respect to any appeals made from initial denials of access, refusal to amend records and lawsuits under the FOIA/PA.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

PURPOSE(S):
The system is used by officials to administratively control and/or process requests for records to ensure compliance with the FOIA/PA and to collect data for the annual and biennial reporting requirements of the FOIA/PA and other Department management report requirements.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:
These records and information in these records may be used to:

1. Disclose pertinent information to appropriate Federal, foreign, State, local, tribal or other public authorities or self-regulatory organizations responsible for investigating or prosecuting the violations of, or for enforcing or implementing, a statute, rule, regulation, order, or license, where the disclosing agency becomes aware of an indication of a violation or potential violation of civil or criminal law or regulation;
2. Disclose information to a court, magistrate, or administrative tribunal in the course of presenting evidence, including disclosures to opposing counsel or witnesses in the course of civil discovery, litigation, or settlement negotiations, in response to a subpoena, or in connection with criminal law proceedings;
3. Provide information to a congressional office in response to an inquiry made at the request of the individual to whom the record pertains;
4. Disclose information to another Federal agency to (a) permit a decision as to access, amendment or correction of records to be made in consultation with or by that agency, or (b) verify the identity of an individual or the accuracy of information submitted by an individual who has requested access to or amendment or correction of records.
5. The Department of Justice when seeking legal advice, or when (a) the agency or (b) any component thereof, or (c) any employee of the agency in his or her official capacity, or (d) any employee of the agency in his or her individual capacity where the Department of Justice has agreed to represent the employee, or (e) the United States, where the agency determines that litigation is likely to affect the agency or any of its components, is a party to litigation or has an interest in such litigation, and the use of such records by the Department of Justice is deemed by the agency to be relevant and necessary to the litigation.
6. Disclose information to the appropriate foreign, State, local, tribal, or other public authority or self-regulatory organization for the purpose of (a) consulting as to the propriety of access to or amendment or correction of information obtained from that authority or organization, or (b) verifying the identity of an individual who has requested access to or amendment or correction of records.
7. Disclose information to contractors and other persons who have been engaged by the Department or one of its bureaus to provide products or services associated with the Department’s or bureau’s responsibility arising under the FOIA/PA.
8. Disclose information to the National Archives and Records Administration for use in records management inspections.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:
Electronic media, computer paper printout, index file cards, and paper records in file folders.

RETRIEVABILITY:
Retrieved by name, subject, request file number or other data element as may be permitted by an automated system.

SAFEGUARDS:
Protection and control of any sensitive but unclassified (SBU) records are in accordance with TD P 71–10, Department of the Treasury Security Manual, and any supplemental guidance issued by individual bureaus. Access to the records is available only to employees responsible for the management of the system and/or employees of program offices who have a need for such information.

RETENTION AND DISPOSAL:
The records pertaining to Freedom of Information Act and Privacy Act requests are retained and disposed of in accordance with the National Archives and Records Administration’s General Record Schedule 14—Information Services Records.

SYSTEM MANAGER(S) AND ADDRESS:
Department of the Treasury: Official prescribing policies and practices—Departmental Disclosure Officer, Department of the Treasury, Room 1054 MT, 1500 Pennsylvania Avenue, NW., Washington, DC 20220.

The system managers for the Treasury components are:
DO: Assistant Director, Disclosure Services, Room 1054–MT, Department of the Treasury, Washington, DC 20220
ATF: Chief, Disclosure Division, 650 Massachusetts Avenue, NW, Washington, DC 20226
BEP: Disclosure Officer, FOIA Office, 14th & C Streets, SW, Washington, DC 20228
FLETC: FOIA/PA Officer, Department of the Treasury, Building 94, Glynco, GA 31524
FMS: Disclosure Officer, 401 14th Street, SW, Washington, DC 20227
Mint: FOIA/PA Officer, Judiciary Square Building, 633 3rd Street, NW, Washington, DC 20220

(c) Office of the Comptroller of the Currency (OCC);
(d) United States Customs Service (CS);
(e) Bureau of Engraving and Printing (BEP);
(f) Federal Law Enforcement Training Center (FLETC);
(g) Financial Management Service (FMS);
(h) United States Mint (MINT);
(i) Bureau of the Public Debt (BPD);
(j) United States Secret Service (USSS);
(k) Office of Thrift Supervision (OTS).
(l) Treasury Inspector General for Tax Administration (TIGTA)
DEPARTMENT OF THE TREASURY

Community Development Financial Institutions Fund; Proposed Collection; Comment Request

ACTION: Notice and request for comments.

SUMMARY: The Department of 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 104–13 (44 U.S.C. 3506(c)(2)(A)). The Community Development Financial Institutions Fund (the Fund) within the Department of the Treasury is soliciting comments concerning its Native American Lending Study surveys of tribal leaders, economic development officials and other public and private sector persons familiar with barriers to lending in Indian Country in order to gather systematic statistical information for the survey.

Type of review: New collection.

Affected Public: Tribal housing and economic development officials and other public and private sector persons familiar with lending in Indian Country.

Estimated Number of Respondents: 1600.

Estimated Annual Time Per Respondent: 30 minutes.

Estimated Total Annual Burden Hours: 800 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; (d) Ways to minimize the burden of the collection of information on respondents, including through the use of technology; and (e) Estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.


Maurice A. Jones,
Deputy Director for Policy and Programs, Community Development Financial Institutions Fund.

[FR Doc. 99–31335 Filed 12–2–99; 8:45 am]
DEPARTMENT OF THE TREASURY

Office of Thrift Supervision

Submission for OMB Review; Comment Request

November 22, 1999.

The Office of Thrift Supervision (OTS) 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. Interested persons may obtain copies of the submission(s) by calling the OTS Clearance Officer listed. Send comments regarding this information collection to the OMB reviewer listed and to the OTS Clearance Officer, Office of Thrift Supervision, 1700 G Street, NW., Washington, D.C. 20552.

DATES: Submit written comments on or before February 1, 2000.

OMB Number: 1550.

Form Number: Not applicable.

Type of Review: New collection.

Title: Voluntary External Audits.

Description: Interagency Policy Statement that recommends that financial institutions with assets less than $500 million voluntarily have an external auditing program that includes an annual audit of the financial statements by an independent public accountant.

Respondents: Savings and Loan Associations and Savings Banks.

Estimated Number of Recordkeepers: 1,100.

Estimated Burden Hours Per Recordkeeper: .75 hour.

Frequency of Response: 3.

Estimated Total Recordkeeping Burden: 825 hours

Clearance Officer: Mary Rawlings-Milton, (202) 906–6028, Office of Thrift Supervision, 1700 G Street, NW., Washington, DC 20552.


John E. Werner,
Director, Information Management and Services.

MORRIS K. UDALL SCHOLARSHIP AND EXCELLENCE IN NATIONAL ENVIRONMENTAL POLICY FOUNDATION

U.S. Institute for Environmental Conflict Resolution; Application for National Roster of Dispute Resolution and Consensus Building Professionals

AGENCY: Morris K. Udall Scholarship and Excellence in National Environmental Policy Foundation.

ACTION: Notice of availability of application.

SUMMARY: The Foundation is publishing this notice on behalf of the U.S. Institute for Environmental Conflict Resolution to provide interested environmental conflict resolution professionals with information regarding the application process for the National Roster of Dispute Resolution and Consensus Building Professionals.

DATES: Application period is open and continuous; however, the initial roster will be constituted at the end of November 1999.


FOR FURTHER INFORMATION CONTACT: Joan C. Calcagno, Roster Manager, 520–670–5299; E-mail: Roster@ecr.gov.

SUPPLEMENTARY INFORMATION: The U.S. Institute for Environmental Conflict Resolution is now accepting applications for the National Roster of Dispute Resolution and Consensus Building Professionals. The roster will include practitioners with experience as neutrals on environmental issues. it will serve as a resource for the Institute in making referrals and subcontracting with practitioners on Federal projects and as a resource for Federal agencies when seeking to contract with a practitioner. The roster will eventually be available to all on the web.

The roster application can be completed and submitted online from the Institute’s web site: www.ecr.gov. Complete information about the Institute, the development and purpose of the roster, the entry criteria and a score sheet are available for your use and review on the Institute’s web site. The application process is ongoing and continuous and you are encouraged to apply at any time; however, an initial roster will be constituted at the end of November 1999. Online applications are encouraged. For those without online capability, hard copy applications are available from the Institute.

Dated the 3rd day of November 1999.

Christopher L. Helms,
Executive Director.

[FR Doc. 99–31317 Filed 12–2–99; 8:45 am]

BILLING CODE 6720–01–P
Friday
December 3, 1999

Part II

Department of Labor
Employment and Training Administration

20 CFR Part 604
Birth and Adoption Unemployment Compensation; Proposed Rule
I. Background
A. General Overview

(1) Need for Birth and Adoption Leave

On May 23, 1999, the President directed the Secretary of Labor to issue a regulation allowing unemployment fund moneys to be used to provide partial wage replacement to mothers and fathers on leave following the birth or adoption of a child. In discussing the importance of providing partial wage replacement, the President stated: “[T]hose first weeks of life are critical to the bonding of parents and children, and they can have long-term positive developments for the children. No parent should have to miss them.” The President also noted that, “We can do this in a way that preserves the soundness of the unemployment insurance system and continues to promote economic growth.”

The President elaborated on this Birth and Adoption UC proposal in a May 24, 1999, memorandum to the heads of executive departments:

First, I hereby direct the Secretary of Labor to propose regulations that enable States to develop innovative ways of using UC to support parents taking approved leave or otherwise leave following the birth or adoption of a child. This effort responds to the President’s Executive Memorandum issued May 24, 1999, directing the Secretary of Labor to allow States the opportunity to develop innovative ways of using UC to support parents taking leave to be with their newborns or newly-adopted children and to evaluate the effectiveness of using the UC system for these or related purposes. This regulation will permit interested States to experiment with methods for allowing the use of the UC program for this purpose.

DATES: DOL invites written comments on this proposal. Comments are to be submitted by January 18, 2000.

ADDRESSES: Submit written comments to Grace A. Kilbane, Director, Unemployment Insurance Service, Employment and Training Administration (ETA), U.S. Department of Labor, 200 Constitution Avenue, N.W., Room S–4231, Washington, DC 20210. Prior to issuance of this Notice of Proposed Rulemaking, the DOL received correspondence on the subject matter of the proposal. This correspondence, along with correspondence received in response to the Notice of Proposed Rulemaking, will be made part of the rulemaking record and will be considered in the development of a final rule.

FOR MORE INFORMATION CONTACT: Gerard Hildebrand, Unemployment Insurance Service, ETA, U.S. Department of Labor, 200 Constitution Avenue, N.W., Room S–4231, Washington, DC 20210. Telephone: (202) 219–5200 ext. 391 (this is not a toll-free number); facsimile: (202) 219–8506.

SUPPLEMENTARY INFORMATION:
In response to practical economic and societal concerns, the DOL has previously, as discussed below, exercised its authority to interpret Federal UC statutes regarding the able and available requirements to address several specific areas: training, illness, jury duty and temporary layoffs. Under its authority to interpret Federal UC law and consistent with its broad oversight responsibility, the DOL interprets the Federal able and available requirements to include a voluntary experimental program for examining the use of the UC program to provide partial wage replacement to employees who take approved leave or otherwise leave employment to be with their newborns or newly-adopted children. This experiment recognizes the impact of women in the workforce and responds to the dramatic societal and economic changes resulting from the large number of families where both parents work. It should allow parents of newborns and newly-adopted children to strengthen their availability for work by providing them with the time and financial support to address several vital needs that accompany the introduction of a new child into the family. The program would allow such parents to provide the initial care that the child will need, to form a strong emotional bond with the child, and to establish a secure system of child care that, once in place, will promote the parents’ long-term attachment to the workforce.

(4) Minimal Tests of the Able and Available Requirements

Consistent with DOL interpretations, some States have imposed minimal tests of the able and available requirements for specific situations, provided the claimant has demonstrated an attachment to the labor force.

Approved Training. Prior to incorporating the training provision into the Federal laws, the DOL encouraged States to treat individuals in training approved by the State agency as meeting the able and available requirements since such training represents the most effective step available to the individual to return to work. The DOL cautioned that State agencies should only approve short-term training that would make individuals job ready. In 1970, Congress, recognizing the importance of training in remedying unemployment, made this training provision mandatory for all States. (Section 3304 (g)(8), FUTA.) The Federal able and available requirements are preserved because individuals who fail to attend training, except by specific waiver, are held to be unavailable for work and ineligible for UC.

Illness. Eleven States allow an individual who initially meets the able and available requirements, but then becomes ill, to receive UC payments without interruption, provided that no suitable work is offered and refused. The DOL approved such State laws in an effort to deter disqualification for UC where a claimant was not “able and available” for perhaps one day, or even one hour, out of a week. Two States, Alaska and Massachusetts, cap the number of weeks ill claimants can collect UC at six weeks and three weeks, respectively; the other States have no statutory limitations. The Federal able and available requirements are preserved because claimants must initially demonstrate their ability to and availability for work before the illness and must be held ineligible if they refuse an offer of suitable work.

Similarly, under the Federal-State Extended Unemployment Compensation Act of 1970 (EB) (26 U.S.C. 3304, note), an ill individual may receive UC only if no suitable work is rejected. The EB program provides additional weeks of compensation to individuals who have exhausted their rights to regular compensation during times of high unemployment and contains a specific “work search” requirement. This work search requirement is suspended for EB claimants who are hospitalized for an emergency or life-threatening condition (20 CFR 615.8 (g)(3)(i)(B)). This suspension is permitted only if the State law contains a similar provision to those explained above, which must be consistent with the Federal able and available requirements.

Jury Duty. The DOL accepts that States may pay UC to individuals serving on jury duty consistent with the Federal availability requirement. This is reasonable because individuals are compelled under the threat of contempt of court by the judicial branch of the government to go on jury duty, and attendance at jury duty may be taken as evidence that the employee would otherwise be available for work. It would be inconsistent for the State to compel jury service and at the same time disqualify unemployed persons from UC for complying. Most employment is not considered an excuse for avoiding jury duty, and unemployment would also likely not be an excuse from jury duty. Indeed, EB claimants are exempt from the work search provision while on jury duty (20 CFR 615.8(g)(3)(i)(A)).

Temporary Layoffs. In a temporary layoff, the employer is unable to provide work for a short period of time, but both the employer and the employee have the expectation that the employee will return to work on a specific date. When the employer recalls the employee, the employee must accept or be denied UC. In these cases, the availability requirement is essentially limited to the employer who laid off the employee. This recognizes that such employees are frequently career employees who would likely quit a new job to return to their former employer when the layoff ends; therefore, other employers would not likely hire such employees.

B. The Birth and Adoption

Unemployment Compensation (BAA–UC) Experiment

(1) Able and Available Requirements for BAA–UC

The DOL previously exercised its authority to interpret the able and available requirements in the areas of training, illness, jury duty, and temporary layoffs. Based on this precedent, the DOL’s experimental BAA–UC program is designed to test whether expansion of its interpretation of the able and available requirements would promote a continued connection to the workforce in parents who receive such payments.

As the number of mothers in the workforce and families with both parents working rises, the need to test this interpretation increases, and collecting data under the BAA–UC program to test the existence and magnitude of this group’s connection to the workforce is increasingly important. Indeed, much in the same way that providing training to laid-off employees enhances their connection to the workforce by making them more marketable, the DOL wants to test whether providing parents with BAA–UC at a point during the first year of a newborn’s life, or after placement for adoption, will help employees maintain or even promote their connection to the workforce by allowing them time to bond with their children and to develop stable child care systems while adjusting to the accompanying changes in lifestyle before returning to work.

The initial time period during which a new child is introduced into a home, and how that child’s care will be assimilated into the working lives of the parents, is critical. It is during this period that secure emotional bonds are formed between children and their parents. It is also during this period that a system of child care, which will foster the parents’ availability for work, can be firmly established. These requirements are universal when any working family has a child. Addressing these needs is fundamental to helping families flourish and is also connected to...
sustaining a stable workforce. Where parents continue to work after the arrival of children, they often need the opportunity to bond with their child as well as arrange a system of care that will allow the parents to continue, and indeed strengthen, their attachment to the workforce. For all the above reasons, the DOL believes that these parents are an appropriate focus of an experimental extension to the able and available requirements. Thus, this expanded interpretation of the Federal able and available requirements applies only to experimental BAA–UC and does not extend to any other facet of the Federal-State UC program. BAA–UC is an experiment being conducted within the regular UC program.

(2) Experimental versus Permanent Program

This proposed rule will give the State agencies that administer the UC program the opportunity to provide UC, under an experimental program, to parents who take approved leave or otherwise leave their employment to be with a newborn or newly-adopted child. The DOL chose to proceed with an experimental rather than a permanent program in order to compile the necessary information to evaluate the following prior to any implementation of a permanent program: whether individuals compensated for birth and adoption leave are more likely to return to employment, and, therefore, are more available than those who are uncompensated; the effects on employers whose employees take such compensated leave; the effects on employers throughout a State who bear the BAA–UC costs; and the effects on the State’s unemployment fund. The DOL anticipates that creating this experimental program, which States can voluntarily choose to put into practice, will give States the necessary latitude to develop innovative programs permitting the DOL to measure employers’ connections to the workforce after availing themselves of BAA–UC, as compared to individuals who take unpaid leave or none at all.

(3) Experimental Program Limitations

The purpose of the able and available requirements is to assure sufficient attachment to the workforce. The BAA–UC experimental program is designed to test the proposition that providing UC to the parents of newborns and newly-adopted children who wish to take approved leave or otherwise leave their employment to be with a newborn or newly-adopted child will produce valuable information for evaluating the program. This information may also serve as a basis for further expanding coverage to assist a broader group of employees to better balance work and family needs. The class of employees covered by this proposed rule is a small, easily-defined group that can be used to test whether compensating absences from employment will assist individuals to maintain, or even improve upon, their connection to the workforce by enabling them to better meet their parental and family needs.

(4) Experimental Program Time Frame and Evaluation

States may enact legislation and begin operation of a BAA–UC program any time after the effective date of the Final Rule. States wishing to enact legislation prior to completion of the rulemaking process should have a contingency provision in their legislation allowing for State agencies to make changes necessary to comply with Federal regulations prior to the implementation of their programs.

The DOL will begin collecting administrative data immediately upon implementation of a BAA–UC program. As States gain experience with their programs, the DOL will evaluate each State individually. A comprehensive evaluation will be performed when at least four States have implemented legislation and operated a BAA–UC program for a minimum of three years. The Federal evaluation methodology has not yet been completed. Because States will have broad latitude in developing BAA–UC experimental programs, the DOL may use a case study evaluation design. Some of the issues that may be addressed in the evaluation include: whether workforce attachment for this population changed; whether employees faced barriers to taking advantage of BAA–UC; and, if so, what can be done to break down these barriers. Though not required by these regulations, it is anticipated that each State will include, as part of its system development, an evaluation component. Once decisions have been made regarding the Federal evaluation process and how the relevant information will be collected, complete information collection instructions will be issued and, if subject to the Paperwork Reduction Act, published for public comment in the Federal Register.

C. Rule Format

In keeping with the Administration’s commitment to writing regulations in plain English, the substance and format of this Proposed Rule is presented in a question-and-answer format so that the regulations will be clear and easy to understand. In addition, the DOL has attempted to anticipate and address issues that may arise during this effort.

II. Explanation

DOL is proposing a rule which is not overly prescriptive. This is consistent with the general structure of the UC program under which States have wide latitude in designing their programs. In accordance with the May 24, 1999, Executive Memorandum, BAA–UC model State legislation has been developed and is appended (Appendix A) for comment. This model legislation is optional and is provided for the convenience of States that choose to implement a BAA–UC program. A commentary on the model legislation and policy issues to aid States in the development of methods provided for under the proposed rule is also appended (Appendix B) for comment. Both appendices are subject to change based upon comments. They will be issued in final form in the Federal Register as a program letter and will not appear in the Code of Federal Regulations.

Description of the Regulation

The proposed rule adds Part 604 to the Code of Federal Regulations. Subparts are organized by subject matter:

Subpart A discusses the purpose and scope of the regulation and defines critical terms.

Subpart B discusses Federal UC requirements as they relate to this experiment.

Subpart C discusses BAA–UC eligibility requirements.

Following is a brief description of each subpart of the proposed regulation.

Subpart A—General Provisions

Subpart A discusses the purpose and scope of the regulation and defines critical terms. The purpose of the regulation is to establish the opportunity for the State agencies that administer the UC program to provide UC, under an experimental program, to parents who take approved leave or otherwise leave employment to be with a newborn or newly-adopted child. This proposal will permit interested States to
The scope of the BAA–UC experiment extends to all State UC programs that provide UC to parents who take approved leave or otherwise leave their employment to be with their newborns or newly-adopted children. This group was identified by the President as the focal group for the experiment with possible expansion, if warranted, after the experiment has been evaluated. State participation is completely voluntary.

Definitions of terms specific to BAA–UC are also in Subpart A:

Approved Leave—Because “approved leave” is commonly interpreted as an approved, temporary separation from a specific employer, that definition has been adopted for BAA–UC purposes.

Birth and Adoption unemployment compensation—This is UC paid only to parents on approved leave or who otherwise leave employment to be with their newborns or newly-adopted children.

Newborns—To establish the distinguishing characteristics of the experimental group, it is necessary to define “newborn.” For purposes of the experiment, newborns are defined as children up to one-year old.

Newly-adopted children—Adoptive parents are included in the experiment. Because adopted children may not be newborns, and a comparable measurement period is necessary for all parents included in the BAA–UC experiment, “newly-adopted” refers to children, regardless of age, who have been placed within the previous 12 calendar months with an adoptive parent(s).

Parents—For BAA–UC experimental purposes, parents are defined as mothers and fathers—biological, legal, or having legal custody of a child during the adoption process. The BAA–UC experiment does not include foster parents unless the child has been placed with the foster parents for adoption.

Placement—The adoption process can be lengthy with completion occurring long after a child has been placed with a family. Consequently, for BAA–UC comparability between parents of newborns and parents of newly-adopted children, “placement” for BAA–UC purposes will be the time a parent becomes legally responsible for a child pending adoption.

Subpart B—Federal UC Requirements

Subpart B discusses how the Federal UC requirements apply to BAA–UC. Beyond the proposed interpretation of the able and available requirements, this regulation does not change Federal UC requirements. Under its authority to interpret the statutes it administers, the DOL is interpreting the Federal able and available requirements to include BAA–UC. This interpretation will give States the opportunity to experiment with, and demonstrate methods of, providing BAA–UC to parents of newborns and newly-adopted children. The experiment will provide compensation only during the periods when parents take approved leave or otherwise leave employment following the birth or placement for adoption of their child. This interpretation of the Federal able and available requirements applies only for purposes of this experiment.

Subpart C—BAA–UC Eligibility

Subpart C discusses the BAA–UC eligibility requirements. Although implementation of BAA–UC is entirely at State discretion and States have wide latitude in BAA–UC program development, certain eligibility parameters apply. For example, only parents of newborns or newly-adopted children are included in the experiment. Also, because all Federal UC law requirements must be met and the insurance nature of the UC program must be maintained, the introduction of eligibility factors that are inconsistent with Federal UC law requirements is not permitted under BAA–UC programs. The introduction of eligibility factors unrelated to the fact or cause of unemployment, such as industry, employer size or whether the spouse of a UC recipient also receives (or has received) UC, is inconsistent with Federal law. Specifically, in a 1964 conformity decision involving the State of South Dakota, the Secretary of Labor held that Federal law prohibits the introduction of any eligibility test unrelated to the fact or cause of the individual’s unemployment. (See Secretary of Labor’s Decision of September 25, 1964, In the Matter of the Hearing to the South Dakota Department of Employment Security Pursuant to Section 3304(a) of the Internal Revenue Code of 1954, transmitted by Unemployment Insurance Program Letter No. 787, October 2, 1964.) Therefore, all individuals covered under a State’s UC law must be covered for BAA–UC.

For BAA–UC purposes, the first compensable week is the week in which birth or placement for adoption takes place. States are free to determine whether to prorate the weekly compensation amount based on the day of the birth or placement for adoption or whether to fully compensate for that week. Weeks preceding the week of the birth or placement and weeks following the end of the one-year period are not compensable.

The purpose of BAA–UC is to provide support to new parents on “leave” from employment to be with their newborns or newly-adopted children. The term “leave” implies that the individual will return to the last employer after a designated period. However, for experimental purposes, the DOL will allow States to pay BAA–UC to parents who otherwise leave employment for this purpose. This will generate data for evaluating how providing compensation affects the connection of these individuals to the workforce. The DOL’s view is that limiting BAA–UC to only those individuals who are assured of job retention could be seen as unfairly excluding parents from BAA–UC who are denied leave by their employers.

Executive Order 12866

This proposed rule is a “significant regulatory action” within the meaning of Executive Order 12866 because it meets the criteria of Section 3(f)(4) of that Order in that it raises novel or legal policy issues arising out of legal mandates, the President’s priorities, or the principles set forth in the Executive Order. Accordingly, the proposed rule has been submitted to, and reviewed by, the Office of Management and Budget.

However, the proposed rule is not considered an “economically significant” rule because it will not have an annual effect on the economy of $100 million or more, will not adversely impact a specific sector of the economy, and will not materially alter the budgeting impact of entitlements, grants, user fees or loan programs or the rights and obligations of recipients thereof.

The Department estimates that the possible annual aggregate BAA–UC cost could range from zero to approximately $68 million. The regulation is permissive, and the DOL does not know how many States will choose to enact experimental BAA–UC programs. The estimate of the annual aggregate BAA–UC cost of $68 million is based on the expressed interest of a small number of States. The cost depends upon such factors as the extent to which BAA–UC affects parents’ incentives to increase their leave duration and the percentage of leave-takers applying for BAA–UC. The derivation of this estimate begins...
with 1997–98 Current Population Survey data showing the annual U.S. average number of women in the labor force with a child under one-year old. After this number is disaggregated by State, the likely proportion of leave-takers for newborns and newly-adopted children is determined based on percentages provided in a report by the Commission on Family and Medical Leave, titled A Workable Balance: Report to Congress on Family and Medical Leave Policies (April 30, 1996). Other factors used in determining the cost estimate include the percent of leave-takers with employer-paid leave, monetary eligibility rates, and average weekly UC payments.

Further, the DOL has evaluated the proposed rule and found it consistent with the regulatory philosophy and principles set forth in Executive Order 12866, which governs agency rulemaking. Although the proposed rule will impact States and State agencies, it will not adversely affect them in a material way. The proposed rule would permit States to voluntarily establish experimental programs to determine the effectiveness of using the UC program to support parents taking leave from their employment to be with their newborns or adopted children; it would not impose any new requirements on States.

**Paperwork Reduction Act**

The DOL has determined that this proposed rule contains no information collection requirements.

**Executive Order 12612**

These proposed regulations have been reviewed in accordance with Executive Order 12612 regarding federalism. The order requires that agencies, to the extent possible, refrain from limiting State policy options, consult with States prior to taking any actions which would restrict States’ policy options, and take such action only when there is clear constitutional authority and the presence of a problem of national scope. Since this proposed rule does not limit State policy options under the current UC program, it complies with the principles of federalism and with Executive Order 12612.

**Executive Order 12988**

This proposed rule has been drafted and reviewed in accordance with Executive Order 12988, Civil Justice Reform, and will not unduly burden the Federal court system. The proposal has been written to minimize litigation and provide a clear legal standard for affected conduct, and has been reviewed carefully to eliminate drafting errors and ambiguities.

**Unfunded Mandates Reform Act of 1995 and Executive Order 12875**

This proposed rule has been reviewed in accordance with the Unfunded Mandates Reform Act of 1995 (UMRA) (2 U.S.C. 1501 et seq.) and Executive Order 12875. The DOL has determined that this proposal does not include any Federal mandate that may result in increased expenditures by State, local, or tribal governments, in the aggregate, or by the private sector, of $100 million or more in any one year.

The States have full discretion to decide whether or not to enact a BAA-UC program. See the section entitled “Executive Order 12866” for further information on the BAA-UC cost estimate.

**Regulatory Flexibility Act**

This proposed rule will not have a significant economic impact on a substantial number of small entities. The proposal affects States and State agencies, which are not within the definition of “small entity” under 5 U.S.C. 601(6). Moreover, States have complete discretion in deciding whether or not they will enact a program permitted under this proposed regulation. Under 5 U.S.C. 605(b), the Secretary has certified to the Chief Counsel for Advocacy of the Small Business Administration to this effect. Accordingly, no regulatory flexibility analysis is required.

**Small Business Regulatory Enforcement Fairness Act**

This proposed rule is not a “major rule” as defined by section 804 of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. Chapter 8). This proposed rule will not result in an annual effect on the economy of $100 million or more; a major increase in costs or prices; or significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of United States-based entities to compete with foreign-based entities in domestic and export markets.

**Effect on Family Life**

The DOL certifies that this proposed rule has been assessed in accordance with section 654 of Pub. L. 105–277, 112 Stat. 2681, for its effect on family well-being. The DOL concludes that the proposed rule will not adversely affect the well-being of the nation’s families. Rather, it should have a positive effect on family well-being by permitting States to enable more parents to take leave from their employment to be with their newborns or newly-adopted children.

**List of Subjects in 20 CFR Part 604**

Employment and Training Administration, Labor, and Unemployment Compensation.

**Catalogue of Federal Domestic Assistance Number**

This program is listed in the Catalogue of Federal Domestic Assistance at No. 17.225, Unemployment Insurance.

Alexis M. Herman, Secretary of Labor.

**Words of Issuance**

For the reasons set forth in the preamble, the DOL proposes that Chapter V of Title 20, Code of Federal Regulations, be amended by adding new part 604 to read as follows:

**PART 604—REGULATIONS FOR BIRTH AND ADOPTION UNEMPLOYMENT COMPENSATION**

**Subpart A—General Provisions**

Sec. 604.1 What is the purpose of this regulation?

604.2 What is the scope of this regulation?

604.3 What definitions apply to this regulation?

**Subpart B—Federal Unemployment Compensation Program Requirements**

604.10 Beyond the interpretation of the able and available requirements for Birth and Adoption unemployment compensation, does this regulation change the Federal requirements for the unemployment compensation program?

**Subpart C—Eligibility**

604.20 Who is covered by Birth and Adoption unemployment compensation?

604.21 When does eligibility for Birth and Adoption unemployment compensation commence?

604.22 Are parents who leave employment to be with their newborns or newly-adopted children eligible for Birth and Adoption unemployment compensation, or is it limited only to parents who take approved leave?

**Authority:** 42 U.S.C. 1302(a); 42 U.S.C. 503(a)(2) and (5); 26 U.S.C. 3304(a)(1) and (4); 26 U.S.C. 3306(h); Secretary’s Order No. 4–75 (40 FR 18515); and Secretary’s Order No. 14–75 (November 12, 1975).

**Subpart A—General Provisions**

§ 604.1 What is the purpose of this regulation?

This regulation allows the States to develop and experiment with innovative methods for paying unemployment compensation to parents on approved leave or who otherwise leave employment to be with their

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**Unemployment Insurance**

Executive Order 12612

Fed. Reg. 64(232) 12-3-99
newborns or newly-adopted children. States’ experiences with Birth and Adoption unemployment compensation will enable the Department of Labor to test whether its interpretation of the Federal “able and available” requirements promotes a continued connection to the workforce in parents who receive such payments.

§ 604.2 What is the scope of the regulation?

This regulation applies to and permits all State unemployment compensation programs to provide benefits to parents on approved leave or who otherwise leave employment to be with their newborns or newly-adopted children. A State’s participation is voluntary.

§ 604.3 What definitions apply to the regulation?

The following definitions apply to this regulation:

(a) **Approved Leave** means a specific period of time, agreed to by both the employee and employer, during which an employee is temporarily separated from employment and after which the employee will return to work for that employer.

(b) **Birth and Adoption unemployment compensation** means unemployment compensation paid only to parents on approved leave or who otherwise leave employment to be with their newborns or newly-adopted children.

(c) **DOL** means the United States Department of Labor.

(d) **Newborns** means children up to one-year-old.

(e) **Newly-adopted children** means children, regardless of age, who have been placed within the previous 12 calendar months with an adoptive parent(s).

(f) **Parents** means mothers and fathers (biological, legal or who have legal custody of a child during the adoption process).

(g) **Placement** means the time a parent becomes legally responsible for a child pending adoption.

(h) **State(s)** means one of the States of the United States of America, the District of Columbia, the Commonwealth of Puerto Rico, and the United States Virgin Islands.

Subpart B—Federal Unemployment Compensation Program Requirements

§ 604.10 Beyond the interpretation of the able and available requirement for Birth and Adoption unemployment compensation, does this regulation change the Federal requirements for the unemployment compensation program?

No. This regulation does not change the Federal unemployment compensation requirements. Under its authority to interpret Federal unemployment compensation law, the DOL interprets the Federal able and available requirements to include experimental Birth and Adoption unemployment compensation. The regulation applies only to parents who take approved leave or otherwise leave employment to be with their newborns or newly-adopted children.

Subpart C—Eligibility

§ 604.20 Who is covered by Birth and Adoption unemployment compensation?

If a State chooses to provide Birth and Adoption unemployment compensation, all individuals covered by the State’s unemployment compensation law must also be covered for Birth and Adoption unemployment compensation. Just as with current unemployment compensation programs, individuals may not be denied experimental Birth and Adoption unemployment compensation based on facts or causes unrelated to the claimant’s unemployment, such as industry, employer size or the unemployment status of a family member. The introduction of such facts or causes would be inconsistent with Federal unemployment compensation law.

§ 604.21 When does eligibility for Birth and Adoption unemployment compensation commence?

Parents may be eligible for Birth and Adoption unemployment compensation during the one-year period commencing with the week in which their child is born or placed with them for adoption. Weeks preceding the week of the birth or placement and weeks following the end of the one-year period are not compensable.

§ 604.22 Are parents who leave employment to be with their newborns or newly-adopted children eligible for Birth and Adoption unemployment compensation, or is it limited only to parents who take approved leave?

States may limit Birth and Adoption unemployment compensation to parents who take approved leave or may extend Birth and Adoption unemployment compensation to parents who otherwise leave employment to be with their newborns or newly-adopted children. However, the intent of Birth and Adoption unemployment compensation is to support all parents who wish to take time from employment to be with their newborns or newly-adopted children.

The following appendix will not appear in the Code of Federal Regulations.

Appendix A—Model State Legislation

Section _______. Birth and Adoption Unemployment Compensation.

(a) An individual who is on a leave of absence from his or her employer or who left employment to be with the individual’s child during the first year of life, or during the first year following placement with the individual for adoption, shall not be denied unemployment compensation under Section _______ for voluntarily leaving employment. Section _______ relating to availability for work, Section _______ relating to inability to work, or Section _______ for failure to actively seek work.

(b) Section _______ concerning the reduction of the amount of compensation due to receipt of qualifying income, shall apply to payments under this section. In addition, the following payments shall cause a reduction in the compensation amount:

1. (a) any payment from the employer resulting from a birth or adoption described in subsection (a); and

2. (b) any payment resulting from a birth or adoption described in subsection (a) from a disability insurance plan contributed to by an employer, in proportion to the employer’s contribution to such plan.

(c) Compensation is payable to an individual under this section for a maximum of 12 weeks with respect to any birth or placement for adoption.

(d) Each employer shall post at each site operated by the employer, in a conspicuous place, accessible to all employees, information relating to the availability of Birth and Adoption unemployment compensation.

(e) Any compensation paid under this section shall not be charged to the account of the individual employer.

(f) Two years following the effective date of this legislation, the commissioner shall issue a report to the governor and the legislature evaluating the effectiveness of the Birth and Adoption unemployment compensation program.

(g) This section shall be applied consistent with regulations issued by the U.S. Department of Labor.

The following appendix will not appear in the Code of Federal Regulations.

Appendix B—Commentary on Model State Legislation, Including Policy Issues

General

Must States Implement a Birth and Adoption Unemployment Compensation (BAA–UC) Program?

No. This program is voluntary for the States. However, implementation of BAA–UC will require some legislation on the part of every State seeking to adopt the program. The Model State Legislation is provided for the convenience of States that wish to implement a BAA–UC program.

Does This Regulation Enable a State To Pay UC for Other Types of Family or Medical Leave?

No. This regulation enables a State to pay UC to parents on approved leave or who...
otherwise leave employment to be with their newborns or newly-adopted children. Permitting payment of UC for other types of family leave or care would be inconsistent with this experimental program.

Must All Employer-Paid Leave Be Exhausted Before BAA–UC Is Available?

No. BAA–UC is designed to provide partial wage replacement to parents of newborns or newly adopted children. The Model State Legislation assumes that any wages paid for the period of employer-provided leave will be deducted. However, States need not deduct these wages from BAA–UC.

Does This Regulation Impose Any Solvency Requirements Upon the States Before They Enact BAA–UC?

No. The DOL expects that a State will not enact changes without assessing the effect on the solvency of its unemployment fund. Each State has the responsibility to assess the cost to the State’s unemployment fund whenever coverage, benefit expansions, or tax changes are considered within the State’s UC program. Consequently, DOL expects prudent decision makers in a State to examine the State’s solvency and projected taxes and benefit payments under current law before deciding to enact BAA–UC legislation.

Monetary Qualifications and Benefits

What Are the Earnings and Employment Requirements for BAA–UC?

States may establish their own requirements. The Model State Legislation assumes that States will use the same earnings and employment criteria that apply to all other individuals.

What Is the Weekly Benefit Amount for Individuals Eligible for BAA–UC?

States may establish their own weekly benefit amounts. The Model State Legislation assumes that individuals eligible for BAA–UC will receive the same weekly benefit amount as other individuals eligible for UC.

How Does the Receipt of Other Income Effect Payment of BAA–UC?

States will determine whether BAA–UC will be reduced by other income. Under the Model State Legislation, the amount of BAA–UC will be reduced in the same manner as any other payment of UC as provided under State law. The Model State Legislation also provides for the deduction of any payment from the employer as a result of the birth or placement for adoption, and for the deduction of any disability insurance payment received as a result of the birth or placement for adoption in proportion to the disability insurance plan. This provision, which is limited to payments triggered by the same event which triggers BAA–UC, reflects the view that the unemployment fund should not be held responsible when wage replacement is available from other sources, particularly when both payments are financed by the employer. States should examine their laws to determine if all types of appropriate income are, or should be, deductible. For example, some leave payments which are not normally deductible under State law may cover costs of birth and adoption leave.

How Does the BAA–UC Entitlement Relate to Regular UC Payments?

States are free to determine this. The Model Legislation assumes that BAA–UC counts toward the maximum number of weeks of regular UC.

Period of Eligibility

When May BAA–UC Benefits Begin?

Under Section 604.21 of the proposed regulations, parents may receive BAA–UC only during the one-year period commencing with the week in which the child is born or placed for adoption. For example, an individual taking leave in the 51st week following birth or placement for adoption, would be eligible for BAA–UC only for weeks 51 and 52. Periods preceding the week of birth or placement for adoption are not compensable. States are free to reduce the one-year period.

How Many Weeks of BAA–UC May Individuals Receive?

States are free to determine this. The Model State Legislation provides a maximum duration of 12 weeks per individual with respect to any one birth or adoption. Since the Family and Medical Leave Act of 1993 (FMLA) allows up to 12 weeks of unpaid leave for such events, States may wish to have an identical amount. States may also relate the duration of leave to the individual’s weekly amount of UC. For example, for each birth or adoption, an individual may receive an amount equal to 12 times the individual’s weekly UC.

To prevent confusion between FMLA and BAA–UC, States should inform potential BAA–UC beneficiaries of the dissimilarities between the two programs (for example, BAA–UC does not guarantee job retention).

If a Child Is Born in the Middle of the Week or the Placement Occurs in the Middle of the Week, Is BAA–UC Payable for This Week?

Under the Model State Legislation, BAA–UC would be payable for this week, assuming all applicable eligibility conditions, such as the deductible income provisions, are met. States may provide the full weekly compensation amount for this week or prorate the weekly amount to reflect only periods following birth or adoption. If the amount is prorated, the State may pay the remaining balance for the last partial week if the individual is still on leave.

Must the Individual Serve a Waiting Period?

No. Nothing in Federal law requires States to have a waiting week for regular UC or BAA–UC. However, not having a waiting week for BAA–UC would eliminate the 50 percent Federal share for the first week of all Extended Benefits claims. Under 20 CFR 615.14(c)(3), a State is not entitled to a Federal share for the first week of Extended Benefits if the State’s law provides “at any time or under any circumstances” for the payment of UC for the first week of unemployment.

When Is a Child Considered “Placed” for Adoption?

Under 604.3(g) of the proposed rule, placement occurs at the time a parent becomes legally responsible for a child pending adoption. State UC agencies should consult the adoption laws of their States to determine precisely when placement occurs.

Other Eligibility Issues

May Both Parents Receive BAA–UC? If So, May They Both Receive Such Compensation at the Same Time?

The answer to both questions is “yes.” States implementing BAA–UC must allow both parents, if otherwise eligible, to receive BAA–UC concurrently or consecutively. A State may not prohibit payment of BAA–UC simply because the other parent is taking leave for the same purpose. A State law which does so is inconsistent with Federal law because the eligibility of one parent will be determined based on whether the other parent is receiving UC. Specifically, in a 1964 conformity decision involving the State of South Dakota, the Secretary of Labor held that Federal law prohibits the introduction of any eligibility test unrelated to the fact or cause of the individual’s unemployment. (See Secretary of Labor’s Decision of September 25, 1964, In the Matter of the Hearing to the South Dakota Department of Employment Security Pursuant to Section 3304(a) of the Internal Revenue Code of 1954, transmitted by Unemployment Insurance Program Letter No. 787, October 2, 1964.) The recipient status of the other parent is unrelated to the fact or cause of an individual’s unemployment. Thus, both parents may receive BAA–UC, whether concurrently or consecutively. Similarly, States may not limit use of BAA–UC to the “primary” parent.

Must BAA–UC Apply to Individuals Employed by All Employers Subject to State UI Law?

Yes. As explained in the previous answer, States may not impose eligibility conditions not related to the fact or cause of the individual’s unemployment. Assuming the services are taxable for UC, States may not, for example, limit BAA–UC based on employer size.

May States Provide BAA–UC to Individuals Who Otherwise Leave Employment (Not on Approved Leave) To Be With Their Newborns or Newly-Adopted Children?

Yes. While States are free to determine their own requirements, there are compelling reasons for providing BAA–UC to individuals who otherwise leave employment. Although many employers may grant leave, others may not. The DOL believes that all parents should be treated identically for UC purposes when they take time away from employment to be with their newborn or newly-adopted child. As such, their eligibility for BAA–UC should not be based on whether an employer is required to grant the leave, but on the parent’s reason for wanting to take the leave.

May Eligibility Be Conditioned on Whether the Individual Gave Notice to the Employer?

Yes. Although the Model State Legislation does not provide for such a condition because it may result in denials due to the technicality of when the individual requested leave, States may impose it. The basis of such a requirement is that employers should be given sufficient time to accommodate the

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leaving/absence of the individual. If such a provision is included, the DOL recommends that the notice be required to be given no more than 30 days prior to birth or placement, but only where practicable. The FMLA contains a 30-day requirement or shorter notice period where giving 30-day notice is not practicable; it does not require notice when the necessity to take leave is unforeseeable. (Section 102(e), Family and Medical Leave Act, Pub. L. 103–3 (February 5, 1993).)

May Eligibility Be Conditioned on Whether the Individual Chooses Not To Return to Work?

Yes. However, based upon Jenkins v. Bowling, 691 F.2d 1225 (7th Cir. 1982), States may not delay payment until after the individual returns to work. Section 303(a)(1), SSA, requires the full payment of benefits when due, precluding States from delaying payment while awaiting the individual's return to work. A State may, however, declare an overpayment of benefits after the individual fails to return to work.

May An Individual Be Paid BAA–UC Under the Federal-State Extended Benefit Program or Any of the Federally Funded Unemployment Programs?

It depends on the program. Benefits under the UC for Federal Employees (UCFE) and UC for Ex-Servicemembers (UCX) programs are, by Federal law, required to be paid on the same terms and subject to the same conditions as State benefits (with exceptions not relevant here). Therefore, BAA–UC will be paid to individuals under these programs to the same extent as under State law.

Individuals may only receive Disaster Unemployment Assistance (DUA) when their unemployment is caused by a disaster as provided in 20 CFR Part 625. However, if they meet their State’s Birth and Adoption UC provision, then they will satisfy the availability requirement at § 625.4(g), and so may qualify for DUA. For example, an individual who is unemployed due to a major disaster may later give birth. If this individual satisfies the BAA–UC requirements in the State’s law, she may receive DUA.

Extended Benefit claimants may not receive Birth and Adoption UC since they cannot meet the systematic and sustained work search requirements in 20 CFR 615.8(g).

Individuals claiming trade readjustment allowances (cash benefits) under the Trade Adjustment Assistance and the North American Free Trade Act Transitional Adjustment Assistance programs will be ineligible since such individuals are required to either be in full-time training or conduct the systematic and sustained work search required for the Extended Benefit program.

Financing Costs of BAA–UC

May BAA–UC Costs Be Socialized Among Employers?

Yes. States are free to socialize or not socialize costs of BAA–UC. The Model State Legislation socializes costs—also called “noncharging.” An employer may be reluctant to bear all the costs of BAA–UC caused by an employee taking leave since the employer will not have caused the individual’s unemployment. Since noncharging is permitted when the unemployment is caused by the employee, it is permitted in this situation. This position applies to both contributory and reimbursable employers.

May BAA–UC Costs Be Paid From a State Fund Other Than the State’s Unemployment Fund, for Example, a State’s Temporary Disability (TDI) Fund?

Yes. Nothing in Federal UC law governs the treatment of moneys in these funds because they are financed by a separate tax and held separately from the State’s unemployment fund. For example, a State with a TDI program may enact a special disability insurance tax on employers and deposit the proceeds in a disability fund. If the State chooses to use one of these funds (or create such a fund) to pay birth and adoption leave benefits, the requirements of DOL’s BAA–UC regulation will not apply.

Administrative Costs

May States Use Administrative Grants Received From the Federal Government To Pay for the Administration of a BAA–UC Program?

Provided that all the requirements of the BAA–UC regulation are met, the use of administrative grants is permissible, including for purposes of studying and evaluating the BAA–UC program. However, if the regulation’s requirements are not met, the expenditures of grant funds are not for the proper and efficient administration of the State’s law as required by section 303(a)(8) of the Social Security Act.

Reporting

Will States Need To Amend Their Laws To Address any Federal Reporting Requirements Concerning BAA–UC?

Although this is a matter for States to determine, the DOL anticipates that few, if any, States will need to amend their laws since most State laws already contain language concerning reporting. Many of these laws are based on the language on page 95 of The Manual of Employment Security Legislation, as revised September 1950, which requires that the agency “make such reports, in such form and containing such information as the Secretary of Labor may from time to time require, and shall comply with such provisions as the Secretary of Labor may from time to time find necessary to assure the correctness and verification of such reports.”

What Are the Reporting Requirements?

The DOL has not yet finalized a methodology for evaluating State BAA–UC programs. When that methodology is completed, State reporting requirements will be issued in a separate information collection request and, if subject to the Paperwork Reduction Act, published for public comment in the Federal Register.

[FR Doc. 99–30445 Filed 11–30–99; 8:45 am]
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Part III

Department of Housing and Urban Development

24 CFR Part 985
Technical Amendment to the Section 8 Management Assessment Program (SEMAP); Final Rule
DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

24 CFR Part 985
[Docket No. FR–4498–F–02]
RIN 2577–AC10

Technical Amendment to the Section 8 Management Assessment Program (SEMAP); Final Rule

AGENCY: Office of the Assistant Secretary for Public and Indian Housing, HUD.

ACTION: Final rule.

SUMMARY: On July 26, 1999, HUD published an interim rule amending its regulations for the Section 8 Management Assessment Program (SEMAP). The interim rule made several technical amendments to conform the SEMAP regulations to the requirements of the Single Audit Act Amendments of 1996. This final rule makes final the amendments made by the July 26, 1999 interim rule. HUD has adopted the interim rule without change. Additionally, this final rule makes several amendments to conform the SEMAP regulations to HUD’s October 21, 1999 final rule implementing the statutory merger of the Section 8 tenant-based certificate and voucher programs.

DATES: Effective Date: January 3, 2000.

FOR FURTHER INFORMATION CONTACT:
Gerald Benoit, Director, Real Estate and Housing Performance Division, Office of Public and Assisted Housing Delivery, Office of Public and Indian Housing, Room 4210, 451 Seventh Street, SW, Room 4210, Washington, DC 20410; telephone: (202) 708–0477 (this is not a toll-free number). Persons with hearing or speech-impairments may access this number via TTY by calling the toll-free Federal Information Relay Service at 1–800–877–8339.

SUPPLEMENTARY INFORMATION:

I. The July 26, 1999 Interim Rule

On July 26, 1999 (64 FR 40496), HUD published an interim rule amending its regulations for the Section 8 Management Assessment Program (SEMAP). The interim rule, which became effective on August 25, 1999, made various technical amendments to conform the SEMAP regulations to the requirements of the Single Audit Act Amendments of 1996. Specifically, the interim rule provides that HUD will base its SEMAP rating for a housing authority (HA) on the HA’s SEMAP certification to HUD, rather than on the independent auditor’s annual audit report. HUD continues to rely on the independent auditor to verify the accuracy of the HA’s SEMAP certification with respect to the eight SEMAP indicators. The July 26, 1999 interim rule also clarifies that HUD confirmatory reviews will be used as an additional method of verification to the extent they are performed.

The July 26, 1999 interim rule requires the HA to submit a SEMAP certification concerning the results of its supervisory quality control reviews of file samples drawn in an unbiased manner to ensure compliance under four SEMAP indicators ((1) Selection from the Waiting List; (2) Reasonable Rent; (3) Determination of Adjusted Income; and (4) HQS Enforcement). The interim rule, therefore, requires the HA to perform annual quality control reviews of its performance under these indicators in order to complete the SEMAP certification form.

The July 26, 1999 interim rule also revises the SEMAP standard under § 985.3(e) for Housing Quality Standards (HQS) quality control inspections. This indicator is changed to require HQS quality control samples of the same minimum sample size as required for other supervisory quality control reviews. The requirement for a 5 percent HQS quality control sample no longer applies.

II. Finalizing the July 26, 1999 Interim Rule

This final rule finalizes the amendments made by the July 26, 1999 interim rule. The public comment period on the interim rule closed on September 24, 1999. No public comments were submitted on the interim rule. Accordingly, HUD is adopting the interim rule without change.

III. Conforming Amendments to 24 CFR Part 985

In addition to finalizing the July 26, 1999 interim rule, this final rule makes various amendments to conform the SEMAP regulations to HUD’s October 21, 1999 (64 FR 56894) final rule implementing the statutory merger of the Section 8 tenant-based certificate and voucher programs. The October 21, 1999 final rule implemented section 545 of the Quality Housing and Work Responsibility Act of 1998 (Title V of the FY 1999 HUD Appropriations Act; Public Law 105–276, approved October 21, 1998). The new tenant-based program (known as the Housing Choice Voucher program) has features of the previously authorized certificate and voucher programs, plus new features. Interested persons should consult the preamble to the October 21, 1999 final rule for additional details.

The conformsing changes made by this final rule do not establish or modify any substantive SEMAP requirements. Rather, these amendments conform the SEMAP regulations at 24 CFR part 985 to the requirements of the new Housing Choice Voucher program. The most significant of the conformsing amendments made by this final rule are as follows:

• Part 985 has been revised to consistently use the term “PHA” rather than “HA” when referring to a public housing agency.
• This final rule updates several regulatory citations to the regulations at 24 CFR part 902.
• The final rule updates 24 CFR part 985 by replacing the terms “area exception rents” and “exception rents” with the term “exception standard amounts.”
• The SEMAP payment standards indicator at § 985.3(i) has been revised to reflect the fact that, under the Housing Choice Voucher program, there are no more initial gross rents under the Section 8 certificate program.
• The discussion of correct tenant rent calculations at § 985.3(k) has been revised to remove all references to over-Fair Market Rent (FMR) tenancies. Such tenancies no longer exist under the Housing Choice Voucher program.

IV. Findings and Certifications

Environmental Impact

A Finding of No Significant Impact with respect to the environment for this rulemaking was made at the interim rule stage, in accordance with HUD regulations at 24 CFR part 50, which implement section 102(2)(C) of the National Environmental Policy Act of 1969. That finding remains applicable to this final rule and is available for public inspection between 7:30 a.m. and 5:30 p.m. weekdays in the Office of the Rules Docket Clerk, Office of the General Counsel, Department of Housing and Urban Development, Room 10276, 451 Seventh Street, SW, Washington, DC 20410.

Regulatory Flexibility Act

The Secretary, in accordance with the Regulatory Flexibility Act (5 U.S.C. 605(b)), has reviewed this rule before publication and by approving it certifies that this rule would not have a significant economic impact on a substantial number of small entities. There are no anti-competitive discriminatory aspects of the rule with regard to small entities, and there are not any unusual procedures that would need to be complied with by small entities.
Executive Order 13132, Federalism

Executive Order 13132 (entitled “Federalism”) prohibits an agency from publishing any rule that has federalism implications if the rule either imposes substantial direct compliance costs on State and local governments and is not required by statute, or the rule preempts State law, unless the agency meets the consultation and funding requirements of section 6 of the Executive Order. This final rule does not have federalism implications and does not impose substantial direct compliance costs on State and local governments or preempt State law within the meaning of the Executive Order.

Catalog of Federal Domestic Assistance

The Catalog of Federal Domestic Assistance Program numbers assigned to the Section 8 Management Assessment Program are 14.855 and 14.857.

List of Subjects for 24 CFR Part 985

Grant programs—housing and community development, Housing, Rent subsidies, Reporting and recordkeeping requirements.

PART 985—SECTION 8 MANAGEMENT ASSESSMENT PROGRAM (SEMAP)

For the reasons discussed in the preamble, HUD adopts the amendments made to 24 CFR part 985 in the interim rule published on July 26, 1999 at 64 FR 40496 without change and makes the following additional amendments to 24 CFR part 985 as follows:

1. The authority citation for Part 985 continues to read as follows:

Authority: 42 U.S.C. 1437a, 1437c, 1437f and 3535d.

1a. In part 985, “HA” is removed and “PHA” is added in its place wherever it appears, and “an HA” is removed and “a PHA” is added in its place wherever it appears.

2. Amend § 985.3 as follows:

a. In paragraph (b)(1), revise the reference to “§ 982.503” to read “§ 982.507”;

b. In paragraph (b)(3)(i)(B), revise the reference to “§ 982.503” to read “§ 982.507”;

c. In paragraph (e)(1), revise the reference to “§ 983.2” to read “§ 985.2”;

d. In paragraph (g)(1), revise the reference to “§ 982.301(b)(5)” to read “§ 982.301(b)(4)”;

e. In paragraph (g)(1) revise the reference to the plural “programs” to the singular “program”;

f. In paragraphs (g)(3)(i)(F), revise the references to “area exception rents” and “exception rents” to read “exception payment standard amounts”;

i. Revise paragraphs (i); and

j. Revise the second sentence of paragraph (k)(2).

§ 985.3 Indicators, HUD verification methods and ratings.

(i) Payment standards. (1) This indicator shows whether the PHA has adopted a payment standard schedule that establishes voucher payment standard amounts by unit size for each FMR area in the PHA jurisdiction, and, if applicable, separate payment standard amounts by unit size for a PHA-designated part of an FMR area, which payment standards do not exceed 110 percent of the current applicable published FMR and which are not less than 90 percent of the current applicable published FMRs (unless a higher or lower payment standard amount is approved by HUD). (§ 982.503 of this chapter.)

(2) HUD verification method: PHA data submitted on the SEMAP certification form concerning payment standards.

(3) Rating:

(i) The PHA’s voucher program payment standard schedule contains payment standards which do not exceed 110 percent of the current applicable published FMR and which are not less than 90 percent of the current applicable published FMR (unless a higher or lower payment standard amount is approved by HUD). 5 points.

(ii) The PHA’s voucher program payment standard schedule contains payment standards which exceed 110 percent of the current applicable published FMRs or which are less than 90 percent of the current applicable published FMRs (unless a higher or lower payment standard amount is approved by HUD). 0 points.

(k) * * *

(2) * * * The MTCS data used for verification cover only voucher program and regular certificate program tenancies, and do not include rent calculation discrepancies for manufactured home owner rentals of manufactured home spaces under the certificate program or for proration of assistance under the noncitizen rule.


Harold Lucas,
Assistant Secretary for Public and Indian Housing.

[FR Doc. 99–31440 Filed 12–2–99; 8:45 am]

BILLING CODE 4210–33–P
Part IV

Department of Defense

General Services Administration

National Aeronautics and Space Administration

48 CFR Parts 1, 22, and 52
Federal Acquisition Regulation; Application of the Davis-Bacon Act to Construction Contracts With Options To Extend the Term of the Contract; Proposed Rule
DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

48 CFR Parts 1, 22, and 52

[FAR Case 1997–613]

RIN 9000–AI47

Federal Acquisition Regulation; Application of the Davis-Bacon Act to Construction Contracts With Options To Extend the Term of the Contract

AGENCIES: Department of Defense (DoD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

ACTION: Proposed rule.

SUMMARY: The Civilian Agency Acquisition Council and the Defense Acquisition Regulations Council (Councils) are proposing to amend the Federal Acquisition Regulation (FAR) to implement the requirement of Department of Labor (DoL) All Agency Memorandum No. 157 (AAM 157), as clarified in the Federal Register on November 20, 1998. The rule requires incorporation of the current Davis-Bacon Act wage determination at the exercise of each option period in construction contracts containing options to extend the term of the contract. Following several years of controversy regarding the authority of DoL to issue AAM 157, DoL Administrative Review Board confirmed on July 17, 1997, the authority of the DoL Administrator’s ruling that a current Davis-Bacon Act wage determination must be incorporated at the exercise of an option to extend the term of the contract. The Review Board also directed DoL to clarify the language of AAM 157 and to republish the memorandum in the Federal Register. The Acting Administrator published the clarification in the Federal Register at 63 FR 64542, November 20, 1998. This rule was not subject to Office of Management and Budget review under Section 6(b) of Executive Order 12866, Regulatory Planning and Review, dated September 30, 1993. This rule is not a major rule under 5 U.S.C. 804.

B. Regulatory Flexibility Act

The changes may have a significant economic impact on a substantial number of small entities within the meaning of the Regulatory Flexibility Act, 5 U.S.C. 601 et seq., because the rule will apply to any contractor, including a small business, that enters into a contract for construction, or a contract that includes substantial and segregable construction work, that contains option provisions to extend the term of the contract. Therefore, the Councils have prepared an Initial Regulatory Flexibility Analysis. It is summarized as follows:

The proposed rule provides four alternative methods of adjusting the contract price when exercising the option to extend the term of the contract.

1. No adjustment in contract price (because the option prices may include an amount to cover estimated increases).
2. Price adjustment based on a separately specified pricing method, such as application of a coefficient to an annually published unit pricing book incorporated at option exercise.
3. A percentage price adjustment, based on a published economic indicator; and
4. A price adjustment based on a specific calculation to reflect the actual increase or decrease in wages and fringe benefits as a result of incorporation of the new wage determination.

The last method, applying calculations similar to the calculations of price adjustments in contracts subject to the Service Contract Act, removes the risk to the contractor, but imposes some reporting requirements, to provide required information upon which to base the price adjustment. However, the contractor is already required to keep payroll records upon which the calculations are based, so the burden is not significant. Data for fiscal year 1998 indicates the Government awarded 229 indefinite-delivery construction contracts, of which 121 were awarded to small businesses. Nearly all construction contracts with options to extend the term are indefinite-delivery contracts and most indefinite-delivery contracts have options to extend the term. Although there is no database to determine the number of contracts for other than construction that have substantial and segregable construction work, we estimate 225 prime contractors and 675 subcontractors, of which approximately 50 percent are small businesses.

The FAR Secretariat has submitted a copy of the IRFA to the Chief Counsel for Advocacy of the Small Business Administration. Interested parties may obtain a copy from the FAR Secretariat. The Councils will consider comments from small entities concerning the affected FAR subparts in accordance with 5 U.S.C. 610. Interested parties must submit such comments separately and should cite 5 U.S.C. 601, et seq, FAR Case 1997–613, in correspondence.

C. Paperwork Reduction Act

The Paperwork Reduction Act (Pub. L. 104–13) applies because the proposed rule contains information collection requirements. Accordingly, the FAR Secretariat submitted a request for approval of a new information collection requirement concerning application of the Davis-Bacon Act to construction contracts with options to extend the term of the contract to the Office of Management and Budget under 44 U.S.C. 3501, et seq.

Annual Reporting Burden

We estimate the public reporting burden for this collection of information is 90 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

We estimate the annual reporting burden is as follows: Respondents: 900; Responses per respondent: 1; Total annual responses: 900; Preparation hours per response: 90; and Total response burden hours: 81,000.
D. Request for Comments Regarding Paperwork Burden

Comments regarding this burden estimate or any other aspect of the collection of information, including suggestions for reducing this burden should be submitted to: FAR Desk Officer, OMB, Room 10102, NEOB, Washington, DC 20503, and a copy to the General Services Administration, FAR Secretariat (MVR), 1800 F Street, NW, Room 4035, Washington, DC 20405.

Requester may obtain a copy of the justification from the General Services Administration, FAR Secretariat (MVR), Room 4035, Washington, DC 20405, telephone (202) 208–7312. Please cite OMB control number 9000–00XX, FAR Case 1997–613, Application of the Davis-Bacon Act to Construction Contracts with Options to Extend the Term of the Contract, in all correspondence.

List of Subjects in 48 CFR Parts 1, 22, and 52

Government procurement.


Edward C. Loeb,
Director, Federal Acquisition Policy Division.

Therefore, DoD, GSA, and NASA propose that 48 CFR Parts 1, 22, and 52 be amended as set forth below:

1. The authority citation for 48 CFR Parts 1, 22, and 52 continues to read as follows:

Authority: 40 U.S.C. 486(c); 10 U.S.C. chapter 137; and 42 U.S.C. 2473(c).

PART 1—FEDERAL ACQUISITION REGULATIONS SYSTEM

2. Amend section 1.106 in the table following the introductory paragraph by adding an entry to read as follows:

1.106 OMB approval under the Paperwork Reduction Act.

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<th>OMB Control No.</th>
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<td></td>
<td></td>
</tr>
<tr>
<td>52.222–32</td>
<td>9000–0154</td>
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</tbody>
</table>

PART 22—APPLICATION OF LABOR LAWS TO GOVERNMENT ACQUISITIONS

3. Amend section 22.404–1(a)(1) by revising the third sentence; and paragraph (b) by revising the fourth sentence to read as follows:

22.404–1 Types of wage determinations.

(a) General wage determinations.

(1) The Department of Labor may modify a wage determination to make it current by specifying only the items being changed or by issuing a "supersedes decision," which is a reissuance of the entire determination with changes incorporated.

(2) All project wage determination modifications expire on the same day as the original determination.

(b) * * * Once incorporated in a contract, a project wage determination normally remains effective for the life of the contract, unless the contracting officer exercises an option to extend the term of the contract.

(3) The agency must time-date stamp all modifications of wage determinations immediately upon receipt. (Note the distinction between receipt by the agency (modification is effective) and receipt by the contracting officer, which may occur later.)

* * * * *

(d) The following applies when modifying a contract to exercise an option to extend the term of a contract:

(1) A modified wage determination is effective if, before execution of the contract modification to exercise the option, the contracting agency receives a written action from DoL, or DoL publishes notice of modifications to general wage determinations in the Federal Register.

(2) If the contracting officer receives an effective wage modification either before or after execution of the contract modification to exercise the option, the contracting officer must modify the contract to incorporate the modified wage determination, and any changed wage rates, effective as of the date of option exercise.

4. Revise section 22.404–2(a) to read as follows:

22.404–2 General requirements.

(a) The contracting officer must incorporate only the appropriate wage determinations in solicitations and contracts and must designate the work to which each determination or part thereof applies. The contracting officer must not include project wage determinations in contracts or options other than those for which they are issued. When exercising an option to extend the term of a contract, the contracting officer must select the most current wage determination from the same schedule as the wage determination in effect at award, unless the type of construction in the option period is significantly different from the type of construction in the preceding contract period.

(b) * * * Accordingly, agencies should submit requests to the Department of Labor at least 45 days (60 days if possible) before issuing the solicitation or exercising an option to extend the term of a contract.

5. In section 22.404–3, revise the last sentence of paragraph (c); remove paragraph (d); and redesignate paragraph (e) as (d) to read as follows:

22.404–3 Procedures for requesting wage determinations.

* * * * *

(c) * * * Accordingly, agencies should submit requests to the Department of Labor at least 45 days (60 days if possible) before issuing the solicitation or exercising an option to extend the term of a contract.

* * * * *

6. In section 22.404–6, revise paragraph (a); and add paragraph (d) to read as follows:

22.404–6 Modifications of wage determinations.

(a) General. (1) The Department of Labor may modify a wage determination to make it current by specifying only the items being changed or by issuing a "supersedes decision," which is a reissuance of the entire determination with changes incorporated.

(2) All project wage determination modifications expire on the same day as the original determination.

(b) * * * Once incorporated in a contract, a project wage determination normally remains effective for the life of the contract, unless the contracting officer exercises an option to extend the term of the contract.

* * * * *

(d) The following applies when modifying a contract to exercise an option to extend the term of a contract:

(1) A modified wage determination is effective if, before execution of the contract modification to exercise the option, the contracting agency receives a written action from DoL, or DoL publishes notice of modifications to general wage determinations in the Federal Register.

(2) If the contracting officer receives an effective wage modification either before or after execution of the contract modification to exercise the option, the contracting officer must modify the contract to incorporate the modified wage determination, and any changed wage rates, effective as of the date of option exercise.

7. Revise section 22.404–7 to read as follows:

22.404–7 Correction of wage determinations containing clerical errors.

Upon the Labor Department’s own initiative or at the request of the contracting agency, the Administrator, Wage and Hour Division, may correct any wage determination found to contain clerical errors. Such corrections will be effective immediately, and will apply to any solicitation or active contract. Before contract award, the contracting officer must follow the procedures in 22.404–5(b)(1), (b)(2)(i) or (ii) in sealed bidding, and the procedures in 22.404–5(c)(3) or (4) in negotiations. After contract award, the contracting officer must follow the procedures at 22.404–6(b)(5), except that the contracting officer may exercise an option to extend the term of the contract, the contracting officer must follow the procedures at 22.404–6(d)(2).

8. In section 22.404–10, revise the first sentence to read as follows:

22.404–10 Posting wage determinations and notice.

The contractor must keep a copy of the applicable wage determination (and any approved additional classifications) posted at the site of the work in a prominent place where the workers can easily see it.

9. Add section 22.404–12 to read as follows:
22.404–12 Labor standards for contracts containing construction requirements and option provisions that extend the term of the contract.

(a) Each time the contracting officer exercises an option to extend the term of a contract for construction, or a contract that includes substantial and segregable construction work, the contracting officer must modify the contract to incorporate the most current wage determination.

(b) If a contract with an option to extend the term of the contract has indefinite-delivery or indefinite-quantity construction requirements, the contracting officer must incorporate the wage determination incorporated into the contract at the exercise of the option into task orders issued during that option period. The wage determination will be effective for the complete period of performance of those task orders without further revision.

(c) The contracting officer must include in fixed-price contracts a clause that specifies one of the following methods, suitable to the interest of the Government, to provide an allowance for any increases or decreases in labor costs that result from the inclusion of the current wage determination at the exercise of an option to extend the term of the contract:

(1) The contracting officer may provide for a contract price adjustment based solely on a percentage rate determined by the contracting officer using a published economic indicator incorporated into the solicitation and resulting contract. The contracting officer must apply the percentage rate, based on the economic indicator, to the portion of the contract price designated in the contract clause as labor costs subject to the provisions of the Davis-Bacon Act. The contracting officer must insert 50 percent as the estimated portion of the contract price that is labor unless the contracting officer determines, prior to issuance of the solicitation, that a different percentage is more appropriate for a particular contract or requirement. This percentage adjustment to the designated labor costs must be the only adjustment made to cover increases in wages and/or benefits resulting from the incorporation of a new or revised wage determination at the exercise of each option to extend the term of the contract. Generally, this method is used in construction-only contracts (with options to extend the term) that are not expected to exceed a total of 3 years.

(2) The contracting officer may include in the contract a separately specified pricing method, that permits an adjustment to the contract price or contract labor unit price at the exercise of each option to extend the term of the contract. At the time of option exercise, the contracting officer must incorporate a new wage determination into the contract, and must apply the specific pricing method to calculate the contract price adjustment. An example of a contract pricing method that the contracting officer might separately specify is incorporation in the solicitation and resulting contract of the pricing data from an annually published unit pricing book (e.g., the R.S. Means Cost Estimating System, or the U.S. Army Computer-Aided Cost Estimating System), which is multiplied in the contract by a factor proposed by the contractor (e.g., .95 or 1.1). At option exercise, the contracting officer incorporates the pricing data from the latest annual edition of the unit pricing book, multiplied by the factor agreed to in the basic contract. The contracting officer must not further adjust the contract price as a result of the incorporation of the new or revised wage determination.

(3) The contracting officer may provide for a contract price adjustment based solely on a percentage rate determined by the contractor using a published economic indicator incorporated into the solicitation and resulting contract. The contracting officer must apply the percentage rate, based on the economic indicator, to the portion of the contract price designated in the contract clause as labor costs subject to the provisions of the Davis-Bacon Act. The contractor must incorporate the pricing data from the latest annual edition of the unit pricing book, multiplied by the factor agreed to in the basic contract. The contracting officer must not further adjust the contract price as a result of the incorporation of the new or revised wage determination.

10. In section 22.406–3, add paragraph (e) to read as follows:

22.406–3 Additional classifications.

(e) In each option to extend the term of the contract, if any laborer or mechanic is to be employed during the option in a classification that is not listed (or no longer listed) on the wage determination incorporated in that option, the contracting officer must require that the contractor submit a request for conformance using the procedures noted in paragraphs (a) through (d) of this section.

11. Add sections 22.407(e), (f), and (g) to read as follows:

22.407 Contract clauses.

(e) Insert the clause at 52.222–30, Davis-Bacon Act—Price Adjustment (None or Separately Specified Pricing Method), in solicitations and contracts if—

(1) The contract is expected to be a fixed-price contract subject to the Davis-Bacon Act that will contain option provisions by which the contracting officer may extend the term of the contract, and the contracting officer determines the most appropriate contract price adjustment method is the method at 22.404–12(c)(1) or (2); or

(2) The contract is expected to be a cost-reimbursable type contract subject to the Davis-Bacon Act that will contain option provisions by which the contracting officer may extend the term of the contract.

(f) Insert the clause at 52.222–31, Davis-Bacon Act—Price Adjustment (Percentage Method), in solicitations and contracts if the contract is expected to be a fixed-price contract subject to the Davis-Bacon Act that will contain option provisions by which the contracting officer may extend the term of the contract, and the contracting officer determines the most appropriate contract price adjustment method is the method at 22.404–12(c)(3).

(g) Insert the clause at 52.222–32, Davis-Bacon Act—Price Adjustment (Actual Method), in solicitations and contracts if the contract is expected to be a fixed-price contract subject to the Davis-Bacon Act that will contain option provisions by which the contracting officer may extend the term of the contract, and the contracting officer determines the most appropriate method to establish contract price is the method at 22.404–12(c)(4).
12. Add sections 52.222–30, 52.222–31, and 52.222–32 to read as follows:

52.222–30 Davis-Bacon Act—Price Adjustment (None or Separately Specified Pricing Method).

As prescribed in 22.407(e), insert the following clause:

Davis-Bacon Act—Price Adjustment (None or Separately Specified Pricing Method) (Date)

(a) The wage determination issued under the Davis-Bacon Act by the Administrator, Wage and Hour Division, Employment Standards Administration, U.S. Department of Labor, that is in effect at the exercise of an option to extend the term of the contract, will apply to that option period.

(b) The Contracting Officer will make no adjustment in contract price, other than provided for elsewhere in this contract, to cover any increases or decreases in wages and benefits as a result of—

(1) Incorporation of the Department of Labor’s wage determination applicable at the exercise of the option to extend the term of the contract;

(2) Incorporation of a wage determination otherwise applied to the contract by operation of law; or

(3) An increase in wages and benefits resulting from any other requirement applicable to workers subject to the Davis-Bacon Act.

(End of clause)

52.222–31 Davis-Bacon Act—Price Adjustment (Percentage Method).

As prescribed in 22.407(f), insert the following clause:

Davis-Bacon Act—Price Adjustment (Percentage Method) (Date)

(a) The wage determination issued under the Davis-Bacon Act by the Administrator, Wage and Hour Division, Employment Standards Administration, U.S. Department of Labor, that is in effect at the exercise of an option to extend the term of the contract, will apply to that option period.

(b) The Contracting Officer will adjust the portion of the contract price or contract unit price containing the labor costs subject to the Davis-Bacon Act by the percentage rate published in ______ [Contracting Officer insert publication].

(c) The Contracting Officer will make the price adjustment at the exercise of each option to extend the term of the contract. This adjustment is the only adjustment that the Contracting Officer will make to cover any increases in wages and benefits as a result of—

(1) Incorporation of the Department of Labor’s wage determination applicable at the exercise of the option to extend the term of the contract;

(2) Incorporation of a wage determination otherwise applied to the contract by operation of law; or

(3) An increase in wages and benefits resulting from any other requirement applicable to workers subject to the Davis-Bacon Act.

(End of clause)

52.222–32 Davis-Bacon Act—Price Adjustment (Actual Method).

As prescribed in 22.407(g), insert the following clause:

Davis-Bacon Act—Price Adjustment (Actual Method) (Date)

(a) The wage determination issued under the Davis-Bacon Act by the Administrator, Wage and Hour Division, Employment Standards Administration, U.S. Department of Labor, that is in effect at the exercise of an option to extend the term of the contract, will apply to that option period.

(b) The Contractor states that the prices in this contract do not include any allowance for any contingency to cover increased costs for which adjustment is provided under this clause.

(c) The Contracting Officer will adjust the contract price or contract unit price labor rates to reflect the Contractor’s actual increase or decrease in wages and fringe benefits to the extent that the increase is made to comply with, or the decrease is voluntarily made by the Contractor as a result of—

(1) Incorporation of the Department of Labor’s Davis-Bacon Act wage determination applicable at the exercise of an option to extend the term of the contract;

(2) Incorporation of a Davis-Bacon Act wage determination otherwise applied to the contract by operation of law.

(d) Any adjustment will be limited to increases or decreases in wages and fringe benefits as described in paragraph (c) of this clause, and the accompanying increases or decreases in social security and unemployment taxes and workers’ compensation insurance, but will not otherwise include any amount for general and administrative costs, overhead, or profit.

(e) The Contractor shall notify the Contracting Officer of any increase claimed under this clause within 30 days after receiving a revised wage determination unless this notification period is extended in writing by the Contracting Officer. The Contractor shall promptly notify the Contracting Officer of any decrease under this clause, but nothing in this clause precludes the Government from asserting a claim within the period permitted by law. The notice shall contain a statement of the amount claimed and any relevant supporting data, including payroll records that the Contracting Officer may reasonably require. Upon agreement of the parties, the Contracting Officer will modify the contract price or contract unit price in writing. The Contractor shall continue performance pending agreement on or determination of any such adjustment and its effective date.

(f) Contract price adjustment computations shall be computed as follows:

(1) Computation for contract unit price per single craft hour for schedule of indefinite-quantity work. For each labor classification, the difference between the actual wage and benefit rates (combined) paid and the wage and benefit rates (combined) required by the new wage determination shall be added to the original contract unit price if the difference results in a combined increase. If the difference computed results in a combined decrease, the contract unit price shall be decreased by that amount if the Contractor provides notification as provided in paragraph (e) of this clause.

(2) Computation for contract unit price containing multiple craft hours for schedule of indefinite-quantity work. For each labor classification, the difference between the actual wage and benefit rates (combined) paid and the wage and benefit rates (combined) required by the new wage determination shall be multiplied by the actual number of hours expended for each craft involved in accomplishing the unit-priced work item. The product of this computation will then be divided by the actual number of units ordered in the preceding contract period. The total of these computations for each craft will be added to the current contract unit price to obtain the new contract unit price. The extended amount for the contract line item will be obtained by multiplying the new unit price by the estimated quantity. If actual hours are not available from the preceding contract period for computation of the adjustment for a specific contract unit of work, the Contractor, in agreement with the Contracting Officer, shall estimate the total hours per craft per contract unit of work.

Example:
**ASPHALT PAVING**

[Current price $3.38 per square yard]

<table>
<thead>
<tr>
<th>DBA craft</th>
<th>New WD</th>
<th>Hourly rate paid</th>
<th>Diff</th>
<th>Actual hrs.</th>
<th>Actual units (sq. yard)</th>
<th>Increase/sq. yard</th>
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<tbody>
<tr>
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<td>$18.00</td>
<td>$.50</td>
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</table>

Total increase per square yard = $0.29*

*Note: Adjustment for labor rate increases or decreases may be accompanied by social security and unemployment taxes and workers' compensation insurance.

Current unit price = $3.38 per square yard
Add DBA price adj. = $0.29

New unit price = $3.67 per square yard

[End of clause]

[FR Doc. 99—31348 Filed 12—2—99; 8:45 am]

BILLING CODE 6820—EP—P
Part V

Department of Defense

General Services Administration

National Aeronautics and Space Administration

48 CFR Parts 12, 13, 22, and 52

Federal Acquisition Regulation; Veterans’ Employment; Proposed Rule
DEPARTMENT OF DEFENSE
GENERAL SERVICES ADMINISTRATION
NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

48 CFR Parts 12, 13, 22, and 52
[FAR Case 1998–614]
RIN 9000–A146

Federal Acquisition Regulation; Veterans’ Employment

AGENCIES: Department of Defense (DoD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

ACTION: Proposed rule.

SUMMARY: The Civilian Agency Acquisition Council and the Defense Acquisition Regulations Council (Councils) are proposing to amend the Federal Acquisition Regulation (FAR) to implement Sections 7 and 8 of the Veterans Employment Opportunities Act of 1998. Section 7 expands and improves veterans’ employment emphasis under Federal contracts. Section 8 amends the veterans’ employment reporting requirements. This proposed rule also implements the Department of Labor’s (DoL) Office of Federal Contract Compliance Programs (OFCCP) final rule amending 41 CFR Part 60–250, Affirmative Action and Nondiscrimination Obligations of Contractors and Subcontractors Regarding Special Disabled Veterans and Veterans of the Vietnam Era, which clarifies DoL implementation of the affirmative action provisions of the Vietnam Era Veterans’ Readjustment Assistance Act of 1974, as amended.

DATES: Comments should be submitted on or before February 1, 2000 to be considered in the formulation of a final rule.

ADDRESSES: Interested parties should submit written comments to: General Services Administration, FAR Secretariat (MVRS), 1800 F Street, NW, Room 4035, ATTN: Laurie Duarte, Washington, DC 20405.

Please submit comments only and cite FAR case 1998–614 in all correspondence related to this case.

FOR FURTHER INFORMATION CONTACT: The FAR Secretariat, Room 4035, GS Building, Washington, DC 20405, at (202) 501–5755 for information pertaining to status or publication schedules. For clarification of content, contact Mr. Jack O’Neill, Procurement Analyst, at (202) 501–3856. Please cite FAR case 1998–614.

SUPPLEMENTARY INFORMATION:

A. Background

This proposed FAR rule amends FAR 12.503, 13.005, 22.13, and the associated clauses and provisions at FAR Part 52 to implement recent statutory and regulatory changes relating to veterans’ employment opportunities and reporting. Paragraph (a) of Section 7 of the Veterans’ Employment Opportunities Act of 1998 (Pub. L. 105–339) amends 38 U.S.C. 4212 in paragraph (a) to increase the threshold for covered contracts from $10,000 to $25,000, and expands applicability beyond “special disabled veterans and veterans of the Vietnam era” to include other eligible veterans, (i.e., any other veterans who served on active duty during a war or in a campaign or an expedition for which a campaign badge has been authorized). Paragraph (b) of Section 7 amends 31 U.S.C. 1354 to specifically prohibit contracting officers from obligating or expending appropriated funds to enter into covered contracts with a contractor that does not meet veteran’s employment reporting requirements (VETS–100 Report). In accordance with 41 U.S.C. 429 and 41 U.S.C. 430, the Councils have listed this law as inapplicable to acquisitions not greater than the simplified acquisition threshold and acquisitions of commercial items.

Paragraph (b) also requires the DoL to maintain a database on those contractors that have submitted the required VETS–100 Reports for the current reporting period. However, the database will not contain data on whether those contractors that did not submit reports were required to do so. The Councils have added a new provision by which the offeror represents that, if subject to the reporting requirements of 38 U.S.C. 4212(d), it has not failed to submit the most recent required VETS–100 Reports. This representation is the least burdensome way to comply with the provisions of 31 U.S.C. 1354.

Specific attention is directed to the proposed changes to FAR 12.503, Applicability of certain laws to Executive agency contracts for the acquisition of commercial items, and FAR 13.005, Federal Acquisition Streamlining Act of 1994 list of inapplicable laws. 31 U.S.C. 1354(a) was enacted subsequent to the Federal Acquisition Streamlining Act of 1994 (FASA), and it does not apply to commercial items or those simplified acquisitions unless the Federal Acquisition Regulatory Council decides to apply them. This rule lists 31 U.S.C. 1354(a) as not applicable to commercial item contracts and acquisitions not greater than the simplified acquisition threshold of $100,000 pursuant to FASA at 41 U.S.C. 429 and 41 U.S.C. 430. This is to avoid encumbering these procurements with Government-unique requirements. Accordingly, the representation in the provision at 52.222–38, Compliance with Veterans’ Employment Reporting Requirements, is not applicable to commercial item acquisitions and acquisitions not greater than the simplified acquisition threshold of $100,000.

The Department of Labor believes a wider application of the funding restrictions, covering commercial items and acquisitions not greater than the simplified acquisition threshold of $100,000, would provide better enforcement of the provisions of the VETS–100 reporting requirement. The Department of Labor believes that all contractors, at a minimum, should self-certify that they are in compliance with the VETS–100 reporting requirements. The Federal Acquisition Regulatory Council is interested in the publics views as to whether the representation should be applied to commercial items and those simplified acquisitions.

Section 8 of Public Law 105–339 amends 38 U.S.C. 4212(d)(1) to require reporting of the maximum number and the minimum number of employees during the period covered by the report. We have added this requirement to the clause at 52.222–37, which summarizes the DoL reporting requirements.


In conformance with the Veterans Employment Opportunities Act of 1998 and the OFCCP final rule, this proposed rule revises the clause at 52.222–35, adding definitions of “special disabled veteran,” “qualified special disabled veteran,” “other eligible veteran,” and “executive and top management,” and changes the definition of “veteran of the Vietnam Era.” The clause requires contractors to list all employment openings, except executive and top management, with the local employment service office. Contractors may fulfill the listing requirement by listing jobs electronically with Americas Job Bank. The requirements for posting employment notices have also changed.
This is not a significant regulatory action and, therefore, was not subject to Office of Management and Budget review under Section 6(b) of Executive Order 12866, Regulatory Planning and Review, dated September 30, 1993. This rule is not a major rule under 5 U.S.C. 804.

B. Regulatory Flexibility Act

This proposed rule is not expected to have a significant economic impact on a substantial number of small entities within the meaning of the Regulatory Flexibility Act, 5 U.S.C. 601, et seq., because the rule implements the Contracting Restrictions of the Veterans Employment Opportunities Act of 1998 (Pub. L. 105–339) which will only affect offerors who were required to submit reports but did not do so; and also, implements the OFCCP final rule, which DoL has certified will not have a significant economic impact on a substantial number of small businesses. An Initial Regulatory Flexibility Analysis has, therefore, not been performed. Comments are invited from small businesses and other interested parties. The Councils will consider comments from small entities concerning the affected FAR subparts in accordance with 5 U.S.C. 610. Interested parties must submit such comments separately and should cite 5 U.S.C. 601, et seq. (FAR case 1998–614), in correspondence.

C. Paperwork Reduction Act

The Paperwork Reduction Act does not apply because the proposed changes to the FAR do not impose any reporting and recordkeeping requirements beyond those imposed by the DoL, for which DoL obtains the required approval from the Office of Management and Budget (OMB Control Numbers 1215–0072, 1215–0073, and 1293–0005).

List of Subjects in 48 CFR Parts 12, 13, 22, and 52

Government procurement.


Edward C. Loeb, Director, Federal Acquisition Policy Division.

Therefore, DoD, GSA, and NASA propose that 48 CFR parts 12, 13, 22, and 52 be amended as set forth below:

1. The authority citation for 48 CFR parts 12, 13, 22, and 52 continues to read as follows:

Authority: 40 U.S.C. 486(c); 10 U.S.C. chapter 137; and 42 U.S.C. 2473(c).

PART 12—ACQUISITION OF COMMERCIAL ITEMS

2. Amend section 12.503 to add paragraph [a](5) to read as follows:

12.503 Applicability of certain laws to Executive agency contracts for the acquisition of commercial items.

(a) * * * * *(5) 31 U.S.C. 1354(a), Limitation on use of appropriated funds for contracts with entities not meeting veterans’ employment reporting requirements (see 22.1302).

* * * * * *

PART 13—SIMPLIFIED ACQUISITION PROCEDURES

3. Amend section 13.005 to add paragraph (a)(10) to read as follows:

13.005 Federal Acquisition Streamlining Act of 1994 list of inapplicable laws.

(a) * * * *(10) 31 U.S.C. 1354(a) Limitation on use of appropriated funds for contracts with entities not meeting veterans’ employment reporting requirements).

* * * * * *

PART 22—APPLICATION OF LABOR LAWS TO GOVERNMENT ACQUISITIONS

4. Revise Subpart 22.13 to read as follows:

Subpart 22.13—Special Disabled Veterans, Veterans of the Vietnam Era, and Other Eligible Veterans

Sec.

22.1300 Scope of subpart.

22.1301 Definition.

22.1302 Policy.

22.1303 Applicability.

22.1304 Procedures.

22.1305 Waivers.

22.1306 Department of Labor notices and reports.

22.1307 Collective bargaining agreements.

22.1308 Complaint procedures.

22.1309 Actions because of noncompliance.

22.1310 Solicitation provision and contract clauses.

22.1300 Scope of subpart.


22.1301 Definition.

United States, as used in this subpart, means the States, the District of Columbia, the Commonwealth of Puerto Rico, the Commonwealth of the Northern Mariana Islands, American Samoa, Guam, the Virgin Islands of the United States, and Wake Island.

22.1302 Policy.

(a) Contractors and subcontractors, when entering into contracts or subcontracts subject to the Act, must—

(1) List all employment openings, with the appropriate local employment service office except for—

(i) Executive and top management positions;

(ii) Positions to be filled from within the contractor’s organization; and

(iii) Positions lasting three days or less.

(2) Take affirmative action to employ, and advance in employment, qualified special disabled veterans, veterans of the Vietnam era, and other eligible veterans without discrimination based on their disability or veteran’s status.

(b) Except for contracts for commercial items or contracts that do not exceed the simplified acquisition threshold, contracting officers must not obligate or expend funds appropriated for the agency for a fiscal year to enter into a contract for the procurement of personal property and nonpersonal services (including construction) with a contractor that has not submitted a required annual Form VETS–100, Federal Contractor Veterans’ Employment Report (VETS–100 Report), with respect to the preceding fiscal year if the contractor was subject to the reporting requirements of 38 U.S.C. 4212(d) for that fiscal year.

22.1303 Applicability.

(a) The Act applies to all contracts and subcontracts for personal property and nonpersonal services (including construction) of $25,000 or more except as waived by the Secretary of Labor.

(b) The requirements of the clause at 52.222–35, Equal Opportunity for Special Disabled Veterans, Veterans of the Vietnam Era, and Other Eligible Veterans, in any contract with a State or local government (or any agency, instrumentality, or subdivision) do not apply to any agency, instrumentality, or subdivision of that government that does not participate in work on or under the contract.

(c) The Act requires submission of the VETS–100 Report in all cases where the contractor or subcontractor has received an award of $25,000 or more except for awards to State and local governments, and foreign organizations where the workers are recruited outside of the United States.

22.1304 Procedures.

To verify if a proposed contractor is current with its submission of the VETS–100 Report, the contracting officer may—

(a) Query the Department of Labor’s VETS–100 Database via the Internet at
http://avti.cudenver.edu/vets/vets100Search.htm using the Validation Code “vets” to proceed with the search in the database; or
(b) Contact the VETS–100 Reporting Systems via e-mail at VETS100@dyncorp.com for confirmation, if the proposed contractor represents that it has submitted the VETS–100 Report and is not listed in the database.

22.1305 Waivers.
(a) The Deputy Assistant Secretary for Federal Contract Compliance Programs (OFCCP), Department of Labor (Deputy Assistant Secretary of Labor), may waive any or all of the terms of the clause at 52.222–35, Equal Opportunity for Special Disabled Veterans, Veterans of the Vietnam Era, and Other Eligible Veterans for—
(1) Any contract if a waiver is deemed to be in the national interest; or
(2) Groups or categories of contracts if a waiver is in the national interest and it is—
(i) Impracticable to act on each request individually; and
(ii) Determined that the waiver will substantially contribute to convenience in administering the Act.
(b) The head of the contracting agency may waive any requirement in this subpart when it is determined that the contract is essential to the national security, and that its award without complying with such requirements is necessary to the national security. Upon making such a determination, the head of the contracting agency must notify the Deputy Assistant Secretary of Labor in writing within 30 days.
(c) The contracting officer must submit requests for waivers in accordance with agency procedures.
(d) The Deputy Assistant Secretary of Labor may withdraw an approved waiver for a specific contract or group of contracts to be awarded, when in the Deputy’s judgment such action is necessary to achieve the purposes of the Act. The withdrawal does not apply to awarded contracts. For procurements entered into by sealed bidding, such withdrawal does not apply unless the withdrawal is made more than 10 calendar days before the date set for the opening of bids.

22.1306 Department of Labor notices and reports.
(a) The contracting officer must furnish to the contractor appropriate notices for posting when they are prescribed by the Deputy Assistant Secretary of Labor.
(b) The Act requires contractors and subcontractors to submit a report at least annually to the Secretary of Labor regarding employment of special disabled veterans, veterans of the Vietnam era, and other eligible veterans unless all of the terms of the clause at 52.222–35, Equal Opportunity for Special Disabled Veterans, Veterans of the Vietnam Era, and Other Eligible Veterans, have been waived (see 22.1305). The contractor and subcontractor must use Standard Form VETS–100, Federal Contractor Veterans’ Employment Report, to submit the required reports.

22.1307 Collective bargaining agreements.
If performance under the clause at 52.222–35, Equal Opportunity for Special Disabled Veterans, Veterans of the Vietnam Era, and Other Eligible Veterans, may necessitate a revision of a collective bargaining agreement, the contracting officer must advise the affected labor unions that the Department of Labor (DoL) will give them appropriate opportunity to present their views. However, neither the contracting officer nor any representative of the contracting officer may discuss with the contractor or any labor representative any aspect of the collective bargaining agreement.

22.1308 Complaint procedures.
Following agency procedures, the contracting office must forward any complaints received about the administration of the Act to the Veterans’ Employment and Training Service of the DoL, or through the local Veterans’ Employment Representative or designee, at the local State employment office. The Deputy Assistant Secretary of Labor is responsible for investigating complaints.

22.1309 Actions because of noncompliance.
The contracting officer must take necessary action as soon as possible upon notification by the appropriate agency official to implement any sanctions imposed on a contractor by the Department of Labor for violations of the clause at 52.222–35, Equal Opportunity for Special Disabled Veterans, Veterans of the Vietnam Era, and Other Eligible Veterans. These sanctions (see 41 CFR 60–250.66) may include—
(a) Withholding payments;
(b) Termination or suspension of the contract; or
(c) Debarment of the contractor.

22.1310 Solicitation provision and contract clauses.
(a) Insert the clause at 52.222–35, Equal Opportunity for Special Disabled Veterans, Veterans of the Vietnam Era, and Other Eligible Veterans, in solicitations and contracts when the contract is for $25,000 or more or is expected to amount to $25,000 or more, except when—
(i) Work is performed outside the United States by employees recruited outside the United States; or
(ii) The Deputy Assistant Secretary of Labor has waived, in accordance with 22.1305(a) or the head of the contracting agency has waived, in accordance with 22.1305(b), all of the terms of the clause.
(2) If the Deputy Assistant Secretary of Labor or the head of the contracting agency waives one or more (but not all) of the terms of the clause, use the basic clause with its Alternate I.
(b) Insert the clause at 52.222–37, Compliance with Veterans’ Employment Reporting Requirements, in solicitations when it is anticipated the contract award will exceed the simplified acquisition threshold and the contract is not for acquisition of commercial items.

PART 52—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

5. Amend section 52.212–5 by revising the date of the clause, paragraphs (b)(13) and (b)(15); by removing from the introductory text of paragraph (e) of the clause “or” and adding “and” in its place; and revising (e)(2) to read as follows:

52.212–5 Contract Terms and Conditions Required to Implement Statutes or Executive Orders—Commercial Items.

* * * * *
Contract Terms and Conditions Required to Implement Statutes or Executive Orders—Commercial Items (Date)

* * * * *
(b) * * *

* * * * *
(15) 52.222–37, Employment Reports on Special Disabled Veterans, Veterans of the Vietnam Era, and Other Eligible Veterans (38 U.S.C. 4212).

* * * * *
(e) * * *

* * * * *
6. Amend section 52.213-4 to revise the date of the clause: in paragraph (b)(1) by redesignating (b)(1)(ii) through (b)(1)(x) as (b)(1)(i)(iii) through (b)(1)(x), and by adding (b)(1)(i). Revise newly redesignated paragraphs (b)(1)(iv) and (b)(1)(v) to read as follows:

52.213-4 Terms and Conditions—Simplified Acquisitions (Other Than Commercial Items). * * * * * Terms and Conditions—Simplified Acquisitions (Other Than Commercial Items) [Date] * * * * * (b) * * * * * (1) * * * * * (ii) 52.222–21, Prohibition of Segregated Facilities (Feb. 1999) (E.O. 11246) (Applies to contracts over $10,000). * * * * * (iv) 52.222–35, Equal Opportunity for Special Disabled Veterans, Veterans of the Vietnam Era, and Other Eligible Veterans (DATE) (38 U.S.C. 4212) (Applies to contracts over $25,000). * * * * * (vi) 52.222–37, Employment Reports on Special Disabled Veterans, Veterans of the Vietnam Era, and Other Eligible Veterans (DATE) (38 U.S.C. 4212) (Applies to contracts over $25,000). * * * * * 7. Revise the section heading and text of 52.222–35 to read as follows:

52.222–35 Equal Opportunity for Special Disabled Veterans, Veterans of the Vietnam Era, and Other Eligible Veterans.

As prescribed in 22.1310(a)(1), insert the following clause:

Equal Opportunity for Special Disabled Veterans, Veterans of the Vietnam Era, and Other Eligible Veterans [DATE].

(a) Definitions. As used in this clause—

All employment openings means all positions except executive and top management, those positions that will be filled from within the Contractor’s organization, and positions lasting 3 days or less. This term includes full-time employment, temporary employment of more than 3 days’ duration, and part-time employment.

Executive and top management means any employee—

(1) Whose primary duty consists of the management of the enterprise in which the individual is employed or of a customarily recognized department or subdivision thereof;

(2) Who customarily and regularly directs the work of two or more other employees;

(3) Who has the authority to hire or fire other employees or whose suggestions and recommendations as to the hiring or firing and as to the advancement and promotion or any other change of status of other employees will be given particular weight;

(4) Who customarily and regularly exercises discretionary powers; and

(5) Who does not devote more than 20 percent or, in the case of an employee of a retail or service establishment, who does not devote as much as 40 percent of total hours of work in the work week to activities that are not directly and closely related to the performance of the work described in paragraphs (1) through (4) of this definition. This paragraph (5) does not apply in the case of an employee who is in sole charge of an establishment or a physically separated branch establishment, or who owns at least a 20 percent interest in the enterprise in which the individual is employed.

Other eligible veteran means any other veteran who served on active duty during a war or in a campaign or expedition for which a campaign badge has been authorized.

Positions that will be filled from within the Contractor’s organization means employment openings for which the Contractor will give no consideration to persons outside the Contractor’s organization (including any affiliates, subsidiaries, and parent companies) and includes any openings the Contractor proposes to fill from regularly established “recall” lists. The exception does not apply to a particular opening once an employer decides to consider applicants outside of its organization.

Qualified special disabled veteran means a special disabled veteran who satisfies the requisite skill, experience, education, and other job-related requirements of the employment position such veteran holds or desires, and who, with or without reasonable accommodation, can perform the essential functions of such position.

Special disabled veteran means—

(1) A veteran who is entitled to compensation or a service-connected disability.

(ii) Rated at 30 percent or more; or

(ii) Rated at 10 or 20 percent in the case of a veteran who has been determined under 38 U.S.C. 3106 to have a serious employment handicap (i.e., a significant impairment of the veteran’s ability to prepare for, obtain, or retain employment consistent with the veteran’s abilities, aptitudes, and interests); or

(2) A person who was discharged or released from active duty because of a service-connected disability.

Veteran of the Vietnam era means a person who—

(1) Served on active duty for a period of more than 180 days and was discharged or released from active duty with other than a dishonorable discharge, if any part of such active duty occurred—

(i) In the Republic of Vietnam between February 28, 1961, and May 7, 1975; or

(ii) Between August 5, 1964, and May 7, 1975, in all other cases; or

(2) Was discharged or released from active duty for a service-connected disability if any part of the active duty was performed—

(i) In the Republic of Vietnam between February 28, 1961, and May 7, 1975; or

(ii) Between August 5, 1964, and May 7, 1975, in all other cases.

(b) General. (1) The Contractor shall not discriminate against the individual because the individual is a special disabled veteran, a veteran of the Vietnam era, or other eligible veteran, regarding any position for which the employee or applicant for employment is qualified. The Contractor shall take affirmative action to employ, advance in employment, and otherwise treat qualified special disabled veterans, veterans of the Vietnam era, and other eligible veterans without discrimination based upon their disability or veterans’ status in all employment practices such as—

(i) Recruitment, advertising, and job application procedures;

(ii) Hiring, upgrading, promotion, award of tenure, demotion, transfer, layoff, termination, right of return from layoff and rehiring;

(iii) Rate of pay or any other form of compensation and changes in compensation;

(iv) Job assignments, job classifications, organizational structures, position descriptions, lines of progression, and seniority lists;

(v) Leaves of absence, sick leave, or any other leave;

(vi) Fringe benefits available by virtue of employment, whether or not administered by the Contractor;

(vii) Selection and financial support for training, including apprenticeship, and on-the-job training under 38 U.S.C. 3687;

(viii) Professional meetings, conferences, and other related activities, and selection for leaves of absence to pursue training;

(viii) Activities sponsored by the Contractor including social or recreational programs; and

(ix) Any other term, condition, or privilege of employment.

(2) The Contractor shall comply with the rules, regulations, and relevant orders of the Secretary of Labor issued under the Vietnam Era Veterans’ Readjustment Assistance Act of 1974 (the Act), as amended (38 U.S.C. 4212).

(c) Listing openings. (1) The Contractor shall immediately list all employment openings that exist at the time of the execution of this contract and those which occur during the performance of this contract, including those not generated by this contract, and including those occurring at an establishment of the Contractor other than the one where the contract is being performed, but excluding those of independently operated corporate affiliates, at an appropriate local public employment service office of the State wherein the opening occurs. Listing employment openings with the U.S. Department of Labor’s America’s Job Bank shall satisfy the requirement to list jobs with the local employment service office.

(2) The Contractor shall make the listing of employment openings with the local employment service office at least concurrently with using any other recruitment source or effort and shall involve the normal obligations of placing a bona fide job order, including accepting referrals of veterans and non-veterans. This listing of employment openings does not require hiring any particular job applicant or hiring from any particular group of job applicants and is not intended to relieve the Contractor from any requirements of Executive orders or
regulations concerning nondiscrimination in employment.

(3) Whenever the Contractor becomes contractually bound to the listing terms of this clause, it shall advise the State public employment agency in each State where it has establishments of the name and location of each hiring location in the State. As long as the Contractor is contractually bound to these terms and has so advised the State agency, it need not advise the State agency of subsequent contracts. The Contractor may advise the State agency when it is no longer bound by this contract clause.

(d) Applicability. This clause does not apply to the listing of employment openings that occur and are filled outside the 50 States, the District of Columbia, the Commonwealth of Puerto Rico, the Commonwealth of the Northern Mariana Islands, American Samoa, Guam, the Virgin Islands of the United States, and Wake Island.

(e) Postings. (1) The Contractor shall post employment notices in conspicuous places that are available to employees and applicants for employment.

(2) The employment notices shall—

(i) State the rights of applicants and employees as well as the Contractor's obligation under the law to take affirmative action to employ and advance in employment qualified employees and applicants who are special disabled veterans, veterans of the Vietnam era, and other eligible veterans; and

(ii) Be in a form prescribed by the Deputy Assistant Secretary for Federal Contract Compliance Programs, Department of Labor (Deputy Assistant Secretary of Labor), and provided by or through the Contracting Officer.

(3) The Contractor shall ensure that applicants or employees who are special disabled veterans are informed of the contents of the notice (e.g., the Contractor may have the notice read to a visually disabled veteran, or may lower the posted notice so that it can be read by a person in a wheelchair).

(4) The Contractor shall notify each labor union or representative of workers with which it has a collective bargaining agreement, or other contract understanding, that the Contractor is bound by the terms of the Act and is committed to take affirmative action to employ, and advance in employment, qualified special disabled veterans, veterans of the Vietnam era, and other eligible veterans.

(f) Noncompliance. If the Contractor does not comply with the requirements of this clause, the Government may take appropriate actions under the rules, regulations, and relevant orders of the Secretary of Labor issued pursuant to the Act.

(g) Subcontracts. The Contractor shall insert the terms of this clause in all subcontracts or purchase orders of $25,000 or more unless exempted by rules, regulations, or orders of the Secretary of Labor. The Contractor shall act as specified by the Deputy Assistant Secretary of Labor to enforce the terms, including action for noncompliance.

(End of clause)

Alternate I (Date). As prescribed in 22.1310(a)(2), add the following as a preamble to the clause:

Notice: The following term(s) of this clause are waived for this contract:

[List term(s)].

8. Revise the section heading and text of 52.222–37 to read as follows:

52.222–37 Employment Reports on Special Disabled Veterans, Veterans of the Vietnam Era, and Other Eligible Veterans.

As prescribed in 22.1310(b), insert the following clause:

Employment Reports on Special Disabled Veterans, Veterans of the Vietnam Era, and Other Eligible Veterans (Date)

(a) Unless the Contractor is a State or local government agency, the Contractor shall report at least annually, as required by the Secretary of Labor, on—

(1) The number of special disabled veterans, the number of veterans of the Vietnam era, and other eligible veterans in the workforce of the Contractor by job category and hiring location; and

(2) The total number of new employees hired during the period covered by the report, and of the total, the number of special disabled veterans, the number of veterans of the Vietnam era, and the number of other eligible veterans; and

(3) The maximum number of employees and the minimum number of employees of such Contractor during the period covered by the report.

(b) The Contractor shall report the above items by completing the Form VETS–100, entitled “Federal Contractor Veterans’ Employment Report (VETS–100 Report)”.

(c) The Contractor shall submit VETS–100 Reports no later than September 30 of each year beginning September 30, 1988.

(d) The employment activity report required by paragraph (a)(2) of this clause shall reflect total hires during the most recent 12-month period as of the ending date selected for the employment profile report required by paragraph (a)(1) of this clause. Contractors may select an ending date—

(1) As of the end of any pay period during the period June through August 1st of the year the report is due; or

(2) As of December 31, if the Contractor has prior written approval from the Equal Employment Opportunity Commission to do so for purposes of submitting the Employer Information Report EEO–1 (Standard Form 100).

(e) The Contractor shall base the count of veterans reported according to paragraph (a) of this clause on voluntary disclosure. Each Contractor subject to the reporting requirements at 38 U.S.C. 4212 shall invite all special disabled veterans, veterans of the Vietnam era, and other eligible veterans who wish to benefit under the affirmative action program at 38 U.S.C. 4212 to identify themselves to the Contractor. The invitation shall state that—

(1) The information is voluntarily provided;

(2) The information will be kept confidential;

(3) Disclosure or refusal to provide the information will not subject the applicant or employee to any adverse treatment; and

(4) The information will be used only in accordance with the regulations promulgated under 38 U.S.C. 4212.

(f) The Contractor shall insert the terms of this clause in all subcontracts or purchase orders of $25,000 or more unless exempted by rules, regulations, or orders of the Secretary of Labor.

(End of clause)

9. Add section 52.222–38 to read as follows:

52.222–38 Compliance with Veterans’ Employment Reporting Requirements.

As prescribed in 22.1310(c), insert the following provision:

Compliance With Veterans’ Employment Reporting Requirements (Date)

By submission of its offer, the offeror represents that, if it is subject to the reporting requirements of 38 U.S.C. 4212(d) (i.e., if it has any contract containing Federal Acquisition Regulation clause 52.222–37, Employment Reports on Disabled Veterans, Veterans of the Vietnam Era, and Other Eligible Veterans), it has submitted the most recent VETS–100 Report required by that clause.

(End of provision)

10. Revise the date of the clause and paragraph (c)(2) of 52.244–6 to read as follows:

52.244–6 Subcontracts for Commercial Items and Commercial Components.

* * * * *

Subcontracts for Commercial Items and Commercial Components (Date)

* * * * *

(c) * * *

(2) 52.222–35, Equal Opportunity for Special Disabled Veterans, Veterans of the Vietnam Era, and Other Eligible Veterans (38 U.S.C. 4212(a));

* * * * *

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Friday, December 3, 1999

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