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Vol. 68, No. 133
Friday, July 11, 2003

Presidential Documents

Title 3—

The President

Presidential Determination No. 2003–27 of June 30, 2003

Waiving Prohibition on United States Military Assistance to Parties to the Rome Statute Establishing the International Criminal Court

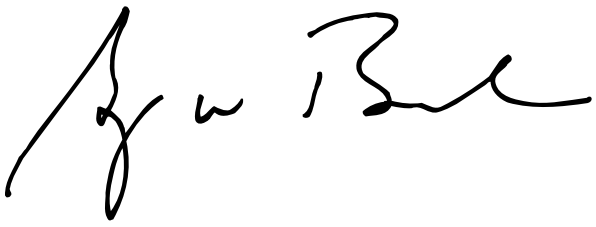
Memorandum for the Secretary of State

Consistent with the authority vested in me by section 2007 of the American Servicemembers' Protection Act of 2002, title II of Public Law 107–206 (22 U.S.C. 7421 *et seq.*), I hereby determine that:

(1) Gabon, the Gambia, Mongolia, Senegal, Sierra Leone, and Tajikistan have each entered into an agreement with the United States pursuant to Article 98 of the Rome Statute preventing the International Criminal Court from proceeding against U.S. personnel present in such countries and waive the prohibition of section 2007(a) of the American Servicemembers' Protection Act with respect to these countries for as long as such agreement remains in force;

(2) it is important to the national interest of the United States to waive, until November 1, 2003, the prohibition of section 2007(a) with respect to Afghanistan, Djibouti, Democratic Republic of Congo, East Timor, Ghana, Honduras, and Romania, and waive that prohibition with respect to these countries until that date; and

(3) it is important to the national interest of the United States to waive, until January 1, 2004, the prohibition of section 2007(a) with respect to Albania, Bolivia, Bosnia-Herzegovina, Botswana, Former Yugoslav Republic of Macedonia, Mauritius, Nigeria, Panama, and Uganda, and waive that prohibition with respect to these countries until that date. You are authorized and directed to report this determination to the Congress, and to arrange for its publication in the **Federal Register**.



THE WHITE HOUSE,
Washington, June 30, 2003.

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Rules and Regulations

Federal Register
Vol. 68, No. 133
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NUCLEAR REGULATORY COMMISSION

10 CFR Part 95

[3150–AH17]

Facility Security Clearance and Safeguarding of National Security Information and Restricted Data—Minor Changes

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Nuclear Regulatory Commission (NRC) is amending its regulations to reflect organizational changes resulting from the creation of the Office of Nuclear Security and Incident Response, to correct a minor error, and to change the example of the derivative classification stamp.

EFFECTIVE DATE: July 11, 2003.

FOR FURTHER INFORMATION CONTACT: J. Keith Everly, Information Security Section, Division of Nuclear Security, Office of Nuclear Security and Incident Response, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, telephone (301) 415–7048.

SUPPLEMENTARY INFORMATION: The events of September 11, 2001, highlighted the need to examine the way NRC was organized to carry out its safeguards, security, and incident response function. After a review of its organizational structure, the NRC, effective on April 7, 2002, added a new Office of Nuclear Security and Incident Response (NSIR) to its organization. As part of the creation of this new office, NRC's Information Security Section, which was part of the Division of Facilities and Security, Office of Administration, was moved to the Division of Nuclear Security, NSIR. This section receives all communications and reports concerning the regulations in 10 CFR part 95, ''Facility Security Clearance and Safeguarding of National Security Information and Restricted Data.'' Therefore, the regulations in this part were changed to reflect the transfer of the Information Security Section to NSIR. Accordingly, in relevant sections of part 95, the organization identification of ''Facilities and Security, Office of Administration'' has been changed to ''Nuclear Security, Office of Nuclear Security and Incident Response.''

In addition, the final rule corrects the first sentence of 10 CFR 95.1 by removing the words ''security facility approval'' and adding in their place the words ''facility security clearance.''

This final rule also amends the example of the derivative classification stamp in paragraph (c)(1)(iii) of 10 CFR 95.37, ''Classification and preparation of documents,'' for derivative classification of classified National Security Information regarding the Originating Agency's Determination Required (OADR) declassification instruction. In accordance with Executive Order 12958, ''Classified National Security Information,'' as implemented in 32 CFR part 2001, OADR is no longer used on newly generated documents as of October 16, 1995. Additionally, documents generated under previous executive orders do not have to be remarked. The derivative classification stamp includes instructions for declassification.

Because these amendments deal solely with NRC organization, procedure, or practice, the notice and comment provisions of the Administrative Procedure Act do not apply under 5 U.S.C. 553 (b)(A). In addition, good cause exists pursuant to 5 U.S.C. 553(d) to dispense with the usual 30-day delay in the effective date, because these amendments are of a minor nature, dealing with the organization and procedures of the NRC. Therefore, these amendments are effective upon publication in the **Federal Register**.

Environmental Impact: Categorical Exclusion

The NRC has determined that this final rule is the type of action described in categorical exclusion 10 CFR 51.22 (c)(2). Therefore, neither an environmental impact statement nor an environmental assessment has been prepared for this final rule.

Paperwork Reduction Act Statement

This final rule does not contain new or amended information collection requirements subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). Existing requirements were approved by the Office of Management and Budget, approval number 3150–0047.

Public Protection Notification

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

Regulatory Analysis

A regulatory analysis has not been prepared for this final rule because this rule is administrative in that it amends the regulations to reflect organizational changes. These are considered minor non-substantive amendments and will not have a significant impact on NRC licensees or the public.

Backfit Analysis

The NRC has determined that the backfit rule does not apply to this final rule because this rule does not involve any provisions that would impose a backfit as defined in 10 CFR Chapter 1. Therefore a backfit analysis is not required for this rule.

List of Subjects in 10 CFR Part 95

Classified information, Criminal penalties, Reporting and record keeping requirements, Security measures.

■ For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and 5 U.S.C. 552 and 553, the NRC is adopting the following amendments to 10 CFR Part 95.

PART 95—-FACILITY SECURITY CLEARANCE AND SAFEGUARDING OF NATIONAL SECURITY INFORMATION AND RESTRICTED DATA

■ 1. The authority citation for part 95 continues to read as follows:

Authority: Secs. 145, 161, 193, 68 Stat. 942, 948, as amended (42 U.S.C. 2165, 2201); sec. 201, 88 Stat. 1242, as amended (42 U.S.C. 5841); E.O. 10865, as amended, 3 CFR 1959–1963 COMP., p. 398 (50 U.S.C. 401,

note); E.O. 12829, 3 CFR 1993 Comp., p.570; E.O. 12958, as amended, 3 CFR, 1995 Comp., p.333; E.O. 12968, 3 CFR 1995 Comp., p. 391.

§ 95.1 [Amended]

■ 2. In § 95.1, in the first sentence, remove the words ''security facility approval,'' and add in their place the words ''facility security clearance.''

§ 95.9 [Amended]

■ 3. In § 95.9, remove the words ''Facilities and'' and add in their place the word ''Nuclear.''

§ 95.19 [Amended]

■ 4. In § 95.19, the introductory text of paragraph (a), in the second sentence, remove the words '' Facilities and Security, Office of Administration'' and add in their place the words ''Nuclear Security, Office of Nuclear Security and Incident Response.'' In the third sentence, remove the words ''Facilities and,'' and add in their place the word ''Nuclear,'' and in paragraph (c), remove the words ''Facilities and'' and add in their place the word ''Nuclear.''

§ 95.20 [Amended]

■ 5. In § 95.20, in the first sentence, remove the words ''Facilities and'' and add in their place the word ''Nuclear.''

§ 95.21 [Amended]

■ 6. In § 95.21, in the first sentence, remove the words ''Facilities and'' and add in their place the word ''Nuclear.''

§ 95.36 [Amended]

■ 7. In § 95.36, in paragraph (a), in the first sentence, remove the words ''Facilities and'' and add in their place the word ''Nuclear.'' In paragraph (c), in the first sentence, remove the words ''Facilities and'' and add in their place the word ''Nuclear,'' and in paragraph (d), in the third and fourth sentences, remove the words ''Facilities and'' and add in their place the word ''Nuclear.''

■ 8. In § 95.37, paragraph (c)(1)(iii) is revised to read as follows:

§ 95.37 Classification and preparation of documents.

(c) * * *

(1) * * *

(iii) An example of the marking stamp is as follows:

Derived from _____
(Source/Date)

Reason: _____

Declassify On: _____
(Date/Event/Exemption)

Classifier: _____
(Name/Title/Number)

* * * * *

§ 95.45 [Amended]

■ 9. In § 95.45, in paragraph (a), in the second sentence, remove the words ''Facilities and Security, Office of Administration,'' and add in their place the words ''Nuclear Security, Office of Nuclear Security and Incident Response,'' and in the third sentence, remove the words ''Facilities and'' and add in their place the word ''Nuclear.''

§ 95.53 [Amended]

■ 10. In § 95.53, in the third sentence, remove the words ''Facilities and'' and add in their place the word ''Nuclear.''

§ 95.57 [Amended]

■ 11. In § 95.57, paragraph (c), in the first sentence, remove the words ''Facilities and'' and add in their place the word ''Nuclear,'' and in the third sentence, remove the words ''Facilities and'' and add in their place the word ''Nuclear.''

Dated at Rockville, Maryland, this 25th day of June 2003.

For the Nuclear Regulatory Commission.

William D. Travers,

Executive Director for Operations.

[FR Doc. 03–17583 Filed 7–10–03; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Parts 1300, 1301, 1304, 1305, and 1307

[Docket No. DEA–108I]

RIN 1117–AA19

Definition and Registration of Reverse Distributors

AGENCY: Drug Enforcement Administration (DEA), Justice.

ACTION: Interim final rule with request for comment.

SUMMARY: DEA is amending its regulations to define the term ''reverse distributor'' and to establish a new category of registration for persons handling controlled substances. The amendments establish the regulatory standards under which reverse distributors may handle unwanted, unusable, or outdated controlled substances acquired from another DEA registrant. These standards ensure the proper documentation and recordkeeping necessary to prevent diversion of such controlled substances to illegal purposes. Since this amendment mostly codifies DEA's existing practices, it will have no significant impact on existing reverse distributors.

DATES: Effective Date: August 11, 2003.

Comment Date: Written comments must be postmarked on or before September 9, 2003.

ADDRESSES: Comments should be submitted to the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, Washington, DC 20537, Attention: DEA **Federal Register** Representative/CCR.

FOR FURTHER INFORMATION CONTACT: Patricia M. Good, Chief, Liaison and Policy Section, Office of Diversion Control, Drug Enforcement Administration, Washington, DC 20537. Telephone (202) 307–7297.

SUPPLEMENTARY INFORMATION:

Overview of and Benefits of This Interim Final Rule

As is more fully discussed in this preamble, this interim final rule mostly codifies existing practices that reverse distributors follow under memoranda of understanding (MOUs) with the Drug Enforcement Administration. This approach is consistent with the comments received (also discussed more fully later in this preamble) that stated that reverse distributors would be significantly and adversely impacted if, as was proposed, they were classified as manufacturers. In recognizing this activity as a separate registration category of distributors, DEA believes the entire controlled substances industry will benefit. Existing reverse distributors operating under MOUs will become fully recognized registrants under DEA rules. Thousands of other registrants who need to dispose of unneeded or outdated inventories will be able to turn to a fully registered group of distributors. Furthermore, by essentially codifying existing practices these benefits will be achieved with minimal need for change or for disruption to the affected industry.

Background

The overall goal of the Controlled Substances Act (CSA) and of DEA's regulations in Title 21, Code of Federal Regulations (CFR), parts 1300–1316 is to provide a closed distribution system so that a controlled substance is at all times under the legal control of a person registered, or specifically exempted from registration, by the Drug Enforcement Administration until it reaches the ultimate user or is destroyed. DEA achieves this goal by registering manufacturers, distributors, and dispensers of controlled substances. Thus, any movement of controlled substances between these registered persons is covered by DEA regulations,

which ensure that all controlled substances are accounted for from their creation until their consumption or destruction.

When a controlled substance has become outdated or otherwise unusable, the registered person who possesses the substance must dispose of it. However, over the past decade, environmental concerns and regulatory changes have caused drug manufacturers and government agencies (including DEA and State authorities) to become increasingly reluctant to be involved in the disposal process. Thus, many disposal options are no longer available.

Nonetheless, disposal of controlled substances can occur in several ways:

1. The distributor or dispenser can return the controlled substances to the pharmaceutical manufacturers who, as a service to their customers, accept returns of outdated/damaged controlled substances. Distributors, dispensers, and manufacturers are all registered with DEA.

2. The distributor, dispenser, or manufacturer can itself dispose of the controlled substances under the procedures outlined in 21 CFR 1307.21. Under 21 CFR 1307.21, any person may request permission to dispose of controlled substances without the benefit of a DEA or State witness. In many cases, blanket permission for disposal of controlled substances is granted to registrants who have an ongoing need to dispose of unwanted controlled substances. The disposal must be authorized by DEA in writing, and DEA may require that a set schedule be established. Other registrants are granted disposal authority on a case-by-case basis. DEA normally requires that the registrant provide two designated responsible individuals to accompany the drugs to the disposal site and witness the destruction. This achieves DEA's goal of assuring the controlled substances are rendered nonrecoverable. Disposal under the authority of 21 CFR 1307.21 maintains the closed distribution system because the controlled substances remain under the legal control of a registered person at all times.

3. The distributor, dispenser, or manufacturer can distribute the controlled substances to a reverse distributor to take control of the controlled substances for the purpose of returning them to the manufacturer or, if necessary, disposing of them.

For many years, DEA opposed granting DEA registrations to firms solely or primarily engaged in the disposal (whether the transportation portion, actual disposal, or both) of controlled substances because they were not considered an essential link in the closed distribution system that the Controlled Substances Act established to control the flow of drugs from the manufacturer to the ultimate user. In recent years, however, increasingly stringent requirements imposed by the U.S. Environmental Protection Agency (EPA) resulted in fewer and fewer approved disposal facilities. As a result, a new type of business has developed that collects controlled substances from registrants and either returns them to the manufacturer or arranges for their disposal. The businesses performing this middleman service refer to themselves as ''reverse distributors'' or ''returns processors.''

This interim final rule deals only with the distribution of controlled substances to reverse distributors. The first two categories—direct returns of controlled substances by distributors or dispensers to manufacturers, and disposals by the distributor, manufacturer or dispenser—are already covered by the existing rules. Only the third category, *i.e.*, persons who distribute controlled substances to reverse distributors, is not expressly covered by the current regulations, although DEA has regulated reverse distributors for many years, first, as distributors generally, and second, as reverse distributors specifically under the terms of Memoranda of Understanding (MOUs), through which they are granted DEA registrations. This rule will eliminate the need for MOUs. However, since this amendment essentially codifies current DEA policies and practices, it does not impose any significant additional burden on reverse distributors.

On August 23, 1995, DEA issued a Notice of Proposed Rulemaking (NPRM) (60 FR 43732) that proposed regulatory standards governing disposers of controlled substances. DEA proposed to accomplish this by amending its regulations to define the term ''Disposer'' to account for this middleman function in the regulations and establish a new category of manufacturer registration under which persons performing this function would be registered. DEA also proposed amending the regulations to exempt disposers from the quota requirements; to identify the records and reports required of disposers; and to establish order form procedures for disposers. Finally, DEA proposed amendments to a number of gender-specific sections to make them gender neutral.

DEA originally based its decision to define the persons performing the reverse distribution function as disposers on the definition of ''manufacturer.'' In 21 CFR 1300.01(b)(27), DEA defines manufacture in part as ''the producing, preparation, propagation, compounding, or processing of a drug or other substance . . . .'' The section further defines a manufacturer as ''a person who manufactures a drug or other substance . . .'' In the proposed rule, DEA stated that by its nature, a disposer processes a drug or other substance. Therefore, DEA proposed to place disposers within the definition of manufacturer, under a new disposer subcategory. Commenters to the proposed rule objected to being categorized as disposers and manufacturers for the reasons explained below under ''Comments.'' Therefore, in this interim final rule, DEA is establishing a definition for ''reverse distributor'' and is establishing a new category of registration as reverse distributors.

DEA is using an interim final rule because it will give interested persons an additional opportunity for comment even though the substance of this interim final rule is consistent with the purpose of the August 1995 NPRM, the comments submitted in response to that NPRM, and with current DEA and industry practice.

Currently DEA registers persons performing reverse distributor functions as distributors. Since reverse distributors are not specifically identified in the current regulations, DEA enters into a Memorandum of Understanding (MOU) with the person performing the reverse distribution function. The Memorandum of Understanding (MOU) specifies conditions which the reverse distributor must follow in addition to the regulations that apply to distributors. These registrations must be renewed annually and operations under them are limited to products in schedules listed on the registration. DEA has not experienced any difficulties in treating reverse distributors as distributors for purposes of registration and other requirements. Any reverse distributor that was registered under the terms of a MOU will be reregistered as a reverse distributor under the terms of this interim final rule in the next renewal cycle and will be specifically identified in DEA's records as a reverse distributor. Persons currently conducting reverse distribution operations must notify DEA by no later than the time of renewal of their registration so that they may be properly identified as reverse distributors in DEA's records.

The requirements for a reverse distributor in this interim final rule are similar to those currently imposed on

all registrants at the distributor level. They include, but are not necessarily limited to:

- *Security:* All applicants must install, at the registered premises, physical security controls that meet the existing standards of 21 CFR 1301.71 and 1301.72.
- *Recordkeeping:* In accordance with 21 CFR part 1304, periodic inventories and records of all controlled substances received, destroyed, or returned to the original, registered manufacturers must be maintained for two years. The registrant must adequately describe the receipt and accountability methods and records to be employed to ensure the establishment of effective controls against diversion.
- *Order Forms* must be completed for all Schedule I and II items received and transferred.
- *Reports* are required under the Automation of Reports and Consolidated Orders System (ARCOS), as specified in 21 CFR 1304.33.

In addition to DEA requirements, reverse distribution applicants must obtain the appropriate State and Federal approvals for controlled substances and disposal activities.

After publication of the August 1995 NPRM, DEA completed a rulemaking project in 1997 (62 FR 13938, March 24, 1997) that reorganized and clarified the regulations that would have been affected by that NPRM. The 1997 rulemaking also addressed the gender-specific and other editorial changes that were contained in the 1995 NPRM. Therefore, proposed changes to 21 CFR 1301.26 (now 21 CFR 1301.24), Exemption of law enforcement officers; 21 CFR 1301.32 (now 21 CFR 1301.13), Application forms; contents; signature; and 21 CFR 1304.34 (now 21 CFR 1304.33(a)), Reports generally, are not included in this interim final rule. For the proposed changes that relate to reverse distributors, this interim final rule amends the appropriate CFR sections as changed in 1997. Throughout the preamble, citations to both previous section number and current section number are provided, where relevant.

Public Comments on the NPRM

Eight comments were received regarding the proposed rule. Commenters included reverse distributors and disposers currently operating under Memoranda of Understanding (*i.e.*, facilities such as incinerators that destroy controlled substances) and some of their representative organizations. While some commenters supported the intent of the rule, all commenters were against some or all aspects of the rule. The following discussion summarizes the issues raised by commenters and DEA's response to these issues.

Proposed Definition and Registration Requirements

Most commenters opposed the proposal to classify the activities they engage in as either disposal or manufacturing and stated that doing so would subject them to unnecessary and burdensome regulations.

One commenter stated that since reverse distributors neither process nor package/repackage controlled substances within the meaning of the statutory definition of ''manufacturer,'' it is beyond DEA's statutory authority to regulate these companies as manufacturers. Another commenter stated that the primary goal of disposers is not to render a controlled substance unusable, but, rather, it is to sort, inventory and perform other activities necessary to distribute products back to the original manufacturer and only secondarily, arrange for the actual destruction of controlled substances.

Four commenters stated that the proposed definition of disposer implies that a disposer is manipulating the product and, therefore, that waste is being accepted. This would, in turn, require disposers to comply with the more burdensome guidelines of the Food and Drug Administration (FDA) and EPA.

DEA Response

In response to these comments, DEA has decided to establish a definition for reverse distributor and is establishing a new category of registration as reverse distributors. In this interim final rule, DEA is adding the definition for ''reverse distributors'' to 21 CFR 1300.01(b). Reverse distributors are defined as ''a person who receives controlled substances acquired from another DEA registrant for the purpose of returning unwanted, unusable, or outdated controlled substances to the manufacturer or the manufacturer's agent, or, where necessary, processing such substances or arranging for processing such substances for disposal.'' When reverse distributors return unwanted, unusable, or outdated controlled substances acquired from legitimate medical, scientific, research or other industrial channels to a manufacturer or a manufacturer's agent, they must follow the same DEA requirements as distributors follow. When reverse distributors process controlled substances or arrange for processing controlled substances for disposal, they must follow the same procedures that distributors would follow in complying with 21 CFR 1307.21, ''Procedure for disposing of controlled substances.''

Applicability to Practitioners and Others

One commenter stated that classifying dentists and other small disposers as manufacturers would be burdensome because they would now have to register and pay burdensome registration fees. This could result in dentists removing themselves from regulatory control by refusing to handle controlled substances, which could adversely affect their patients. This commenter recommended that the proposed rule either exempt dentists and other small disposers by quantity, or state that they are not members of the ''disposer'' subcategory.

Another commenter stated that previous contacts with DEA indicated that the rulemaking is intended to regulate disposers that dispose of or offer controlled substances for disposal over which they have legal control. This commenter requested that DEA clarify that it should not be subject to the proposed rule provided that it is acting as an agent of DEA through a contract; or that it disposes of controlled substances for manufacturers provided that the manufacturer's representatives bring the controlled substances to a disposal facility and witness the destruction, thus maintaining legal responsibility for the controlled substances.

DEA Response

In this interim final rule, DEA is not changing the procedures for disposing of controlled substances under 21 CFR 1307.21. Those procedures are designed to ensure that controlled substances are under the control of a DEA registrant until they are destroyed or rendered unusable. If a disposal company never takes legal control of a controlled substance and the actual destruction is witnessed by two representatives of a DEA registrant, the disposal company itself is not required to obtain a DEA registration. On the other hand, if a disposal company receives controlled substances from a DEA registrant and then disposes of them later, the disposal company becomes part of the chain of responsible parties and must therefore be registered by DEA as a reverse distributor.

Under the interim final rule, DEA registrants who need to periodically dispose of controlled substances, such as practitioners, would continue to follow their current procedures for disposal of controlled substances.

Usually this involves obtaining authority and instructions from the local DEA field office as specified in 21 CFR 1307.21. Such registrants also have the option of returning controlled substances to the manufacturer or to a reverse distributor.

Appropriateness of Security and Other Requirements That Apply to Manufacturers

Commenters recommended creating a separate category for reverse distributors, as a subcategory of distributors, who would be subject to the existing registration and other requirements for distributors. Commenters stated that reverse distributors should, therefore, not be subject to the security, inventory, recordkeeping, and reporting requirements of the proposed rule that apply to manufacturers.

DEA's Response

Since DEA has decided to create a completely separate category for reverse distributors, persons who fall under this category will be required to comply with the same security, reporting, and other requirements that apply to distributors rather than the requirements that apply to manufacturers.

Proposed Security Requirements: Monitoring Systems

DEA received one comment on the language in proposed 21 CFR 1301.71(b)(14) which requires the applicant or registrant to document the adequacy of its system for monitoring the receipt, manufacture, distribution, and disposal of controlled substances. The commenter stated that all of the ''waste to energy'' facilities that it operates have demonstrated that the implementation of supervised monitoring of the receipt and disposal process, by the disposer, has proven effective and that it would be physically impossible for them to construct the vaults or other security barriers that the regulations require for storage at manufacturer's locations (under 21 CFR 1301.72). Instead, this commenter recommended that disposers be required to develop a set of Standard Operating Procedures, to be approved by DEA, for the receipt and disposal of controlled substances.

DEA Response

With respect to the issue of physical security, it should be noted that the commenter does not take possession of the controlled substances that are to be destroyed. Instead, the commenter maintains incineration facilities at which DEA registrants carry out witnessed destruction of their controlled substances. As a result, the commenter is not subject to DEA's requirements and does not have to establish or maintain physical security as required under 21 CFR 1301.72 of the regulations.

Proposed Security Requirements: Compliance With Other Laws

One commenter commented on proposed 21 CFR 1301.71(b)(15), which would require DEA to consider the applicability of the security requirements contained in all Federal, State, and local laws and regulations governing the management of waste, as they would apply to applicants and registrants. The commenter stated that this requirement would be inappropriate because it would exceed DEA's statutory authority. While DEA inspectors should be concerned with compliance with DEA statutes and regulations during audits, the inspectors should not be empowered to look for violations of other Federal, State, and local laws governing the management of waste. Enforcement of those laws should be left to the other Federal agencies and individual jurisdictions. Therefore, the commenter requested DEA clarification on this issue.

DEA Response

With respect to this comment, the items listed in 21 CFR 1301.71(b)(1) through new (b)(15) are factors that the Administrator may consider in evaluating whether the security controls provided by a DEA registrant are adequate to guard against theft and diversion of controlled substances and appropriate to the registrant's business. Not all of the factors may be relevant for evaluation of a particular registrant's operation. DEA is adding a new factor regarding the applicability of other Federal, State, or local laws, not as an enforcement issue for those specific laws, but only as guidance to the registrant that DEA may consider how the registrant is complying with such laws in making an evaluation of the adequacy of the registrant's security system. DEA has the statutory authority under 21 U.S.C. 823 to consider an applicant's compliance with applicable State and local laws before granting a registration.

Proposed Inventory Requirements

A commenter that provides disposal facilities at which registrants may conduct witnessed destructions recommended that additional language be added to the end of proposed 21 CFR 1304.20 (current 21 CFR 1304.11) to require that the information required under 21 CFR 1304.15(a), (c), and (d) be provided by the manufacturer or its agent when tendering the substances for disposal.

DEA Response

The commenter's suggested change is not necessary because in witnessed destructions the registrant conducting the destruction must accurately document the controlled substances being destroyed on DEA Form 41. Further, a disposal facility of the type operated by the commenter does not take possession of the controlled substances being destroyed and, thus, is not subject to the registration, inventory, and recordkeeping requirements under the law.

Proposed Recordkeeping Requirements

Several commenters made recommendations to change the language of proposed 21 CFR 1304.30(a) (current 21 CFR 1304.22) to make the specific requirements clear.

A commenter also expressed concern about proposed paragraph (b) and stated that the disposer should not be expected to recount and itemize the individual dosage units and containers for each substance being delivered for disposal. This would put their employees at possible risk for exposure to these substances, increase opportunities for diversion, and significantly slow down the disposal operation. Instead, the commenter recommended that sufficient controls be placed on the manufacturer and its representatives prior to disposal so that the disposer can focus on rapid and effective disposal procedures.

DEA Response

The comments primarily address problems that could have arisen if the reverse distribution function was included under manufacturing, as proposed. These concerns are mostly addressed by treating reverse distribution as a separate category of registration. The concerns expressed by disposers are, as previously discussed, not relevant as long as legal control of the controlled substances remains with a person who is registered with DEA.

Recordkeeping requirements for reverse distributors are set forth in new paragraph (e) of 21 CFR 1304.22. These requirements are tailored to the reverse distributor role and address recordkeeping for controlled substances in both bulk and finished form. These requirements are consistent with existing practice.

Witness Requirement

A commenter stated that DEA would require two responsible individuals to accompany the drugs to the disposal site and actually witness the destruction. The commenter stated that this would significantly increase the costs of controlled substances destruction for all registrants and that the rule should, therefore, require a regulatory flexibility analysis.

DEA Response

The requirement to have two responsible individuals accompany the drugs to the disposal site is also consistent with existing practice. DEA Form 41, Registrants Inventory of Drugs Surrendered, must be completed by a registrant's representative and witnessed by a second representative of the registrant, to document the disposal of controlled substances. This form must be sent to DEA.

Proposed Reporting Requirements

A commenter stated that ARCOS reporting becomes difficult and costly when a disposer receives a quantity of a controlled substance listed in Schedule I and II and a narcotic controlled substance listed in Schedule III which is contained in a compound, mixture or preparation which is not assigned an NDC number. The commenter stated that this reporting ''will become more difficult as more returns are accepted from Pharmacies, Home Infusion Pharmacies, Provider Pharmacies to Long Term Care Facilities, Hospitals, and dispensers.''

The commenter recommended adding a new paragraph (e) to current 21 CFR 1304.33 (formerly 21 CFR 1304.39) that would provide for the following exception: ''Exceptions. Any controlled substance listed in Schedule I and II and on each narcotic controlled substance listed in Schedule III which material, compounded, mixture or preparation containing a quantity of a substance from a registered dispenser, practitioner, researchers, and analytical registrants, *e.g.*, prescription, IV mixture or non NDC material, may be exempted from filing reports under this section to ARCOS Units of the Administration.'' The commenter also stated that proposed paragraphs (b) and (c) (with regard to ARCOS reports being filed no later than the 15th day of the month or no later than January 15th) would have a significant economic impact and lead to ARCOS delays. This is because disposers (unlike manufacturers or distributors) deal with open containers that need validation (by count, weight, and/or volume) before the containers can be placed into inventory; this can be a slow and tedious process. The commenter added that the economic impact and ARCOS delays would increase as the disposer class registration utilization grows.

DEA Response

While the commenter addressed the reporting requirements in proposed 21 CFR 1304.39(b) and (c), the commenter's real concern appears to be related to inventory requirements currently in 21 CFR 1304.11. This interim final rule will allow reverse distributors to follow the inventory requirements that currently apply to dispensers and researchers. This would mean that in the circumstances described in 21 CFR 1304.11(e)(3)(ii), it would not be necessary to make an exact count or measure of the contents in all cases, *i.e.*, if the controlled substance is listed in Schedule III, IV, or V, and the container holds fewer than 1,000 tablets or capsules, the reverse distributor could make an estimated count or measure.

Notwithstanding this change, a reverse distributor is required to know what it has on hand from the moment it is received. It is the reverse distributor's responsibility to have the proper documentation and accountability for any controlled substances in his or her possession. The best way for reverse distributors to accomplish this is by doing the following: (1) Require customers to provide a list of the controlled substances to be sent in advance of the shipment; (2) Complete a form or invoice indicating the amount that the customer will be sending, keep a copy of this document, and send 2 copies to the customer; and (3) Require the customer to keep one copy of the document and put the other copy in the package with the shipment. This procedure would maintain a paper trail and provide the data on inventory from the moment the shipment is received by the reverse distributor. Reverse distributors who follow this procedure should not have difficulty preparing the ARCOS reports that are required by current 21 CFR 1304.33 for controlled substances listed in Schedules I and II, and for narcotic controlled substances listed in Schedules III, IV, and V.

With respect to the issue of non-NDC material, such as compounded prescription products or infusion products, DEA's ARCOS Unit has established a listing of generic codes that can be used to identify products that do not have an NDC number assigned. If a product being handled does not have a generic code, please contact the ARCOS Unit of the Administration for assistance.

Reverse distributors are encouraged to make use of electronic identification and tracking systems, such as bar codes, to aid in meeting the inventory and reporting requirements. Also, reverse distributors may use electronic versions of DEA Form 41 if the electronic version is an exact reproduction of the form. If the electronic version is not identical to the paper version, it is not the official form, and may not be used.

DEA invites manufacturers, reverse distributors, and other distributors to work with the Administration to establish standard operating procedures so there is a standard recordkeeping system for transferring, receiving, and inventorying partial containers. With a standardized system there would be fewer inconsistencies among the records of each registrant when controlled substances are transferred from one to another.

Proposed Order Form Requirements

A commenter stated that in the preamble, DEA stated that ''Order Forms must be completed for all Schedule I and III items received and transferred.'' The commenter stated that this is incorrect and that the correct statement should be: ''Order Forms must be completed for all Schedule I and II items received and transferred.''

DEA Response

DEA agrees that there was a typographical error in the preamble and is clarifying that order forms (DEA Form 222) required by part 1305 are for Schedule I and II controlled substances received and transferred.

Reverse Distributor Receipt of Controlled Substances From Non-registrants

Under the interim final rule, reverse distributors may only receive controlled substances from DEA registrants. Non-registrants, such as long term care facilities, do not have direct authority to handle controlled substances. Further, the substances in their possession are no longer part of the closed system of distribution and are no longer subject to DEA's system of corresponding accountability. In cases where long term care facilities must dispose of controlled substances, they should follow the guidelines within their State for disposing of the drugs and maintain appropriate documentation of the disposal. Likewise, a former registrant, such as a pharmacy, whose registration has expired or has been surrendered, would need to coordinate with the local DEA office to develop a procedure to

dispose of any controlled substances on hand.

Why Is DEA Publishing This Action as an Interim Final Rule?

As discussed previously, the goal of the NPRM was to give codified status to reverse distributors. While DEA initially proposed doing this by registering reverse distributors in the manufacturer category, comments on the NPRM made it clear that this approach would adversely affect the existing industry (*e.g.* by subjecting reverse distributors to certain EPA and FDA regulations). By registering reverse distributors as distributors, DEA accomplishes its original goal in a manner that is consistent with the intent of the NPRM and with public comments on the NPRM. Also, this approach is beneficial rather than detrimental to the entire controlled substances industry. However, recognizing the time which has elapsed between publication of the NPRM and this action, as well as the growth and evolution of the reverse distributor industry during that time, DEA has determined that, rather than publishing final regulations on this issue, it is in the best interest of industry that DEA publish an interim final rule. Publishing an interim final rule will permit further comment from the affected industry, ensuring that final regulations appropriately address industry evolution and concerns.

Summary

In summary, the registration and other requirements for reverse distributors under this interim final rule are the same as those currently imposed on distributors and the same as currently imposed on reverse distributors under MOUs; Registration requirements under existing 21 CFR 1301.13; Security requirements under existing 21 CFR 1301.71 and 1301.72; Inventory requirements under existing 21 CFR 1304.11; Recordkeeping requirements under existing 21 CFR 1304.22; Reporting requirements under existing 21 CFR 1304.33 (ARCOS reports); Order form requirements under existing 21 CFR 1305.08 (Persons entitled to fill order forms). In some cases these rules have been modified to apply specifically to reverse distributors. In addition, DEA is amending 21 CFR 1307.11 and 1307.12 to clarify that registrants can transfer (''distribute'') controlled substances to a reverse distributor, even if the registrant is not registered as a distributor. As a result of DEA's decision to classify reverse distributors as a new category of registration, instead of as a manufacturer, proposed 21 CFR 1303.12 on quotas is not applicable.

The closed system of distribution established under the CSA for controlled substances relies on certain fundamental principles, including registration, security, and accountability (*i.e.*, inventories, recordkeeping, and reporting), to achieve a system of controls that allows for legitimate commerce while minimizing the potential for diversion. The fact that reverse distributors engage in a unique activity within the controlled substances chain and are faced with certain challenges that other registrants do not normally encounter does not override the fundamental principals of DEA's controls. Reverse distributors must register, provide security, and maintain accurate records for all controlled substances in their possession. However, the regulatory structure does provide some flexibility and, where possible, DEA has made adjustments to address some of the problems the industry has encountered, including use of a separate category of registration and application of the inventory requirements for dispensers and researchers.

Because of the length of time since the NPRM was published and the evolving nature of this industry, DEA is using an interim final rule to give an additional opportunity for comment. DEA will consider comments on the appropriateness and the practical application of these rules to current industry practice and will be flexible where possible in developing final rules.

Application for Registration for Reverse Distributors

As has been previously noted in this rulemaking, persons wishing to conduct reverse distributor activities must register with DEA to do so. To apply for registration, persons must complete a DEA Form 225, Application for Registration. To renew a DEA registration, persons must complete a DEA Form 225a, Application for Registration Renewal. As DEA has not yet issued updated forms specifically referencing the reverse distributor business activity, persons wishing to register as reverse distributors must choose the distributor business activity on the form and then must attach a written statement signed by the person signing the registration or registration renewal application acknowledging that the applicant is conducting or wishes to conduct reverse distributor activities.

Regulatory Certifications

Regulatory Flexibility Act

The Deputy Assistant Administrator hereby certifies that this interim final rulemaking has been drafted in accordance with the Regulatory Flexibility Act (5 U.S.C. 605(b)), and by approving it certifies that this regulation will not have a significant economic impact upon a substantial number of small entities. Therefore, no regulatory flexibility analysis is required.

Executive Order 12866

The Deputy Assistant Administrator further certifies that this rulemaking has been drafted in accordance with the principles of Executive Order 12866 Section 1(b). DEA has determined that this rule is a significant regulatory action. Therefore, this action has been reviewed by the Office of Management and Budget.

Executive Order 12988

The Deputy Assistant Administrator further certifies that this regulation meets the applicable standards set forth in Sections 3(a) and 3(b)(2) of Executive Order 12988.

Executive Order 13132

This rulemaking does not preempt or modify any provision of State law; nor does it impose enforcement responsibilities on any State; nor does it diminish the power of any State to enforce its own laws. Accordingly, this rulemaking does not have federalism implications warranting the application of Executive Order 13132.

Unfunded Mandates Reform Act of 1995

This rule will not 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, and will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

Small Business Regulatory Enforcement Fairness Act of 1996

This rule is not a major rule as defined by Section 804 of the Small Business Regulatory Enforcement Fairness Act of 1996. This rule will not result in an annual effect on the economy of $100,000,000 or more; a major increase in costs or prices; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based companies to compete with foreign-

based companies in domestic and export markets.

List of Subjects

21 CFR Part 1300

Definitions, Drug traffic control.

21 CFR Part 1301

Administrative practice and procedure, Drug traffic control, Security measures.

21 CFR Part 1304

Drug traffic control, Reporting requirements.

21 CFR Part 1305

Drug traffic control, Reporting requirements.

21 CFR Part 1307

Drug traffic control.

■ For the reasons set out above, 21 CFR parts 1300, 1301, 1304, 1305, and 1307 are amended as follows:

PART 1300—DEFINITIONS

■ 1. The authority citation for part 1300 continues to read as follows:

Authority: 21 U.S.C. 802, 871(b), 951, 958(f).

■ 2. Section 1300.01 is amended by redesignating paragraphs (b)(41) through (b)(43) as paragraphs (b)(42) through (b)(44), and adding a new paragraph (b)(41) to read as follows:

§ 1300.01 Definitions relating to controlled substances.

* * * * *

(b) * * *

(41) The term *reverse distributor* means a registrant who receives controlled substances acquired from another DEA registrant for the purpose of—

(i) Returning unwanted, unusable, or outdated controlled substances to the manufacturer or the manufacturer's agent; or

(ii) Where necessary, processing such substances or arranging for processing such substances for disposal.

* * * * *

PART 1301—REGISTRATION OF MANUFACTURERS, DISTRIBUTORS, AND DISPENSERS OF CONTROLLED SUBSTANCES

■ 3. The authority citation for part 1301 continues to read as follows:

Authority: 21 U.S.C. 821, 822, 823, 824, 871(b), 875, 877.

■ 4. Section 1301.13 is amended by revising paragraph (c), redesignating paragraphs (e)(1)(iii) through (e)(1)(ix) as paragraphs (e)(1)(iv) through (e)(1)(x) and adding a new paragraph (e)(1)(iii) to read as follows:

§ 1301.13 Application for registration; time for application; expiration date; registration for independent activities; application forms, fees, contents and signature; coincident activities.

* * * * *

(c) At the time a manufacturer, distributor, reverse distributor, researcher, analytical lab, importer, exporter or narcotic treatment program is first registered, that business activity shall be assigned to one of twelve groups, which shall correspond to the months of the year. The expiration date of the registrations of all registrants within any group will be the last date of the month designated for that group. In assigning any of these business activities to a group, the Administration may select a group the expiration date of which is less than one year from the date such business activity was registered. If the business activity is assigned to a group which has an expiration date less than three months from the date of which the business activity is registered, the registration shall not expire until one year from that expiration date; in all other cases, the registration shall expire on the expiration date following the date on which the business activity is registered.

* * * * *

(e) * * *

(1) * * *

(iii) Reverse distributing	Schedules I–V	New—225 Renewal—225a	438 438	1

* * * * * * *

■ 5. Section 1301.71 is amended by revising paragraphs (b)(13) and (b)(14) and adding a new paragraph (b)(15) to read as follows:

§ 1301.71 Security requirements generally.

* * * * *

(b) * * *

(13) The availability of local police protection or of the registrant's or applicant's security personnel;

(14) The adequacy of the registrant's or applicant's system for monitoring the receipt, manufacture, distribution, and disposition of controlled substances in its operations; and

(15) The applicability of the security requirements contained in all Federal, State, and local laws and regulations governing the management of waste.

* * * * *

■ 6. Section 1301.72 is amended by revising paragraph (b)(7) to read as follows:

§ 1301.72 Physical security controls for non-practitioners; narcotic treatment programs and compounders for narcotic treatment programs; storage areas.

* * * * *

(b) * * *

(7) Such other secure storage areas as may be approved by the Administrator after considering the factors listed in § 1301.71(b);

* * * * *

PART 1304—RECORDS AND REPORTS OF REGISTRANTS

■ 7. The authority citation for part 1304 continues to read as follows:

Authority: 21 U.S.C. 821, 827, 871(b), 958(e), 965, unless otherwise noted.

■ 8. Section 1304.11 is amended by revising paragraph (e)(2) and the introductory text of paragraph (e)(3) to read as follows:

§ 1304.11 Inventory requirements.

* * * * *

(e) * * *

(2) *Inventories of distributors.* Except for reverse distributors covered by paragraph (e)(3) of this section, each person registered or authorized to distribute controlled substances shall include in the inventory the same information required of manufacturers pursuant to paragraphs (e)(1)(iii) and (iv) of this section.

(3) *Inventories of dispensers, researchers, and reverse distributors.* Each person registered or authorized to dispense, conduct research, or act as a reverse distributor with controlled substances shall include in the inventory the same information required of manufacturers pursuant to paragraphs (e)(1)(iii) and (iv) of this section. In determining the number of units of each finished form of a controlled substance in a commercial container which has been opened, the dispenser, researcher,

or reverse distributor shall do as follows:

* * * * *

■ 9. Section 1304.22 is amended by revising paragraph (b) and adding new paragraph (e) to read as follows:

§ 1304.22 Records for manufacturers, distributors, dispensers, researchers, importers, and exporters.

* * * * *

(b) *Records for distributors.* Except as provided in paragraph (e) of this section, each person registered or authorized to distribute controlled substances shall maintain records with the same information required of manufacturers pursuant to paragraphs (a)(2)(i), (ii), (iv), (v), (vii), (viii) and (ix) of this section.

* * * * *

(e) *Records for reverse distributors.* Each person registered to distribute controlled substances as a reverse distributor shall maintain records with the following information for each controlled substance:

(1) For each controlled substance in bulk form the following:

(i) The name of the controlled substance.

(ii) The total quantity of the controlled substance to the nearest metric unit weight consistent with unit size.

(iii) The quantity received from other persons, including the date and quantity of each receipt and the name, address, and registration number of the other person from whom the controlled substance was received.

(iv) The quantity returned to the original manufacturer of the controlled substance or the manufacturer's agent, including the date of and quantity of each distribution and the name, address and registration number of the manufacturer or manufacturer's agent to whom the controlled substance was distributed.

(v) The quantity disposed of including the date and manner of disposal and the signatures of two responsible employees of the registrant who witnessed the disposal.

(2) For each controlled substance in finished form the following:

(i) The name of the substance.

(ii) Each finished form (*e.g.*, 10-milligram tablet or 10-milligram concentration per fluid ounce or milliliter) and the number of units or volume of finished form in each commercial container (*e.g.*, 100-tablet bottle or 3-milliliter vial).

(iii) The number of commercial containers of each such finished form received from other persons, including the date of and number of containers in each receipt and the name, address, and registration number of the person from whom the containers were received.

(iv) The number of commercial containers of each such finished form distributed back to the original manufacturer of the substance or the manufacturer's agent, including the date of and number of containers in each distribution and the name, address, and registration number of the manufacturer or manufacturer's agent to whom the containers were distributed.

(v) The number of units or volume of finished forms and/or commercial containers disposed of including the date and manner of disposal, the quantity of the substance in finished form disposed, and the signatures of two responsible employees of the registrant who witnessed the disposal.

■ 10. Section 1304.33 is amended by revising paragraph (c) to read as follows:

§ 1304.33 Reports to ARCOS.

* * * * *

(c) *Persons reporting.* For controlled substances in Schedules I, II or narcotic controlled substances in Schedule III, each person who is registered to manufacture in bulk or dosage form, or to package, repackage, label or relabel, and each person who is registered to distribute, including each person who is registered to reverse distribute, shall report acquisition/distribution transactions. In addition to reporting acquisition/distribution transactions, each person who is registered to manufacture controlled substances in bulk or dosage form shall report manufacturing transactions on controlled substances in Schedules I and II, each narcotic controlled substance listed in Schedules III, IV, and V, and on each psychotropic controlled substance listed in Schedules III and IV as identified in paragraph (d) of this section.

* * * * *

PART 1305—ORDER FORMS

■ 11. The authority citation for part 1305 continues to read as follows:

Authority: 21 U.S.C. 821, 828, 871(b), unless otherwise noted.

■ 12. Section 1305.08 is amended by revising paragraph (b) to read as follows:

§ 1305.08 Persons entitled to fill order forms.

* * * * *

(b) A person who has obtained any controlled substance in Schedule I or II by order form may return such substance, or portion thereof, to the person from whom he/she obtained the substance, to the manufacturer of the substance, or to a registered reverse distributor pursuant to the order form of the latter person;

* * * * *

PART 1307—MISCELLANEOUS

■ 13. The authority citation for part 1307 continues to read as follows:

Authority: 21 U.S.C. 821, 822(d), 871(b), unless otherwise noted.

■ 14. Section 1307.11 is revised to read as follows:

§ 1307.11 Distribution by dispenser to another practitioner or reverse distributor.

(a) A practitioner who is registered to dispense a controlled substance may distribute (without being registered to distribute) a quantity of such substance to—

(1) Another practitioner for the purpose of general dispensing by the practitioner to patients, provided that—

(i) The practitioner to whom the controlled substance is to be distributed is registered under the Act to dispense that controlled substance;

(ii) The distribution is recorded by the distributing practitioner in accordance with § 1304.22(c) of this chapter and by the receiving practitioner in accordance with § 1304.22(c) of this chapter;

(iii) If the substance is listed in Schedule I or II, an order form is used as required in part 1305 of this chapter; and

(iv) The total number of dosage units of all controlled substances distributed by the practitioner pursuant to this section and § 1301.25 of this chapter during each calendar year in which the practitioner is registered to dispense does not exceed 5 percent of the total number of dosage units of all controlled substances distributed and dispensed by the practitioner during the same calendar year.

(2) A reverse distributor who is registered to receive such controlled substances.

(b) If, during any calendar year in which the practitioner is registered to dispense, the practitioner has reason to believe that the total number of dosage units of all controlled substances which will be distributed by him pursuant to paragraph (a)(1) of this section and § 1301.25 of this chapter will exceed 5 percent of this total number of dosage units of all controlled substances distributed and dispensed by him during that calendar year, the practitioner shall obtain a registration to distribute controlled substances.

■ 15. Section 1307.12 is amended by revising the title and revising paragraph (a) to read as follows:

§ 1307.12 Distribution to supplier or manufacturer.

(a) Any person lawfully in possession of a controlled substance listed in any schedule may distribute (without being registered to distribute) that substance to the person from whom he/she obtained it or to the manufacturer of the substance, or, if designated, to the manufacturer's registered agent for accepting returns, provided that a written record is maintained which indicates the date of the transaction, the name, form and quantity of the substance, the name, address, and registration number, if any, of the person making the distribution, and the name, address, and registration number, if known, of the supplier or manufacturer. In the case of returning a controlled substance in Schedule I or II, an order form shall be used in the manner prescribed in part 1305 of this chapter and be maintained as the written record of the transaction. Any person not required to register pursuant to sections 302(c) or 1007(b)(1) of the Act (21 U.S.C. 822(c) or 957(b)(1)) shall be exempt from maintaining the records required by this section.

* * * * *

Dated: July 3, 2003.

Laura M. Nagel,

Deputy Assistant Administrator, Office of Diversion Control.

[FR Doc. 03–17578 Filed 7–10–03; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Parts 1 and 602

[TD 9075]

RIN 1545–AX52

Compensation Deferred Under Eligible Deferred Compensation Plans

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final regulations.

SUMMARY: This document contains final regulations that provide guidance on deferred compensation plans of state and local governments and tax-exempt entities. The regulations reflect the changes made to section 457 by the Tax Reform Act of 1986, the Small Business Job Protection Act of 1996, the Taxpayer Relief Act of 1997, the Economic Growth and Tax Relief Reconciliation Act of 2001, the Job Creation and Worker Assistance Act of 2002, and other legislation. The regulations also make various technical changes and clarifications to the existing final regulations on many discrete issues. These regulations provide the public with guidance necessary to comply with the law and will affect plan sponsors, administrators, participants, and beneficiaries.

DATES: *Effective Date:* These final regulations are effective July 11, 2003.

Applicability Date: These regulations apply to taxable years beginning after December 31, 2001. See ''Effective date of the regulations'' for additional information concerning the applicability of these regulations.

FOR FURTHER INFORMATION CONTACT: Cheryl Press, (202) 622–6060 (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 1545–1580. 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 control number assigned by the Office of Management and Budget.

The estimated burden per respondent varies from .033 hour to 2 hours per trust established depending upon individual respondents' circumstances, with an estimated average of one hour for each trust established, and from 20 hours to 50 hours per application for approval as a custodian with an estimated average of 35 hours for each application submitted to qualify as a custodian.

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, W:CAR:MP:T:T:SP 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 become 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

Section 131 of the Revenue Act of 1978 (92 Stat. 2779) added section 457 to the Internal Revenue Code of 1954. On September 27, 1982, final regulations (TD 7836, 1982–2 C.B. 91) under section 457 (the 1982 regulations) were published in the **Federal Register** (47 FR 42335). The 1982 regulations provided guidance for complying with the changes to the applicable tax law made by the Revenue Act of 1978 relating to deferred compensation plans maintained by state and local governments and rural electric cooperatives.

Section 1107 of the Tax Reform Act of 1986 (100 Stat. 2494) extended section 457 to tax-exempt organizations. Section 6064 of the Technical and Miscellaneous Act of 1988 (102 Stat. 3700) codified certain exceptions for certain plans. Notice 88–68, 1988–1 C.B. 556, addressed the treatment of nonelective deferred compensation of nonemployees, and provided an exception under which section 457 does not to apply to certain church plans.

Section 1404 of the Small Business Job Protection Act of 1996 (110 Stat. 1755) added section 457(g) which requires that section 457(b) plans maintained by state and local government employers hold all plan assets and income in trust, or in custodial accounts or annuity contracts (described in section 401(f) of the Internal Revenue Code), for the exclusive benefit of participants and beneficiaries.

Section 1071 of the Taxpayer Relief Act of 1997 (111 Stat. 788) permits certain accrued benefits to be cashed out.

Sections 615, 631, 632, 634, 635, 641, 647, and 649 of the Economic Growth and Tax Relief Reconciliation Act of 2001 (EGTRRA) (115 Stat. 38) included increases in elective deferral limits, repeal of the rules coordinating the section 457 plan limit with contributions to certain other types of plans, catch-up contributions for individuals age 50 or over, extension of qualified domestic relation order rules to section 457 plans, rollovers among various qualified plans, section 403(b) contracts and individual retirement arrangements (IRAs), and transfers to purchase service credits under governmental pension plans.

Section 411(o)(8) and (p)(5) of the Job Creation and Worker Assistance Act of 2002 (116 Stat. 21) clarified certain provisions in EGTRRA concerning section 457 plans, including the use of certain compensation reduction

elections to be taken into account in determining includible compensation.

On May 8, 2002, a notice of proposed rulemaking (REG–105885–99) was published in the **Federal Register** (67 FR 30826) to issue new regulations under section 457, including amending the 1982 regulations to conform them to the legislative changes that had been made to section 457 since 1982.

Following publication of the proposed regulations, comments were received and a public hearing was held on August 28, 2002. After consideration of the comments received, the proposed regulations are adopted by this Treasury decision, subject to a number of changes that are generally summarized below.

Summary of Comments Received and Changes Made

1. Excess Deferrals

The proposed regulations addressed the income tax treatment of excess deferrals and the effect of excess deferrals on plan eligibility under section 457(b). The proposed regulations provided that an eligible governmental plan may self-correct and distribute excess deferrals and continue to satisfy the eligibility requirements of section 457(b) (including the distribution rules and the funding rules) by reason of a distribution of excess deferrals. However, the proposed regulations provided that if an excess deferral arose under an eligible plan of a tax-exempt employer, the plan was no longer an eligible plan.

Commentators objected to the less favorable treatment for eligible plans of tax-exempt employers.

After consideration of the comments received, the regulations extend self-correction for excess deferrals to eligible plans of tax-exempt employers. If there is an excess deferral under such plan, the plan may distribute to a participant any excess deferrals (and any income allocable to such amount) not later than the first April 15 following the close of the taxable year of the excess deferrals, comparable to the rules for qualified plans under section 402(g). In such a case, the plan will continue to be treated as an eligible plan. However, in accordance with section 457(c), any excess deferral is included in the gross income of a participant for the taxable year of the excess deferral. If an excess deferral is not corrected by distribution, the plan is an ineligible plan under which benefits are taxable in accordance with ineligible plan rules.

The income tax treatment and payroll tax reporting of distributions of excess deferrals from eligible section 457(b) governmental plans are similar to the treatment and reporting of distribution of excess deferrals from tax-qualified plans. Such amounts should be reported on Form 1099 and taxed in the year of distribution to the extent of distributed earnings on the excess deferrals. For eligible section 457(b) tax-exempt plans, the excess deferrals are subject to income tax in the year of distribution to the extent of distributed earnings on the excess deferrals and such earnings should be reported on Form W–2 for the year of distribution. See also Notice 2003–20, 2003–19 I.R.B. 894, for information regarding the withholding and reporting requirements applicable to eligible plans generally.

2. Aggregation Rules in the Proposed Regulations

The proposed regulations included several rules that aggregate multiple plans for purposes of meeting the eligibility requirements of section 457(b). These regulations retain all of these rules. For example, the regulations provide that in any case in which multiple plans are used to avoid or evade the eligibility requirements under the regulations, the Commissioner may apply the eligibility requirements as if the plans were a single plan. Also, an eligible employer is required to have no more than one normal retirement age for each participant under all of the eligible plans it sponsors. In addition, all deferrals under all eligible plans under which an individual participates by virtue of his or her relationship with a single employer are treated as though deferred under a single plan for purposes of determining excess deferrals. Finally, annual deferrals under all eligible plans are combined for purposes of determining the maximum deferral limits.

Few comments were received with respect to the aggregation rules under the proposed regulations. However, one commentator requested that, where it is determined that multiple eligible plans maintained by a single employer, which have been aggregated pursuant to the proposed regulations, contain excess deferrals, the employer have the ability to disaggregate those plans solely for the purpose of either (1) distributing the excess deferrals under the self-correcting mechanism or (2) limiting the characterization of such plans as ''ineligible'' to the one(s) that actually contain the excess deferrals. Taking into account the ability for all eligible plans to self-correct by distribution, these regulations retain without material revision the aggregation rules that were in the proposed regulations.

3. Deferral of Sick, Vacation, and Back Pay

The proposed regulations would have allowed an eligible plan to permit participants to elect to defer compensation, including accumulated sick and vacation pay and back pay, only if an agreement providing for the deferral is entered into before the beginning of the month in which the amounts would otherwise be paid or made available and the participant is an employee in that month. Comments requested that terminating participants be allowed to elect deferral for accumulated sick and vacation pay and back pay even if the participant is not employed at the time of the deferral.

The final regulations retain the rule under which the deferral election must be made during employment and before the beginning of the month when the compensation would have been payable. However, the regulations include a special rule that allows an election for sick pay, vacation pay, or back pay that is not yet payable (subject of course to the maximum deferral limitations of section 457 in the year of deferral). Under the special rule, an employee who is retiring or otherwise having a severance from employment during a month may nevertheless elect to defer, for example, his or her unused vacation pay after the beginning of the month, provided that the vacation pay would otherwise have been payable before the employee has a severance from employment and the election is made before the date on which the vacation pay would otherwise have been payable.

4. Unforeseeable Emergency Distributions

The proposed regulations added examples that would illustrate when an unforeseeable emergency occurred. In particular, one example provided that the need to pay for the funeral expenses of a family member may constitute an unforeseeable emergency. Several commentators requested clarification in the final regulations of the definition of family member. The regulations have been modified to define a family member as a spouse or dependent as defined in section 152(a).

5. Plan Terminations, Plan-to-Plan Transfers, and Rollovers

The regulations include certain rules regarding plan terminations, plan-to-plan transfers, and rollovers. These topics have been affected by the statutory changes that impose a trust requirement on eligible governmental plans. The direct rollovers that were permitted by EGTRRA beginning in

2002 for eligible governmental plans provide participants affected by these types of events the ability to retain their retirement savings in a funded, tax-deferred savings vehicle by rollover to an IRA, qualified plan, or section 403(b) contract. The regulations provide a outline for the different plan termination and plan-to-plan transfer alternatives available to sponsors of eligible governmental plans in these situations.

a. Plan Terminations

The regulations allow a plan to have provisions permitting plan termination whereupon amounts can be distributed without violating the distribution requirements of section 457. Under the regulations, an eligible plan is terminated only if all amounts deferred under the plan are paid to participants as soon as administratively practicable. If the amounts deferred under the plan are not distributed, the plan is treated as a frozen plan and must continue to comply with all of the applicable statutory requirements necessary for plan eligibility.

b. Plan-to-Plan Transfers Among Eligible Governmental Plans and Purchase of Permissive Service Credit by Plan-to-Plan Transfer

The proposed regulations would have allowed plan-to-plan transfers between eligible governmental plans under new circumstances, as well as the purchase of permissive service credits by transfer from an eligible governmental plan to a governmental defined benefit plan, but only if the transfers were made by plans within the same State. Commentators objected to the requirement under the new transfer rules that the transfers be to plans within the same State.

Upon consideration of the comments received, the regulations allow transfers among eligible governmental plans in three situations. In each case, the transferor plan must provide for transfers, the receiving plan must provide for the receipt of transfers, and the participant or beneficiary whose amounts deferred are being transferred must be entitled to an amount deferred immediately after the transfer that is at least equal to the amount deferred with respect to that participant or beneficiary immediately before the transfer. Transfers are permitted among eligible governmental plans in the following three cases:

- A person-by-person transfer is permitted for any beneficiary and for any participant who has had a severance from employment with the transferring employer and is performing services for the entity maintaining the receiving plan (whether or not the other plan is within the same State).
- No severance from employment is required if the entire plan's assets for all participants and beneficiaries are transferred to another eligible governmental plan within the same State.
- No severance from employment is required for a transfer from one eligible governmental plan of an employer to another eligible governmental plan of the same employer.

The final regulations also allow a plan-to-plan transfer from an eligible governmental plan to a governmental defined benefit plan for permissive service credit, without regard to whether the defined benefit plan is maintained by a governmental entity that is in the same State. In addition, language that was in an example which implied that section 415(n) (which addresses the application of maximum benefit limitations with respect to certain contributions) might apply to such a transfer has been eliminated because Treasury and the IRS have concluded that section 415(n) does not apply to such a transfer in any case in which the actuarial value of the benefit increase that results from the transfer does not exceed the amount transferred.

c. Plan-to-Plan Transfers Among Eligible Plans of Tax-Exempt Entities

The regulations retain the rule from the 1982 regulations allowing a plan-to-plan transfer after a participant has had a severance from employment.

d. Rollovers

The proposed regulations specified the treatment of amounts rolled into or out of an eligible governmental plan and stated that amounts rolled into the plan are treated as amounts deferred under the plan for purposes of the regulations. Some commentators requested that consideration be given to allowing eligible governmental plans to have the same flexibility that they claimed was permitted for qualified plans with respect to the timing of distributions of rolled-in assets. Specifically, these commentators requested the ability for an eligible governmental plan to allow a participant to receive a distribution of rolled-in assets even though the participant may not yet be eligible for a distribution of other assets held under the plan.

Commentators pointed out that, since section 402(c)(10) allows an eligible governmental plan to accept a rollover contribution only if the rolled-in assets from other plan types are separately accounted for (in order to apply the section 72(t) early withdrawal income tax for distributions from these assets), this ability should not cause administrative problems for plan sponsors. Commentators also asserted that the flexibility to design an eligible governmental plan to permit such distributions would be beneficial to its participants.

These regulations do not permit an eligible governmental plan to distribute rolled-in assets to a participant who is not yet eligible for a distribution until future guidance of general applicability is published that addresses this issue. Treasury and the IRS intend to issue, in the near future, guidance of general applicability resolving this issue in coordination with the applicable rules for qualified plans and section 403(b) contracts.

Commentators also requested clarification on the order of accounts for partial distributions to participants who have rolled-in assets that are subject to the early withdrawal income tax. They requested that consideration be given in final regulations to clarifying that the participant may be treated as receiving a partial distribution first from other plan assets to minimize the early withdrawal income tax that would otherwise apply. These regulations clarify that, if a rollover is received by an eligible governmental plan from an IRA, qualified plan, or section 403(b) contract, then distributions from the eligible governmental plan are subject to the early withdrawal income tax in accordance with the plan's method of accounting, *i.e.,* for purposes of applying the section 72(t) early withdrawal income tax, a distribution is treated as made from an eligible governmental plan's separate account for rollovers from an IRA, qualified plan, or section 403(b) contract only if the plan accounts for the distribution as a distribution from that account. Thus, for example, an eligible governmental plan may provide that any unforeseeable emergency withdrawal is made from other accounts to the extent possible, in which event the early withdrawal tax will not apply assuming that the plan only debits such other accounts to reflect the distribution.

The proposed regulations had requested comments on the issue of separate accounting for rolled-in amounts and asked if there are any special characteristics that would be lost if multiple types of separate accounts were not maintained. Commentators asked for the regulations to permit maintenance of a single rollover account for all amounts that are rolled into the eligible governmental plan. These regulations require separate accounting only to the extent mandated by section

402(c)(10), *i.e.,* only for rollovers from IRAs, qualified plans and section 403(b) contracts. Section 72(t)(9) provides that the early withdrawal income tax applies to distributions from rollovers attributable to IRAs, qualified plans, and section 403(b) contracts. Thus, if an eligible governmental plan accepts a rollover *from another eligible governmental plan* of an amount that was originally deferred under an eligible governmental plan and commingles that rollover in the same separate account that includes a rollover amount from an IRA, qualified plan, or section 403(b) contract, then distributions from that account will be subject to the early withdrawal income tax. Accordingly, in order to avoid this result, eligible governmental plans may choose to establish *three separate accounts* for a participant even though these regulations only require that a single separate rollover account be maintained for all amounts that are rolled into an eligible governmental plan: First, an account for all amounts deferred under that plan; second, an account for any rollover from another eligible governmental plan (disregarding any amounts that originated from an IRA, qualified plan, or section 403(b) contract); and third, an account for any rollover amount from an IRA, qualified plan, or section 403(b) contract (including any amounts rolled over from another eligible governmental plan that originated from an IRA, qualified plan, or section 403(b) contract). These regulations include an example illustrating that the early withdrawal income tax would not apply to a partial distribution from a plan with such accounts assuming that the plan debits either of the first two such other accounts to reflect the distribution.

6. Ineligible Plans

The proposed regulations included guidance regarding ineligible plans under section 457(f). Section 457(f) generally provides that, in the case of an agreement or arrangement for the deferral of compensation, the deferred compensation is included in gross income when deferred or, if later, when the rights to payment of the deferred compensation cease to be subject to a substantial risk of forfeiture. Section 457(f) was in section 457 when it was added to the Code in 1978 for governmental employees, and extended to employees of tax-exempt organizations (other than churches or certain church-controlled organizations) in 1986, because unfunded amounts held by a tax-exempt entity compound tax free like an eligible plan, a qualified plan, or a section 403(b) contract. Section 457(f) was viewed as essential in order to provide an incentive for employers that are not subject to income taxes to adopt an eligible plan, a qualified plan, or a section 403(b) contract.[1]

Section 457(f) does not apply to an eligible plan, a qualified plan, a section 403(b) contract, a section 403(c) contract, a transfer of property described in section 83, a trust to which section 402(b) applies, or a qualified governmental excess benefit arrangement described in section 415(m). The proposed regulations stated that section 457(f) applies if the date on which there is no substantial risk of forfeiture with respect to the compensation deferred precedes the date on which there is a transfer of property to which section 83 applies. The proposed regulations included several examples, including an example illustrating that section 457(f) does not fail to apply merely because benefits are subsequently paid by a transfer of property. Comments were requested on the coordination of sections 457(f) and 83 under the proposed regulations.

In response, a number of commentators objected to the proposed coordination of sections 457(f) and 83, including arguing that the proposed regulation would place tax-exempt organizations at a competitive disadvantage when it comes to attracting and retaining executive talent because it would effectively eliminate the use of discounted mutual fund options as a tax effective component of total compensation. Some commentators also asserted that the proposed regulations were ambiguous as to their applicability to steeply discounted mutual fund options, and recommended that, if the provision is not removed, at a minimum future guidance should be more specific.

The final regulations retain the interpretation of the coordination of sections 457(f) and 83 that was in the proposed regulations, and also clarify the application of the rule by adding an example involving an option grant. The regulations also include a clarification that, when benefits are paid or made available under an ineligible plan, the amount included in gross income is equal to the amount paid or made available, but only to the extent that the amount exceeds the amount the participant included in gross income when he or she obtained a vested right to the benefit.

7. Severance Pay and Other Exceptions

In 2000, the IRS issued Announcement 2000–1 (2000–1 C.B. 294), which provided interim guidance on certain broad-based, nonelective plans of a state or local government that were in existence before 1999. Comments were requested on arrangements, such as those maintained by certain state or local governmental educational institutions, under which supplemental compensation is payable as an incentive to terminate employment, or as an incentive to retain retirement-eligible employees, to ensure an appropriate workforce during periods in which a temporary surplus or deficit in workforce is anticipated. Treasury and the IRS continue to be interested in receiving comments on this issue, which should be sent to the following address: Internal Revenue Service, Attn: CC:DOM:CORP:R (Section 457 Plans), Room 5201, P.O. Box 7604, Ben Franklin Station, Washington, DC 20044. Written comments may be hand delivered Monday through Friday between 8 a.m. and 4 p.m. to: Internal Revenue Service, Courier's Desk, Attn: CC:PA:RU (Section 457 Plans), 1111 Constitution Avenue, NW., Washington, DC 20224. Alternatively, written comments may be submitted electronically via the Internet by selecting the ''Tax Regs'' option on the IRS Home Page, or by submitting them directly to the IRS Internet site at: *http://www.irs.gov/tax_regs/reglist.html.* Comments should be received by October 9, 2003.

8. Effective Date of the Regulations

The proposed regulations included a general effective date under which the regulations would have applied to taxable years beginning after December 31, 2001. This is the general effective date for the changes made in section 457 by EGTRRA. Commentators did not express concern about this effective date and some commentators also stated that eligible governmental plans have adopted plan amendments to address the changes that have been allowed by EGTRRA, so that it would be appropriate to have the final regulations effective date coincide with the effective date for EGTRRA.

These regulations are generally applicable to taxable years beginning after December 31, 2001, subject to certain specific transition rules. Under one of these transition rules, for taxable years beginning after December 31, 2001, and before January 1, 2004, a plan will not fail to be an eligible plan if it

[1] See generally the *Report to the Congress on the Tax Treatment of Deferred Compensation under Section 457,* Department of the Treasury, January 1992 (available from the Office of Tax Policy, Room 5315, Treasury Department, 1500 Pennsylvania Avenue NW., Washington DC 20220).

is operated in accordance with a reasonable, good faith interpretation of section 457(b). Whether a plan is operated in accordance with a reasonable, good faith interpretation of section 457(b) will generally be determined based on all of the relevant facts and circumstances, including the extent to which the employer has resolved unclear issues in its favor. The regulations state that a plan will be deemed to be operated in accordance with a reasonable, good faith interpretation of section 457(b) if it is operated in accordance with the terms of these regulations. The IRS will also deem a plan to be operated in accordance with a reasonable, good faith interpretation of section 457(b) if it is operated in accordance with the terms of the 1982 regulations as in effect for taxable years beginning before January 1, 2002 (to the extent those 1982 regulations are consistent with subsequent changes in law, including EGTRRA) or in accordance with the terms of the 2001 proposed regulations. However, a plan will be deemed not to be operated in accordance with a reasonable, good faith interpretation of section 457(b) if it is operated in a manner that is inconsistent with the terms of the 1982 regulations as in effect for taxable years beginning before January 1, 2002 (to the extent those 1982 regulations are consistent with subsequent changes in law, including EGTRRA) except to the extent permitted under either these final regulations or the 2001 proposed regulations.

Further, there is a special delayed effective date for the rule under which an eligible governmental plan cannot distribute rollover account benefits to a participant who is not yet eligible for a distribution. Thus, this rule is not applicable until years beginning after December 31, 2003, since this issue is expected to be resolved before that date.

The regulations also retain the rule in the proposed regulations under which the regulations do not apply with respect to an option that lacked a readily ascertainable fair market value (within the meaning of section 83(e)(3)) at grant that was granted on or before May 8, 2002. Thus, the status of such an option under section 457(f) would be determined without regard to these regulations.

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 has also been determined that section 553(b) of the Administrative Procedure Act (5 U.S.C. chapter 5) does not apply to these regulations. It is hereby certified that the collection of information in these regulations will not have a significant economic impact on a substantial number of small entities. The collection of information in the regulations is in section 1.457–8(a)(3)(ii)(B) and consists of the requirement that a custodian of a custodial account may be a person other than a bank only if the person demonstrates to the satisfaction of the Commissioner that the manner in which the person will administer the custodial account will be consistent with the requirement of section 457(g)(1) and (3) of the Code. This certification is based on the fact that the cost of submitting this information is small, even for small entities. Therefore, a Regulatory Flexibility Analysis under the Regulatory Flexibility Act (5 U.S.C. chapter 6) is not required. Pursuant to section 7805(f) of the Code, the notice of proposed rulemaking preceding these regulations was submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on its impact on small business.

List of Subjects

26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

26 CFR Part 602

Reporting and recordkeeping requirements.

Amendments to the Regulations

■ Accordingly, 26 CFR part 1 is amended as follows:

PART 1—INCOME TAXES

■ **Paragraph 1.** The authority citation for part 1 continues to read in part as follows:

Authority: 26 U.S.C. 7805 * * *.

■ **Par. 2.** Sections 1.457–1, 1.457–2, 1.457–3 and 1.457–4 are revised to read as follows:

§ 1.457–1 General overviews of section 457.

Section 457 provides rules for nonqualified deferred compensation plans established by eligible employers as defined under § 1.457–2(d). Eligible employers can establish either deferred compensation plans that are eligible plans and that meet the requirements of section 457(b) and §§ 1.457–3 through 1.457–10, or deferred compensation plans or arrangements that do not meet the requirements of section 457(b) and §§ 1.457–3 through 1.457–10 and that are subject to tax treatment under section 457(f) and § 1.457–11.

§ 1.457–2 Definitions.

This section sets forth the definitions that are used under §§ 1.457–1 through 1.457–11.

(a) *Amount(s) deferred. Amount(s) deferred* means the total annual deferrals under an eligible plan in the current and prior years, adjusted for gain or loss. Except as provided at §§ 1.457–4(c)(1)(iii) and 1.457–6(a), amount(s) deferred includes any rollover amount held by an eligible plan as provided under § 1.457–10(e).

(b) *Annual deferral(s)*—(1) *Annual deferral(s)* means, with respect to a taxable year, the amount of compensation deferred under an eligible plan, whether by salary reduction or by nonelective employer contribution. The amount of compensation deferred under an eligible plan is taken into account as an annual deferral in the taxable year of the participant in which deferred, or, if later, the year in which the amount of compensation deferred is no longer subject to a substantial risk of forfeiture.

(2) If the amount of compensation deferred under the plan during a taxable year is not subject to a substantial risk of forfeiture, the amount taken into account as an annual deferral is not adjusted to reflect gain or loss allocable to the compensation deferred. If, however, the amount of compensation deferred under the plan during the taxable year is subject to a substantial risk of forfeiture, the amount of compensation deferred that is taken into account as an annual deferral in the taxable year in which the substantial risk of forfeiture lapses must be adjusted to reflect gain or loss allocable to the compensation deferred until the substantial risk of forfeiture lapses.

(3) If the eligible plan is a defined benefit plan within the meaning of section 414(j), the annual deferral for a taxable year is the present value of the increase during the taxable year of the participant's accrued benefit that is not subject to a substantial risk of forfeiture (disregarding any such increase attributable to prior annual deferrals). For this purpose, present value must be determined using actuarial assumptions and methods that are reasonable (both individually and in the aggregate), as determined by the Commissioner.

(4) For purposes solely of applying § 1.457–4 to determine the maximum amount of the annual deferral for a participant for a taxable year under an eligible plan, the maximum amount is reduced by the amount of any deferral for the participant under a plan described at paragraph (k)(4)(i) of this

section (relating to certain plans in existence before January 1, 1987) as if that deferral were an annual deferral under another eligible plan of the employer.

(c) *Beneficiary. Beneficiary* means a person who is entitled to benefits in respect of a participant following the participant's death or an alternate payee as described in § 1.457–10(c).

(d) *Catch-up. Catch-up* amount or *catch-up* limitation for a participant for a taxable year means the annual deferral permitted under section 414(v) (as described in § 1.457–4(c)(2)) or section 457(b)(3) (as described in § 1.457–4(c)(3)) to the extent the amount of the annual deferral for the participant for the taxable year is permitted to exceed the plan ceiling applicable under section 457(b)(2) (as described in § 1.457–4(c)(1)).

(e) *Eligible employer. Eligible employer* means an entity that is a State that establishes a plan or a tax-exempt entity that establishes a plan. The performance of services as an independent contractor for a State or local government or a tax-exempt entity is treated as the performance of services for an eligible employer. The term *eligible employer* does not include a church as defined in section 3121(w)(3)(A), a qualified church-controlled organization as defined in section 3121(w)(3)(B), or the Federal government or any agency or instrumentality thereof. Thus, for example, a nursing home which is associated with a church, but which is not itself a church (as defined in section 3121(w)(3)(A)) or a qualified church-controlled organization as defined in section 3121(w)(3)(B)), would be an eligible employer if it is a tax-exempt entity as defined in paragraph (m) of this section.

(f) *Eligible plan.* An *eligible plan* is a plan that meets the requirements of §§ 1.457–3 through 1.457–10 that is established and maintained by an eligible employer. An *eligible governmental plan* is an eligible plan that is established and maintained by an eligible employer as defined in paragraph (l) of this section. An arrangement does not fail to constitute a single eligible governmental plan merely because the arrangement is funded through more than one trustee, custodian, or insurance carrier. An *eligible plan of a tax-exempt entity* is an eligible plan that is established and maintained by an eligible employer as defined in paragraph (m) of this section.

(g) *Includible compensation. Includible compensation* of a participant means, with respect to a taxable year, the participant's compensation, as defined in section 415(c)(3), for services performed for the eligible employer. The amount of includible compensation is determined without regard to any community property laws.

(h) *Ineligible plan. Ineligible plan* means a plan established and maintained by an eligible employer that is not maintained in accordance with §§ 1.457–3 through 1.457–10. A plan that is not established by an eligible employer as defined in paragraph (e) of this section is neither an eligible nor an ineligible plan.

(i) *Nonelective employer contribution.* A *nonelective employer contribution* is a contribution made by an eligible employer for the participant with respect to which the participant does not have the choice to receive the contribution in cash or property. Solely for purposes of section 457 and §§ 1.457–2 through 1.457–11, the term *nonelective employer contribution* includes employer contributions that would be described in section 401(m) if they were contributions to a qualified plan.

(j) *Participant. Participant* in an eligible plan means an individual who is currently deferring compensation, or who has previously deferred compensation under the plan by salary reduction or by nonelective employer contribution and who has not received a distribution of his or her entire benefit under the eligible plan. Only individuals who perform services for the eligible employer, either as an employee or as an independent contractor, may defer compensation under the eligible plan.

(k) *Plan. Plan* includes any agreement or arrangement between an eligible employer and a participant or participants (including an individual employment agreement) under which the payment of compensation is deferred (whether by salary reduction or by nonelective employer contribution). The following types of plans are not treated as agreements or arrangement under which compensation is deferred: a bona fide vacation leave, sick leave, compensatory time, severance pay, disability pay, or death benefit plan described in section 457(e)(11)(A)(i) and any plan paying length of service awards to bona fide volunteers (and their beneficiaries) on account of qualified services performed by such volunteers as described in section 457(e)(11)(A)(ii). Further, the term *plan* does not include any of the following (and section 457 and §§ 1.457–2 through 1.457–11 do not apply to any of the following)—

(1) Any nonelective deferred compensation under which all individuals (other than those who have not satisfied any applicable initial service requirement) with the same relationship with the eligible employer are covered under the same plan with no individual variations or options under the plan as described in section 457(e)(12), but only to the extent the compensation is attributable to services performed as an independent contractor;

(2) An agreement or arrangement described in § 1.457–11(b);

(3) Any plan satisfying the conditions in section 1107(c)(4) of the Tax Reform Act of 1986 (100 Stat. 2494) (TRA '86) (relating to certain plans for State judges); and

(4) Any of the following plans or arrangements (to which specific transitional statutory exclusions apply)—

(i) A plan or arrangement of a tax-exempt entity in existence prior to January 1, 1987, if the conditions of section 1107(c)(3)(B) of the TRA '86, as amended by section 1011(e)(6) of Technical and Miscellaneous Revenue Act of 1988 (102 Stat. 3700) (TAMRA), are satisfied (see § 1.457–2(b)(4) for a special rule regarding such plan);

(ii) A collectively bargained nonelective deferred a compensation plan in effect on December 31, 1987, if the conditions of section 6064(d)(2) of TAMRA are satisfied;

(iii) Amounts described in section 6064(d)(3) of TAMRA (relating to certain nonelective deferred compensation arrangements in effect before 1989); and

(iv) Any plan satisfying the conditions in section 1107(c)(4) or (5) of TRA '86 (relating to certain plans for certain individuals with respect to which the Service issued guidance before 1977).

(l) *State. State* means a State (treating the District of Columbia as a State as provided under section 7701(a)(10)), a political subdivision of a State, and any agency or instrumentality of a State.

(m) *Tax-exempt entity. Tax-exempt entity* includes any organization exempt from tax under subtitle A of the Internal Revenue Code, except that a governmental unit (including an international governmental organization) is not a tax-exempt entity.

(n) *Trust. Trust* means a trust described under section 457(g) and § 1.457–8. Custodial accounts and contracts described in section 401(f) are treated as trusts under the rules described in § 1.457–8(a)(2).

§ 1.457–3 General introduction to eligible plans.

(a) *Compliance in form and operation.* An eligible plan is a written plan established and maintained by an eligible employer that is maintained, in both form and operation, in accordance with the requirements of §§ 1.457–4 through 1.457–10. An eligible plan must contain all the material terms and conditions for benefits under the plan. An eligible plan may contain certain optional features not required for plan eligibility under section 457(b), such as distributions for unforeseeable emergencies, loans, plan-to-plan transfers, additional deferral elections, acceptance of rollovers to the plan, and distributions of smaller accounts to eligible participants. However, except as otherwise specifically provided in §§ 1.457–4 through 1.457–10, if an eligible plan contains any optional provisions, the optional provisions must meet, in both form and operation, the relevant requirements under section 457 and §§ 1.457–2 through 1.457–10.

(b) *Treatment as single plan.* In any case in which multiple plans are used to avoid or evade the requirements of §§ 1.457–4 through 1.457–10, the Commissioner may apply the rules under §§ 1.457–4 through 1.457–10 as if the plans were a single plan. See also § 1.457–4(c)(3)(v) (requiring an eligible employer to have no more than one normal retirement age for each participant under all of the eligible plans it sponsors), the second sentence of § 1.457–4(e)(2) (treating deferrals under all eligible plans under which an individual participates by virtue of his or her relationship with a single employer as a single plan for purposes of determining excess deferrals), and § 1.457–5 (combining annual deferrals under all eligible plans).

§ 1.457–4 Annual deferrals, deferral limitations, and deferral agreements under eligible plans.

(a) *Taxation of annual deferrals.* Annual deferrals that satisfy the requirements of paragraphs (b) and (c) of this section are excluded from the gross income of a participant in the year deferred or contributed and are not includible in gross income until paid to the participant in the case of an eligible governmental plan, or until paid or otherwise made available to the participant in the case of an eligible plan of a tax-exempt entity. See § 1.457–7.

(b) *Agreement for deferral.* In order to be an eligible plan, the plan must provide that compensation may be deferred for any calendar month by salary reduction only if an agreement providing for the deferral has been entered into before the first day of the month in which the compensation is paid or made available. A new employee may defer compensation payable in the calendar month during which the participant first becomes an employee if an agreement providing for the deferral is entered into on or before the first day on which the participant performs services for the eligible employer. An eligible plan may provide that if a participant enters into an agreement providing for deferral by salary reduction under the plan, the agreement will remain in effect until the participant revokes or alters the terms of the agreement. Nonelective employer contributions are treated as being made under an agreement entered into before the first day of the calendar month.

(c) *Maximum deferral limitations*—(1) *Basic annual limitation.* (i) Except as described in paragraphs (c)(2) and (3) of this section, in order to be an eligible plan, the plan must provide that the annual deferral amount for a taxable year (the plan ceiling) may not exceed the lesser of—

(A) The applicable annual dollar amount specified in section 457(e)(15): $11,000 for 2002; $12,000 for 2003; $13,000 for 2004; $14,000 for 2005; and $15,000 for 2006 and thereafter. After 2006, the $15,000 amount is adjusted for cost-of-living in the manner described in paragraph (c)(4) of this section; or

(B) 100 percent of the participant's includible compensation for the taxable year.

(ii) The amount of annual deferrals permitted by the 100 percent of includible compensation limitation under paragraph (c)(1)(i)(B) of this section is determined under section 457(e)(5) and § 1.457–2(g).

(iii) For purposes of determining the plan ceiling under this paragraph (c), the annual deferral amount does not include any rollover amounts received by the eligible plan under § 1.457–10(e).

(iv) The provisions of this paragraph (c)(1) are illustrated by the following examples:

Example 1. (i) *Facts.* Participant A, who earns $14,000 a year, enters into a salary reduction agreement in 2006 with A's eligible employer and elects to defer $13,000 of A's compensation for that year. Participant A is not eligible for the catch-up described in paragraph (c)(2) or (3) of this section, participates in no other retirement plan, and has no other income exclusions taken into account in computing includible compensation.

(ii) *Conclusion.* The annual deferral limit for A in 2006 is the lesser of $15,000 or 100 percent of includible compensation, $14,000. A's annual deferral of $13,000 is permitted under the plan because it is not in excess of $14,000 and thus does not exceed 100 percent of A's includible compensation.

Example 2. (i) *Facts.* Assume the same facts as in *Example 1,* except that A's eligible employer provides an immediately vested, matching employer contribution under the plan for participants who make salary reduction deferrals under A's eligible plan. The matching contribution is equal to 100 percent of elective contributions, but not in excess of 10 percent of compensation (in A's case, $1,400).

(ii) *Conclusion.* Participant A's annual deferral exceeds the limitations of this paragraph (c)(1). A's maximum deferral limitation in 2006 is $14,000. A's salary reduction deferral of $13,000 combined with A's eligible employer's nonelective employer contribution of $1,400 exceeds the basic annual limitation of this paragraph (c)(1) because A's annual deferrals total $14,400. A has an excess deferral for the taxable year of $400, the amount exceeding A's permitted annual deferral limitation. The $400 excess deferral is treated as described in paragraph (e) of this section.

Example 3. (i) *Facts.* Beginning in year 2002, Eligible Employer X contributes $3,000 per year for five years to Participant B's eligible plan account. B's interest in the account vests in 2006. B has annual compensation of $50,000 in each of the five years 2002 through 2006. Participant B is 41 years old. B is not eligible for the catch-up described in paragraph (c)(2) or (3) of this section, participates in no other retirement plan, and has no other income exclusions taken into account in computing includible compensation. Adjusted for gain or loss, the value of B's benefit when B's interest in the account vests in 2006 is $17,000.

(ii) *Conclusion.* Under this vesting schedule, $17,000 is taken into account as an annual deferral in 2006. B's annual deferrals under the plan are limited to a maximum of $15,000 in 2006. Thus, the aggregate of the amounts deferred, $17,000, is in excess of the B's maximum deferral limitation by $2,000. The $2,000 is treated as an excess deferral described in paragraph (e) of this section.

(2) *Age 50 catch-up*—(i) *In general.* In accordance with section 414(v) and the regulations thereunder, an eligible governmental plan may provide for catch-up contributions for a participant who is age 50 by the end of the year, provided that such age 50 catch-up contributions do not exceed the catch-up limit under section 414(v)(2) for the taxable year. The maximum amount of age 50 catch-up contributions for a taxable year under section 414(v) is as follows: $1,000 for 2002; $2,000 for 2003; $3,000 for 2004; $4,000 for 2005; and $5,000 for 2006 and thereafter. After 2006, the $5,000 amount is adjusted for cost-of-living. For additional guidance, see regulations under section 414(v).

(ii) *Coordination with special section 457 catch-up.* In accordance with sections 414(v)(6)(C) and 457(e)(18), the age 50 catch-up described in this paragraph (c)(2) does not apply for any

taxable year for which a higher limitation applies under the special section 457 catch-up under paragraph (c)(3) of this section. Thus, for purposes of this paragraph (c)(2)(ii) and paragraph (c)(3) of this section, the special section 457 catch-up under paragraph (c)(3) of this section applies for any taxable year if and only if the plan ceiling taking into account paragraph (c)(1) of this section and the special section 457 catch-up described in paragraph (c)(3) of this section (and disregarding the age 50 catch-up described in this paragraph (c)(2)) is larger than the plan ceiling taking into account paragraph (c)(1) of this section and the age 50 catch-up described in this paragraph (c)(2) (and disregarding the special section 457 catch-up described in paragraph (c)(3) of this section). Thus, if a plan so provides, a participant who is eligible for the age 50 catch-up for a year and for whom the year is also one of the participant's last three taxable years ending before the participant attains normal retirement age is eligible for the larger of—

(A) The plan ceiling under paragraph (c)(1) of this section and the age 50 catch-up described in this paragraph (c)(2) (and disregarding the special section 457 catch-up described in paragraph (c)(3) of this section) or

(B) The plan ceiling under paragraph (c)(1) of this section and the special section 457 catch-up described in paragraph (c)(3) of this section (and disregarding the age 50 catch-up described in this paragraph (c)(2)).

(iii) *Examples.* The provisions of this paragraph (c)(2) are illustrated by the following examples:

Example 1. (i) *Facts.* Participant C, who is 55, is eligible to participate in an eligible governmental plan in 2006. The plan provides a normal retirement age of 65. The plan provides limitations on annual deferrals up to the maximum permitted under paragraphs (c)(1) and (3) of this section and the age 50 catch-up described in this paragraph (c)(2). For 2006, C will receive compensation of $40,000 from the eligible employer. C desires to defer the maximum amount possible in 2006. The applicable basic dollar limit of paragraph (c)(1)(i)(A) of this section is $15,000 for 2006 and the additional dollar amount permitted under the age 50 catch-up is $5,000 for 2006.

(ii) *Conclusion.* C is eligible for the age 50 catch-up in 2006 because C is 55 in 2006. However, C is not eligible for the special section 457 catch-up under paragraph (c)(3) of this section in 2006 because 2006 is not one of the last three taxable years ending before C attains normal retirement age. Accordingly, the maximum that C may defer for 2006 is $20,000.

Example 2. (i) *Facts.* The facts are the same as in *Example 1*, except that, in 2006, C will attain age 62. The maximum amount that C can elect under the special section 457 catch-up under paragraph (c)(3) of this section is $2,000 for 2006.

(ii) *Conclusion.* The maximum that C may defer for 2006 is $20,000. This is the sum of the basic plan ceiling under paragraph (c)(1) of this section equal to $15,000 and the age 50 catch-up equal to $5,000. The special section 457 catch-up under paragraph (c)(3) of this section is not applicable since it provides a smaller plan ceiling.

Example 3. (i) *Facts.* The facts are the same as in *Example 2*, except that the maximum additional amount that C can elect under the special section 457 catch-up under paragraph (c)(3) of this section is $7,000 for 2006.

(ii) *Conclusion.* The maximum that C may defer for 2006 is $22,000. This is the sum of the basic plan ceiling under paragraph (c)(1) of this section equal to $15,000, plus the additional special section 457 catch-up under paragraph (c)(3) of this section equal to $7,000. The additional dollar amount permitted under the age 50 catch-up is not applicable to C for 2006 because it provides a smaller plan ceiling.

(3) *Special section 457 catch-up*—(i) *In general.* Except as provided in paragraph (c)(2)(ii) of this section, an eligible plan may provide that, for one or more of the participant's last three taxable years ending before the participant attains normal retirement age, the plan ceiling is an amount not in excess of the lesser of—

(A) Twice the dollar amount in effect under paragraph (c)(1)(i)(A) of this section; or

(B) The underutilized limitation determined under paragraph (c)(3)(ii) of this section.

(ii) *Underutilized limitation.* The underutilized amount determined under this paragraph (c)(3)(ii) is the sum of—

(A) The plan ceiling established under paragraph (c)(1) of this section for the taxable year; plus

(B) The plan ceiling established under paragraph (c)(1) of this section (or under section 457(b)(2) for any year before the applicability date of this section) for any prior taxable year or years, less the amount of annual deferrals under the plan for such prior taxable year or years (disregarding any annual deferrals under the plan permitted under the age 50 catch-up under paragraph (c)(2) of this section).

(iii) *Determining underutilized limitation under paragraph (c)(3)(ii)(B) of this section.* A prior taxable year is taken into account under paragraph (c)(3)(ii)(B) of this section only if it is a year beginning after December 31, 1978, in which the participant was eligible to participate in the plan, and in which compensation deferred (if any) under the plan during the year was subject to a plan ceiling established under paragraph (c)(1) of this section. This paragraph (c)(3)(iii) is subject to the special rules in paragraph (c)(3)(iv) of this section.

(iv) *Special rules concerning application of the coordination limit for years prior to 2002 for purposes of determining the underutilized limitation*—(A) *General rule.* For purposes of determining the underutilized limitation for years prior to 2002, participants remain subject to the rules in effect prior to the repeal of the coordination limitation under section 457(c)(2). Thus, the applicable basic annual limitation under paragraph (c)(1) of this section and the special section 457 catch-up under this paragraph (c)(3) for years in effect prior to 2002 are reduced, for purposes of determining a participant's underutilized amount under a plan, by amounts excluded from the participant's income for any prior taxable year by reason of a nonelective employer contribution, salary reduction or elective contribution under any other eligible section 457(b) plan, or a salary reduction or elective contribution under any 401(k) qualified cash or deferred arrangement, section 402(h)(1)(B) simplified employee pension (SARSEP), section 403(b) annuity contract, and section 408(p) simple retirement account, or under any plan for which a deduction is allowed because of a contribution to an organization described in section 501(c)(18) (pre-2002 coordination plans). Similarly, in applying the section 457(b)(2)(B) limitation for includible compensation for years prior to 2002, the limitation is 33⅓ percent of the participant's compensation includible in gross income.

(B) *Coordination limitation applied to participant.* For purposes of determining the underutilized limitation for years prior to 2002, the coordination limitation applies to pre-2002 coordination plans of all employers for whom a participant has performed services, whether or not those are plans of the participant's current eligible employer. Thus, for purposes of determining the amount excluded from a participant's gross income in any prior taxable year under paragraph (c)(3)(ii)(B) of this section, the participant's annual deferrals under an eligible plan, and salary reduction or elective deferrals under all other pre-2002 coordination plans, must be determined on an aggregate basis. To the extent that the combined deferrals for years prior to 2002 exceeded the maximum deferral limitations, the amount is treated as an excess deferral under paragraph (e) of this section for those prior years.

(C) *Special rule where no annual deferrals under the eligible plan.* A participant who, although eligible, did not defer any compensation under the eligible plan in any year before 2002 is not subject to the coordinated deferral limit, even though the participant may have deferred compensation under one of the other pre-2002 coordination plans. An individual is treated as not having deferred compensation under an eligible plan for a prior taxable year if all annual deferrals under the plan are distributed in accordance with paragraph (e) of this section. Thus, to the extent that a participant participated solely in one or more of the other pre-2002 coordination plans during a prior taxable year (and not the eligible plan), the participant is not subject to the coordinated limitation for that prior taxable year. However, the participant is treated as having deferred an amount in a prior taxable year, for purposes of determining the underutilized limitation for that prior taxable year under this paragraph (c)(3)(iv)(C), to the extent of the participant's aggregate salary reduction contributions and elective deferrals under all pre-2002 coordination plans up to the maximum deferral limitations in effect under section 457(b) for that prior taxable year. To the extent an employer did not offer an eligible plan to an individual in a prior given year, no underutilized limitation is available to the individual for that prior year, even if the employee subsequently becomes eligible to participate in an eligible plan of the employer.

(D) *Examples.* The provisions of this paragraph (c)(3)(iv) are illustrated by the following examples:

Example 1. (i) *Facts.* In 2001 and in years prior to 2001, Participant D earned $50,000 a year and was eligible to participate in both an eligible plan and a section 401(k) plan. However, D had always participated only in the section 401(k) plan and had always deferred the maximum amount possible. For each year before 2002, the maximum amount permitted under section 401(k) exceeded the limitation of paragraph (c)(3)(i) of this section. In 2002, D is in the 3-year period prior to D's attainment of the eligible plan's normal retirement age of 65, and D now wants to participate in the eligible plan and make annual deferrals of up to $30,000 under the plan's special section 457 catch-up provisions.

(ii) *Conclusion.* Participant D is treated as having no underutilized amount under paragraph (c)(3)(ii)(B) of this section for 2002 for purposes of the catch-up limitation under section 457(b)(3) and paragraph (c)(3) of this section because, in each of the years before 2002, D has deferred an amount equal to or in excess of the limitation of paragraph (c)(3)(i) of this section under all of D's coordinated plans.

Example 2. (i) *Facts.* Assume the same facts as in *Example 1*, except that D only deferred $2,500 per year under the section 401(k) plan for one year before 2002.

(ii) *Conclusion.* D is treated as having an underutilized amount under paragraph (c)(3)(ii)(B) of this section for 2002 for purposes of the special section 457 catch-up limitation. This is because D has deferred an amount for prior years that is less than the limitation of paragraph (c)(1)(i) of this section under all of D's coordinated plans.

Example 3. (i) *Facts.* Participant E, who earned $15,000 for 2000, entered into a salary reduction agreement in 2000 with E's eligible employer and elected to defer $3,000 for that year under E's eligible plan. For 2000, E's eligible employer provided an immediately vested, matching employer contribution under the plan for participants who make salary reduction deferrals under E's eligible plan. The matching contribution was equal to 67 percent of elective contributions, but not in excess of 10 percent of compensation before salary reduction deferrals (in E's case, $1,000). For 2000, E was not eligible for any catch-up contribution, participated in no other retirement plan, and had no other income exclusions taken into account in computing taxable compensation.

(ii) *Conclusion.* Participant E's annual deferral equaled the maximum limitation of section 457(b) for 2000. E's maximum deferral limitation in 2000 was $4,000 because E's includible compensation was $12,000 ($15,000 minus the deferral of $3,000) and the applicable limitation for 2000 was one third of the individual's includible compensation (one-third of $12,000 equals $4,000). E's salary reduction deferral of $3,000 combined with E's eligible employer's matching contribution of $1,000 equals the limitation of section 457(b) for 2000 because E's annual deferrals totaled $4,000. E's underutilized amount for 2000 is zero.

(v) *Normal retirement age*—(A) *General rule.* For purposes of the special section 457 catch-up in this paragraph (c)(3), a plan must specify the normal retirement age under the plan. A plan may define normal retirement age as any age that is on or after the earlier of age 65 or the age at which participants have the right to retire and receive, under the basic defined benefit pension plan of the State or tax-exempt entity (or a money purchase pension plan in which the participant also participates if the participant is not eligible to participate in a defined benefit plan), immediate retirement benefits without actuarial or similar reduction because of retirement before some later specified age, and that is not later than age 70½. Alternatively, a plan may provide that a participant is allowed to designate a normal retirement age within these ages. For purposes of the special section 457 catch-up in this paragraph (c)(3), an entity sponsoring more than one eligible plan may not permit a participant to have more than one normal retirement age under the eligible plans it sponsors.

(B) *Special rule for eligible plans of qualified police or firefighters.* An eligible plan with participants that include qualified police or firefighters as defined under section 415(b)(2)(H)(ii)(I) may designate a normal retirement age for such qualified police or firefighters that is earlier than the earliest normal retirement age designated under the general rule of paragraph (c)(3)(i)(A) of this section, but in no event may the normal retirement age be earlier than age 40. Alternatively, a plan may allow a qualified police or firefighter participant to designate a normal retirement age that is between age 40 and age 70½.

(vi) *Examples.* The provisions of this paragraph (c)(3) are illustrated by the following examples:

Example 1. (i) *Facts.* Participant F, who will turn 61 on April 1, 2006, becomes eligible to participate in an eligible plan on January 1, 2006. The plan provides a normal retirement age of 65. The plan provides limitations on annual deferrals up to the maximum permitted under paragraphs (c)(1) through (3) of this section. For 2006, F will receive compensation of $40,000 from the eligible employer. F desires to defer the maximum amount possible in 2006. The applicable basic dollar limit of paragraph (c)(1)(i)(A) of this section is $15,000 for 2006 and the additional dollar amount permitted under the age 50 catch-up in paragraph (c)(2) of this section for an individual who is at least age 50 is $5,000 for 2006.

(ii) *Conclusion.* F is not eligible for the special section 457 catch-up under paragraph (c)(3) of this section in 2006 because 2006 is not one of the last three taxable years ending before F attains normal retirement age. Accordingly, the maximum that F may defer for 2006 is $20,000. See also paragraph (c)(2)(iii) *Example 1* of this section.

Example 2. (i) *Facts.* The facts are the same as in *Example 1* except that, in 2006, F elects to defer only $2,000 under the plan (rather than the maximum permitted amount of $20,000). In addition, assume that the applicable basic dollar limit of paragraph (c)(1)(i)(A) of this section continues to be $15,000 for 2007 and the additional dollar amount permitted under the age 50 catch-up in paragraph (c)(2) of this section for an individual who is at least age 50 continues to be $5,000 for 2007. In F's taxable year 2007, which is one of the last three taxable years ending before F attains the plan's normal retirement age of 65, F again receives a salary of $40,000 and elects to defer the maximum amount permissible under the plan's catch-up provisions prescribed under paragraph (c) of this section.

(ii) *Conclusion.* For 2007, which is one of the last three taxable years ending before F attains the plan's normal retirement age of 65, the applicable limit on deferrals for F is the larger of the amount under the special section 457 catch-up or $20,000, which is the basic annual limitation ($15,000) and the age

50 catch-up limit of section 414(v) ($5,000). For 2007, F's special section 457 catch-up amount is the lesser of two times the basic annual limitation ($30,000) or the sum of the basic annual limitation ($15,000) plus the $13,000 underutilized limitation under paragraph (c)(3)(ii) of this section (the $15,000 plan ceiling in 2006, minus the $2,000 contributed for F in 2006), or $28,000. Thus, the maximum amount that F may defer in 2007 is $28,000.

Example 3. (i) *Facts.* The facts are the same as in *Examples 1* and *2*, except that F does not make any contributions to the plan before 2010. In addition, assume that the applicable basic dollar limitation of paragraph (c)(1)(i)(A) of this section continues to be $15,000 for 2010 and the additional dollar amount permitted under the age 50 catch-up in paragraph (c)(2) of this section for an individual who is at least age 50 continues to be $5,000 for 2010. In F's taxable year 2010, the year in which F attains age 65 (which is the normal retirement age under the plan), F desires to defer the maximum amount possible under the plan. F's compensation for 2010 is again $40,000.

(ii) *Conclusion.* For 2010, the maximum amount that F may defer is $20,000. The special section 457 catch-up provisions under paragraph (c)(3) of this section are not applicable because 2010 is not a taxable year ending before the year in which F attains normal retirement age.

(4) *Cost-of-living adjustment.* For years beginning after December 31, 2006, the $15,000 dollar limitation in paragraph (c)(1)(i)(A) of this section will be adjusted to take into account increases in the cost-of-living. The adjustment in the dollar limitation is made at the same time and in the same manner as under section 415(d) (relating to qualified plans under section 401(a)), except that the base period is the calendar quarter beginning July 1, 2005 and any increase which is not a multiple of $500 will be rounded to the next lowest multiple of $500.

(d) *Deferral of sick, vacation, and back pay under an eligible plan*—(1) *In general.* An eligible plan may provide that a participant may elect to defer accumulated sick pay, accumulated vacation pay, and back pay under an eligible plan if the requirements of section 457(b) are satisfied. For example, the plan must provide, in accordance with paragraph (b) of this section, that these amounts may be deferred for any calendar month only if an agreement providing for the deferral is entered into before the beginning of the month in which the amounts would otherwise be paid or made available and the participant is an employee in that month. In the case of accumulated sick pay, vacation pay, or back pay that is payable before the participant has a severance from employment, the requirements of the preceding sentence are deemed to be satisfied if the agreement providing for the deferral is entered into before the amount is currently available (as defined in regulations under section 401(k)).

(2) *Examples.* The provisions of this paragraph (d) are illustrated by the following examples:

Example 1. (i) *Facts.* Participant G, who is age 62 in 2003, is an employee who participates in an eligible plan providing a normal retirement age of 65. Under the terms of G's employer's eligible plan and G's sick leave plan, G may, during November of 2003 (which is one of the three years prior to normal retirement age), make a one-time election to contribute amounts representing accumulated sick pay to the eligible plan in December of 2003 (within the maximum deferral limitations). Alternatively, such amounts may remain in the ''bank'' under the sick leave plan. No cash out of the sick pay is available until the month in which a participant ceases to be employed by the employer. The total value of G's accumulated sick pay (determined, in accordance with the terms of the sick leave plan, by reference to G's current salary) is $4,000 in December of 2003.

(ii) *Conclusion.* Under the terms of the eligible plan and sick leave plan, G may elect before December of 2003 to defer the $4,000 value of accumulated sick pay under the eligible plan, provided that G's other annual deferrals to the eligible plan for 2003, when added to the $4,000, do not exceed G's maximum deferral limitation for the year.

Example 2. (i) *Facts.* Same facts as in *Example 1,* except that G will separate from service on January 17, 2004, and elects, on January 4, 2004, to defer G's accumulated sick and vacation pay (which totals $12,000) that is payable on January 15, 2004.

(ii) *Conclusion.* G may elect before January 15, 2004 to defer the accumulated sick and vacation pay under the eligible plan, even if the election is made after the beginning of January, because the agreement providing for the deferral is entered into before the amount is currently available and G does not cease to be an employee before the amount is currently available. G will have $12,000 of includible compensation in 2004 because the deferral is taken into account in the definition of includible compensation.

Example 3. (i) *Facts.* Employer X maintains an eligible plan and a vacation leave plan. Under the terms of the vacation leave plan, employees generally accrue three weeks of vacation per year. Up to one week's unused vacation may be carried over from one year to the next, so that in any single year an employee may have a maximum of four weeks vacation time. At the beginning of each calendar year, under the terms of the eligible plan (which constitutes an agreement providing for the deferral), the value of any unused vacation time from the prior year in excess of one week is automatically contributed to the eligible plan, to the extent of the employee's maximum deferral limitations. Amounts in excess of the maximum deferral limitations are forfeited.

(ii) *Conclusion.* The value of the unused vacation pay contributed to X's eligible plan pursuant to the terms of the plan and the terms of the vacation leave plan is treated as an annual deferral to the eligible plan in the calendar year the contribution is made. No amounts contributed to the eligible plan will be considered made available to a participant in X's eligible plan.

(e) *Excess deferrals under an eligible plan*—(1) *In general.* Any amount deferred under an eligible plan for the taxable year of a participant that exceeds the maximum deferral limitations set forth in paragraphs (c)(1) through (3) of this section, and any amount that exceeds the individual limitation under § 1.457–5, constitutes an excess deferral that is taxable in accordance with § 1.457–11 for that taxable year. Thus, an excess deferral is includible in gross income in the taxable year deferred or, if later, the first taxable year in which there is no substantial risk of forfeiture.

(2) *Excess deferrals under an eligible governmental plan other than as a result of the individual limitation.* In order to be an eligible governmental plan, the plan must provide that any excess deferral resulting from a failure of a plan to apply the limitations of paragraphs (c)(1) through (3) of this section to amounts deferred under the eligible plan (computed without regard to the individual limitation under § 1.457–5) will be distributed to the participant, with allocable net income, as soon as administratively practicable after the plan determines that the amount is an excess deferral. For purposes of determining whether there is an excess deferral resulting from a failure of a plan to apply the limitations of paragraphs (c)(1) through (3) of this section, all plans under which an individual participates by virtue of his or her relationship with a single employer are treated as a single plan (without regard to any differences in funding). An eligible governmental plan does not fail to satisfy the requirements of paragraphs (a) through (d) of this section or §§ 1.457–6 through 1.457–10 (including the distribution rules under § 1.457–6 and the funding rules under § 1.457–8) solely by reason of a distribution made under this paragraph (e)(2). If such excess deferrals are not corrected by distribution under this paragraph (e)(2), the plan will be an ineligible plan under which benefits are taxable in accordance with § 1.457–11.

(3) *Excess deferrals under an eligible plan of a tax-exempt employer other than as a result of the individual limitation.* If a plan of a tax-exempt employer fails to comply with the limitations of paragraphs (c)(1) through (3) of this section, the plan will be an ineligible plan under which benefits are taxable in accordance with § 1.457–11.

However, a plan may distribute to a participant any excess deferrals (and any income allocable to such amount) not later than the first April 15 following the close of the taxable year of the excess deferrals. In such a case, the plan will continue to be treated as an eligible plan. However, any excess deferral is included in the gross income of a participant for the taxable year of the excess deferral. If the excess deferrals are not corrected by distribution under this paragraph (e)(3), the plan is an ineligible plan under which benefits are taxable in accordance with § 1.457–11. For purposes of determining whether there is an excess deferral resulting from a failure of a plan to apply the limitations of paragraphs (c)(1) through (3) of this section, all eligible plans under which an individual participates by virtue of his or her relationship with a single employer are treated as a single plan.

(4) *Excess deferrals arising from application of the individual limitation.* An eligible plan may provide that an excess deferral that is a result solely of a failure to comply with the individual limitation under § 1.457–5 for a taxable year may be distributed to the participant, with allocable net income, as soon as administratively practicable after the plan determines that the amount is an excess deferral. An eligible plan does not fail to satisfy the requirements of paragraphs (a) through (d) of this section or §§ 1.457–6 through 1.457–10 (including the distribution rules under § 1.457–6 and the funding rules under § 1.457–8) solely by reason of a distribution made under this paragraph (e)(4). Although a plan will still maintain eligible status if excess deferrals are not distributed under this paragraph (e)(4), a participant must include the excess amounts in income as provided in paragraph (e)(1) of this section.

(5) *Examples.* The provisions of this paragraph (e) are illustrated by the following examples:

Example 1. (i) *Facts.* In 2006, the eligible plan of State Employer X in which Participant H participates permits a maximum deferral of the lesser of $15,000 or 100 percent of includible compensation. In 2006, H, who has compensation of $28,000, nevertheless defers $16,000 under the eligible plan. Participant H is age 45 and normal retirement age under the plan is age 65. For 2006, the applicable dollar limit under paragraph (c)(1)(i)(A) of this section is $15,000. Employer X discovers the error in January of 2007 when it completes H's 2006 Form W–2 and promptly distributes $1,022 to H (which is the sum of the $1,000 excess and $22 of allocable net income).

(ii) *Conclusion.* Participant H has deferred $1,000 in excess of the $15,000 limitation provided for under the plan for 2006. The $1,000 excess must be included by H in H's income for 2006. In order to correct the failure and still be an eligible plan, the plan must distribute the excess deferral, with allocable net income, as soon as administratively practicable after determining that the amount exceeds the plan deferral limitations. In this case, $22 of the distribution of $1,022 is included in H's gross income for 2007 (and is not an eligible rollover distribution). If the excess deferral were not distributed, the plan would be an ineligible plan with respect to which benefits are taxable in accordance with § 1.457–11.

Example 2. (i) *Facts.* The facts are the same as in *Example 1,* except that X uses a number of separate arrangements with different trustees and annuity insurers to permit employees to defer and H elects deferrals under several of the funding arrangements none of which exceeds $15,000 for any individual funding arrangement, but which total $16,000.

(ii) *Conclusion.* The conclusion is the same as in *Example 1.*

Example 3. (i) *Facts.* The facts are the same as in *Example 1,* except that H's deferral under the eligible plan is limited to $11,000 and H also makes a salary reduction contribution of $5,000 to an annuity contract under section 403(b) with the same Employer X.

(ii) *Conclusion.* H's deferrals are within the plan deferral limitations of Employer X. Because of the repeal of the application of the coordination limitation under former paragraph (2) of section 457(c), H's salary reduction deferrals under the annuity contract are no longer considered in determining H's applicable deferral limits under paragraphs (c)(1) through (3) of this section.

Example 4. (i) *Facts.* The facts are the same as in *Example 1,* except that H's deferral under the eligible governmental plan is limited to $14,000 and H also makes a deferral of $4,000 to an eligible governmental plan of a different employer. Participant H is age 45 and normal retirement age under both eligible plans is age 65.

(ii) *Conclusion.* Because of the application of the individual limitation under § 1.457–5, H has an excess deferral of $3,000 (the sum of $14,000 plus $4,000 equals $18,000, which is $3,000 in excess of the dollar limitation of $15,000). The $3,000 excess deferral, with allocable net income, may be distributed from either plan as soon as administratively practicable after determining that the combined amount exceeds the deferral limitations. If the $3,000 excess deferral is not distributed to H, each plan will continue to be an eligible plan, but the $3,000 must be included by H in H's income for 2006.

Example 5. (i) *Facts.* Assume the same facts as in *Example 3,* except that H's deferral under the eligible governmental plan is limited to $14,000 and H also makes a deferral of $4,000 to an eligible plan of Employer Y, a tax-exempt entity.

(ii) *Conclusion.* The results are the same as in *Example 3,* namely, because of the application of the individual limitation under § 1.457–5, H has an excess deferral of $3,000. If the $3,000 excess deferral is not distributed to H, each plan will continue to be an eligible plan, but the $3,000 must be included by H in H's income for 2006.

Example 6. (i) Facts. Assume the same facts as in *Example 5,* except that X is a tax-exempt entity and thus its plan is an eligible plan of a tax-exempt entity.

(ii) *Conclusion.* The results are the same as in Example 5, namely, because of the application of the individual limitation under § 1.457–5, H has an excess deferral of $3,000. If the $3,000 excess deferral is not distributed to H, each plan will continue to be an eligible plan, but the $3,000 must be included by H into H's income for 2006.

■ **Par. 3.** Sections 1.457–5 through 1.457–12 are added to read as follows:

§ 1.457–5 Individual limitation for combined annual deferrals under multiple eligible plans

(a) *General rule.* The individual limitation under section 457(c) and this section equals the basic annual deferral limitation under § 1.457–4(c)(1)(i)(A), plus either the age 50 catch-up amount under § 1.457–4(c)(2), or the special section 457 catch-up amount under § 1.457–4(c)(3), applied by taking into account the combined annual deferral for the participant for any taxable year under all eligible plans. While an eligible plan may include provisions under which it will limit deferrals to meet the individual limitation under section 457(c) and this section, annual deferrals by a participant that exceed the individual limit under section 457(c) and this section (but do not exceed the limits under § 1.457–4(c)) will not cause a plan to lose its eligible status. However, to the extent the combined annual deferrals for a participant for any taxable year exceed the individual limitation under section 457(c) and this section for that year, the amounts are treated as excess deferrals as described in § 1.457–4(e).

(b) *Limitation applied to participant.* The individual limitation in this section applies to eligible plans of all employers for whom a participant has performed services, including both eligible governmental plans and eligible plans of a tax-exempt entity and both eligible plans of the employer and eligible plans of other employers. Thus, for purposes of determining the amount excluded from a participant's gross income in any taxable year (including the underutilized limitation under § 1.457–4 (c)(3)(ii)(B)), the participant's annual deferral under an eligible plan, and the participant's annual deferrals under all other eligible plans, must be determined on an aggregate basis. To the extent that the combined annual deferral amount exceeds the maximum deferral limitation applicable under § 1.457–4 (c)(1)(i)(A), (c)(2), or (c)(3), the amount

is treated as an excess deferral under § 1.457–4(e).

(c) *Special rules for catch-up amounts under multiple eligible plans.* For purposes of applying section 457(c) and this section, the special section 457 catch-up under § 1.457–4 (c)(3) is taken into account only to the extent that an annual deferral is made for a participant under an eligible plan as a result of plan provisions permitted under § 1.457–4 (c)(3). In addition, if a participant has annual deferrals under more than one eligible plan and the applicable catch-up amount under § 1.457–4 (c)(2) or (3) is not the same for each such eligible plan for the taxable year, section 457(c) and this section are applied using the catch-up amount under whichever plan has the largest catch-up amount applicable to the participant.

(d) *Examples.* The provisions of this section are illustrated by the following examples:

Example 1. (i) *Facts.* Participant F is age 62 in 2006 and participates in two eligible plans during 2006, Plans J and K, which are each eligible plans of two different governmental entities. Each plan includes provisions allowing the maximum annual deferral permitted under § 1.457–4(c)(1) through (3). For 2006, the underutilized amount under § 1.457–4 (c)(3)(ii)(B) is $20,000 under Plan J and is $40,000 under Plan K. Normal retirement age is age 65 under both plans. Participant F defers $15,000 under each plan. Participant F's includible compensation is in each case in excess of the deferral. Neither plan designates the $15,000 contribution as a catch-up permitted under each plan's special section 457 catch-up provisions.

(ii) *Conclusion.* For purposes of applying this section to Participant F for 2006, the maximum exclusion is $20,000. This is equal to the sum of $15,000 plus $5,000, which is the age 50 catch-up amount. Thus, F has an excess amount of $10,000 which is treated as an excess deferral for Participant F for 2006 under § 1.457–4(e).

Example 2. (i) *Facts.* Participant E, who will turn 63 on April 1, 2006, participates in four eligible plans during 2006: Plan W which is an eligible governmental plan; and Plans X, Y, and Z which are each eligible plans of three different tax-exempt entities. For 2006, the limitation that applies to Participant E under all four plans under § 1.457–4 (c)(1)(i)(A) is $15,000. For 2006, the additional age 50 catch-up limitation that applies to Participant E under all four plans under § 1.457–4 (c)(2) is $5,000. Further, for 2006, different limitations under § 1.457–4(c)(3) and (c)(3)(ii)(B) apply to Participant E under each of these plans, as follows: under Plan W, the underutilized limitation under § 1.457–4 (c)(3)(ii)(B) is $7,000; under Plan X, the underutilized limitation under § 1.457–4 (c)(3)(ii)(B) is $2,000; under Plan Y, the underutilized limitation under § 1.457–4 (c)(3)(ii)(B) is $8,000; and under Plan Z, § 1.457–4 (c)(3) is not applicable since normal retirement age is age 62 under Plan Z. Participant E's includible compensation is in each case in excess of any applicable deferral.

(ii) *Conclusion.* For purposes of applying this section to Participant E for 2006, Participant E could elect to defer $23,000 under Plan Y, which is the maximum deferral limitation under § 1.457–4 (c)(1) through (3), and to defer no amount under Plans W, X, and Z. The $23,000 maximum amount is equal to the sum of $15,000 plus $8,000, which is the catch-up amount applicable to Participant E under Plan Y and which is the largest catch-up amount applicable to Participant E under any of the four plans for 2006. Alternatively, Participant E could instead elect to defer the following combination of amounts: an aggregate total of $20,000 to any of the four plans; or $22,000 to Plan W and none to any of the other three plans.

(iii) If the underutilized amount under Plans W, X, and Y for 2006 were in each case zero (because E had always contributed the maximum amount or E was a new participant) or an amount not in excess of $5,000, the maximum exclusion under this section would be $20,000 for Participant E for 2006 ($15,000 plus the $5,000 age 50 catch-up amount), which Participant E could contribute to any of the plans.

§ 1.457–6 Timing of distributions under eligible plans.

(a) *In general.* Except as provided in paragraph (c) of this section (relating to distributions on account of an unforeseeable emergency), paragraph (e) of this section (relating to distributions of small accounts), § 1.457–10(a) (relating to plan terminations), or § 1.457–10(c) (relating to domestic relations orders), amounts deferred under an eligible governmental plan may not be paid to a participant or beneficiary before the participant has a severance from employment with the eligible employer or when the participant attains age 70½, if earlier. For rules relating to loans, see paragraph (f) of this section. This section does not apply to distributions of excess amounts under § 1.457–4(e). However, except to the extent set forth by the Commissioner in revenue rulings, notices, and other guidance published in the Internal Revenue Bulletin, this section applies to amounts held in a separate account for eligible rollover distributions maintained by an eligible governmental plan as described in § 1.457–10(e)(2).

(b) *Severance from employment*—(1) *Employees.* An employee has a severance from employment with the eligible employer if the employee dies, retires, or otherwise has a severance from employment with the eligible employer. See regulations under section 401(k) for additional guidance concerning severance from employment.

(2) *Independent contractors*—(i) *In general.* An independent contractor is considered to have a severance from employment with the eligible employer upon the expiration of the contract (or in the case of more than one contract, all contracts) under which services are performed for the eligible employer if the expiration constitutes a good-faith and complete termination of the contractual relationship. An expiration does not constitute a good faith and complete termination of the contractual relationship if the eligible employer anticipates a renewal of a contractual relationship or the independent contractor becoming an employee. For this purpose, an eligible employer is considered to anticipate the renewal of the contractual relationship with an independent contractor if it intends to contract again for the services provided under the expired contract, and neither the eligible employer nor the independent contractor has eliminated the independent contractor as a possible provider of services under any such new contract. Further, an eligible employer is considered to intend to contract again for the services provided under an expired contract if the eligible employer's doing so is conditioned only upon incurring a need for the services, the availability of funds, or both.

(ii) *Special rule.* Notwithstanding paragraph (b)(2)(i) of this section, the plan is considered to satisfy the requirement described in paragraph (a) of this section that no amounts deferred under the plan be paid or made available to the participant before the participant has a severance from employment with the eligible employer if, with respect to amounts payable to a participant who is an independent contractor, an eligible plan provides that—

(A) No amount will be paid to the participant before a date at least 12 months after the day on which the contract expires under which services are performed for the eligible employer (or, in the case of more than one contract, all such contracts expire); and

(B) No amount payable to the participant on that date will be paid to the participant if, after the expiration of the contract (or contracts) and before that date, the participant performs services for the eligible employer as an independent contractor or an employee.

(c) *Rules applicable to distributions for unforeseeable emergencies*—(1) *In general.* An eligible plan may permit a distribution to a participant or beneficiary faced with an unforeseeable emergency. The distribution must satisfy the requirements of paragraph (c)(2) of this section.

(2) *Requirements*—(i) *Unforeseeable emergency defined.* An unforeseeable emergency must be defined in the plan

as a severe financial hardship of the participant or beneficiary resulting from an illness or accident of the participant or beneficiary, the participant's or beneficiary's spouse, or the participant's or beneficiary's dependent (as defined in section 152(a)); loss of the participant's or beneficiary's property due to casualty (including the need to rebuild a home following damage to a home not otherwise covered by homeowner's insurance, *e.g.*, as a result of a natural disaster); or other similar extraordinary and unforeseeable circumstances arising as a result of events beyond the control of the participant or the beneficiary. For example, the imminent foreclosure of or eviction from the participant's or beneficiary's primary residence may constitute an unforeseeable emergency. In addition, the need to pay for medical expenses, including non-refundable deductibles, as well as for the cost of prescription drug medication, may constitute an unforeseeable emergency. Finally, the need to pay for the funeral expenses of a spouse or a dependent (as defined in section 152(a)) may also constitute an unforeseeable emergency. Except as otherwise specifically provided in this paragraph (c)(2)(i), the purchase of a home and the payment of college tuition are not unforeseeable emergencies under this paragraph (c)(2)(i).

(ii) *Unforeseeable emergency distribution standard.* Whether a participant or beneficiary is faced with an unforeseeable emergency permitting a distribution under this paragraph (c) is to be determined based on the relevant facts and circumstances of each case, but, in any case, a distribution on account of unforeseeable emergency may not be made to the extent that such emergency is or may be relieved through reimbursement or compensation from insurance or otherwise, by liquidation of the participant's assets, to the extent the liquidation of such assets would not itself cause severe financial hardship, or by cessation of deferrals under the plan.

(iii) *Distribution necessary to satisfy emergency need.* Distributions because of an unforeseeable emergency must be limited to the amount reasonably necessary to satisfy the emergency need (which may include any amounts necessary to pay any federal, state, or local income taxes or penalties reasonably anticipated to result from the distribution).

(d) *Minimum required distributions for eligible plans.* In order to be an eligible plan, a plan must meet the distribution requirements of section 457(d)(1) and (2). Under section 457(d)(2), a plan must meet the minimum distribution requirements of section 401(a)(9). See section 401(a)(9) and the regulations thereunder for these requirements. Section 401(a)(9) requires that a plan begin lifetime distributions to a participant no later than April 1 of the calendar year following the later of the calendar year in which the participant attains age 70½ or the calendar year in which the participant retires.

(e) *Distributions of smaller accounts*—(1) *In general.* An eligible plan may provide for a distribution of all or a portion of a participant's benefit if this paragraph (e)(1) is satisfied. This paragraph (e)(1) is satisfied if the participant's total amount deferred (the participant's total account balance) which is not attributable to rollover contributions (as defined in section 411(a)(11)(D)) is not in excess of the dollar limit under section 411(a)(11)(A), no amount has been deferred under the plan by or for the participant during the two-year period ending on the date of the distribution, and there has been no prior distribution under the plan to the participant under this paragraph (e). An eligible plan is not required to permit distributions under this paragraph (e).

(2) *Alternative provisions possible.* Consistent with the provisions of paragraph (e)(1) of this section, a plan may provide that the total amount deferred for a participant or beneficiary will be distributed automatically to the participant or beneficiary if the requirements of paragraph (e)(1) of this section are met. Alternatively, if the requirements of paragraph (e)(1) of this section are met, the plan may provide for the total amount deferred for a participant or beneficiary to be distributed to the participant or beneficiary only if the participant or beneficiary so elects. The plan is permitted to substitute a specified dollar amount that is less than the total amount deferred. In addition, these two alternatives can be combined; for example, a plan could provide for automatic distributions for up to $500, but allow participants or beneficiary to elect a distribution if the total account balance is above $500.

(f) *Loans from eligible plans*—(1) *Eligible plans of tax-exempt entities.* If a participant or beneficiary receives (directly or indirectly) any amount deferred as a loan from an eligible plan of a tax-exempt entity, that amount will be treated as having been paid or made available to the individual as a distribution under the plan, in violation of the distribution requirements of section 457(d).

(2) *Eligible governmental plans.* The determination of whether the availability of a loan, the making of a loan, or a failure to repay a loan made from a trustee (or a person treated as a trustee under section 457(g)) of an eligible governmental plan to a participant or beneficiary is treated as a distribution (directly or indirectly) for purposes of this section, and the determination of whether the availability of the loan, the making of the loan, or a failure to repay the loan is in any other respect a violation of the requirements of section 457(b) and the regulations, depends on the facts and circumstances. Among the facts and circumstances are whether the loan has a fixed repayment schedule and bears a reasonable rate of interest, and whether there are repayment safeguards to which a prudent lender would adhere. Thus, for example, a loan must bear a reasonable rate of interest in order to satisfy the exclusive benefit requirement of section 457(g)(1) and § 1.457–8(a)(1). See also § 1.457–7(b)(3) relating to the application of section 72(p) with respect to the taxation of a loan made under an eligible governmental plan, and § 1.72(p)-1 relating to section 72(p)(2).

(3) *Example.* The provisions of paragraph (f)(2) of this section are illustrated by the following example:

Example. (i) *Facts.* Eligible Plan X of State Y is funded through Trust Z. Plan X permits an employee's account balance under Plan X to be paid in a single sum at severance from employment with State Y. Plan X includes a loan program under which any active employee with a vested account balance may receive a loan from Trust Z. Loans are made pursuant to plan provisions regarding loans that are set forth in the plan under which loans bear a reasonable rate of interest and are secured by the employee's account balance. In order to avoid taxation under § 1.457–7(b)(3) and section 72(p)(1), the plan provisions limit the amount of loans and require loans to be repaid in level installments as required under section 72(p)(2). Participant J's vested account balance under Plan X is $50,000. J receives a loan from Trust Z in the amount of $5,000 on December 1, 2003, to be repaid in level installments made quarterly over the 5-year period ending on November 30, 2008. Participant J makes the required repayments until J has a severance from employment from State Y in 2005 and subsequently fails to repay the outstanding loan balance of $2,250. The $2,250 loan balance is offset against J's $80,000 account balance benefit under Plan X, and J elects to be paid the remaining $77,750 in 2005.

(ii) *Conclusion.* The making of the loan to J will not be treated as a violation of the requirements of section 457(b) or the regulations. The cancellation of the loan at severance from employment does not cause Plan X to fail to satisfy the requirements for plan eligibility under section 457. In addition, because the loan satisfies the maximum amount and repayment

requirements of section 72(p)(2), J is not required to include any amount in income as a result of the loan until 2005, when J has income of $2,250 as a result of the offset (which is a permissible distribution under this section) and income of $77,750 as a result of the distribution made in 2005.

§ 1.457–7 Taxation of Distributions Under Eligible Plans.

(a) *General rules for when amounts are included in gross income.* The rules for determining when an amount deferred under an eligible plan is includible in the gross income of a participant or beneficiary depend on whether the plan is an eligible governmental plan or an eligible plan of a tax-exempt entity. Paragraph (b) of this section sets forth the rules for an eligible governmental plan. Paragraph (c) of this section sets forth the rules for an eligible plan of a tax-exempt entity.

(b) *Amounts included in gross income under an eligible governmental plan*—(1) *Amounts included in gross income in year paid under an eligible governmental plan.* Except as provided in paragraphs (b)(2) and (3) of this section (or in § 1.457–10(c) relating to payments to a spouse or former spouse pursuant to a qualified domestic relations order), amounts deferred under an eligible governmental plan are includible in the gross income of a participant or beneficiary for the taxable year in which paid to the participant or beneficiary under the plan.

(2) *Rollovers to individual retirement arrangements and other eligible retirement plans.* A trustee-to-trustee transfer in accordance with section 401(a)(31) (generally referred to as a direct rollover) from an eligible government plan is not includible in gross income of a participant or beneficiary in the year transferred. In addition, any payment made from an eligible government plan in the form of an eligible rollover distribution (as defined in section 402(c)(4)) is not includible in gross income in the year paid to the extent the payment is transferred to an eligible retirement plan (as defined in section 402(c)(8)(B)) within 60 days, including the transfer to the eligible retirement plan of any property distributed from the eligible governmental plan. For this purpose, the rules of section 402(c)(2) through (7) and (9) apply. Any trustee-to-trustee transfer under this paragraph (b)(2) from an eligible government plan is a distribution that is subject to the distribution requirements of § 1.457–6.

(3) *Amounts taxable under section 72(p)(1).* In accordance with section 72(p), the amount of any loan from an eligible governmental plan to a participant or beneficiary (including any pledge or assignment treated as a loan under section 72(p)(1)(B)) is treated as having been received as a distribution from the plan under section 72(p)(1), except to the extent set forth in section 72(p)(2) (relating to loans that do not exceed a maximum amount and that are repayable in accordance with certain terms) and § 1.72(p)–1. Thus, except to the extent a loan satisfies section 72(p)(2), any amount loaned from an eligible governmental plan to a participant or beneficiary (including any pledge or assignment treated as a loan under section 72(p)(1)(B)) is includible in the gross income of the participant or beneficiary for the taxable year in which the loan is made. See generally § 1.72(p)–1.

(4) *Examples.* The provisions of this paragraph (b) are illustrated by the following examples:

Example 1. (i) *Facts.* Eligible Plan G of a governmental entity permits distribution of benefits in a single sum or in installments of up to 20 years, with such benefits to commence at any date that is after severance from employment (up to the later of severance from employment or the plan's normal retirement age of 65). Effective for participants who have a severance from employment after December 31, 2001, Plan X allows an election—as to both the date on which payments are to begin and the form in which payments are to be made—to be made by the participant at any time that is before the commencement date selected. However, Plan X chooses to require elections to be filed at least 30 days before the commencement date selected in order for Plan X to have enough time to be able to effectuate the election.

(ii) *Conclusion.* No amounts are included in gross income before actual payments begin. If installment payments begin (and the installment payments are payable over at least 10 years so as not to be eligible rollover distributions), the amount included in gross income for any year is equal to the amount of the installment payment paid during the year.

Example 2. (i) *Facts.* Same facts as in *Example 1*, except that the same rules are extended to participants who had a severance from employment before January 1, 2002.

(ii) *Conclusion.* For all participants (that is, both those who have a severance from employment after December 31, 2001, and those who have a severance from employment before January 1, 2002, including those whose benefit payments have commenced before January 1, 2002), no amounts are included in gross income before actual payments begin. If installment payments begin (and the installment payments are payable over at least 10 years so as not to be eligible rollover distributions), the amount included in gross income for any year is equal to the amount of the installment payment paid during the year.

(c) *Amounts included in gross income under an eligible plan of a tax-exempt entity*—(1) *Amounts included in gross income in year paid or made available under an eligible plan of a tax-exempt entity.* Amounts deferred under an eligible plan of a tax-exempt entity are includible in the gross income of a participant or beneficiary for the taxable year in which paid or otherwise made available to the participant or beneficiary under the plan. Thus, amounts deferred under an eligible plan of a tax-exempt entity are includible in the gross income of the participant or beneficiary in the year the amounts are first made available under the terms of the plan, even if the plan has not distributed the amounts deferred. Amounts deferred under an eligible plan of a tax-exempt entity are not considered made available to the participant or beneficiary solely because the participant or beneficiary is permitted to choose among various investments under the plan.

(2) *When amounts deferred are considered to be made available under an eligible plan of a tax-exempt entity*—(i) *General rule.* Except as provided in paragraphs (c)(2)(ii) through (iv) of this section, amounts deferred under an eligible plan of a tax-exempt entity are considered made available (and, thus, are includible in the gross income of the participant or beneficiary under this paragraph (c)) at the earliest date, on or after severance from employment, on which the plan allows distributions to commence, but in no event later than the date on which distributions must commence pursuant to section 401(a)(9). For example, in the case of a plan that permits distribution to commence on the date that is 60 days after the close of the plan year in which the participant has a severance from employment with the eligible employer, amounts deferred are considered to be made available on that date. However, distributions deferred in accordance with paragraphs (c)(2)(ii) through (iv) of this section are not considered made available prior to the applicable date under paragraphs (c)(2)(ii) through (iv) of this section. In addition, no portion of a participant or beneficiary's account is treated as made available (and thus currently includible in income) under an eligible plan of a tax-exempt entity merely because the participant or beneficiary under the plan may elect to receive a distribution in any of the following circumstances:

(A) A distribution in the event of an unforeseeable emergency to the extent the distribution is permitted under § 1.457–6(c).

(B) A distribution from an account for which the total amount deferred is not in excess of the dollar limit under section 411(a)(11)(A) to the extent the

distribution is permitted under § 1.457–6(e).

(ii) *Initial election to defer commencement of distributions*—(A) *In general.* An eligible plan of a tax-exempt entity may provide a period for making an initial election during which the participant or beneficiary may elect, in accordance with the terms of the plan, to defer the payment of some or all of the amounts deferred to a fixed or determinable future time. The period for making this initial election must expire prior to the first time that any such amounts would be considered made available under the plan under paragraph (c)(2)(i) of this section.

(B) *Failure to make initial election to defer commencement of distributions.* Generally, if no initial election is made by a participant or beneficiary under this paragraph (c)(2)(ii), then the amounts deferred under an eligible plan of a tax-exempt entity are considered made available and taxable to the participant or beneficiary in accordance with paragraph (c)(2)(i) of this section at the earliest time, on or after severance from employment (but in no event later than the date on which distributions must commence pursuant to section 401(a)(9)), that distribution is permitted to commence under the terms of the plan. However, the plan may provide for a default payment schedule that applies if no election is made. If the plan provides for a default payment schedule, the amounts deferred are includible in the gross income of the participant or beneficiary in the year the amounts deferred are first made available under the terms of the default payment schedule.

(iii) *Additional election to defer commencement of distribution.* An eligible plan of a tax-exempt entity is permitted to provide that a participant or beneficiary who has made an initial election under paragraph (c)(2)(ii)(A) of this section may make one additional election to defer (but not accelerate) commencement of distributions under the plan before distributions have commenced in accordance with the initial deferral election under paragraph (c)(2)(ii)(A) of this section. Amounts payable to a participant or beneficiary under an eligible plan of a tax-exempt entity are not treated as made available merely because the plan allows the participant to make an additional election under this paragraph (c)(2)(iii). A participant or beneficiary is not precluded from making an additional election to defer commencement of distributions merely because the participant or beneficiary has previously received a distribution under § 1.457–6(c) because of an unforeseeable emergency, has received a distribution of smaller amounts under § 1.457–6(e), has made (and revoked) other deferral or method of payment elections within the initial election period, or is subject to a default payment schedule under which the commencement of benefits is deferred (for example, until a participant is age 65).

(iv) *Election as to method of payment.* An eligible plan of a tax-exempt entity may provide that an election as to the method of payment under the plan may be made at any time prior to the time the amounts are distributed in accordance with the participant or beneficiary's initial or additional election to defer commencement of distributions under paragraph (c)(2)(ii) or (iii) of this section. Where no method of payment is elected, the entire amount deferred will be includible in the gross income of the participant or beneficiary when the amounts first become made available in accordance with a participant's initial or additional elections to defer under paragraphs (c)(2)(ii) and (iii) of this section, unless the eligible plan provides for a default method of payment (in which case amounts are considered made available and taxable when paid under the terms of the default payment schedule). A method of payment means a distribution or a series of periodic distributions commencing on a date determined in accordance with paragraph (c)(2)(ii) or (iii) of this section.

(3) *Examples.* The provisions of this paragraph (c) are illustrated by the following examples:

Example 1. (i) *Facts.* Eligible Plan X of a tax-exempt entity provides that a participant's total account balance, representing all amounts deferred under the plan, is payable to a participant in a single sum 60 days after severance from employment throughout these examples, unless, during a 30-day period immediately following the severance, the participant elects to receive the single sum payment at a later date (that is not later than the plan's normal retirement age of 65) or elects to receive distribution in 10 annual installments to begin 60 days after severance from employment (or at a later date, if so elected, that is not later than the plan's normal retirement age of 65). On November 13, 2004, participant K, a calendar year taxpayer, has a severance from employment with the eligible employer. K does not, within the 30-day window period, elect to postpone distributions to a later date or to receive payment in 10 fixed annual installments.

(ii) *Conclusion.* The single sum payment is payable to K 60 days after the date K has a severance from employment (January 12, 2005), and is includible in the gross income of K in 2005 under section 457(a).

Example 2. (i) *Facts.* The terms of eligible Plan X are the same as described in *Example 1.* Participant L participates in eligible Plan X. On November 11, 2003, L has a severance from the employment of the eligible employer. On November 24, 2003, L makes an initial deferral election not to receive the single-sum payment payable 60 days after the severance, and instead elects to receive the amounts in 10 annual installments to begin 60 days after severance from employment.

(ii) *Conclusion.* No portion of L's account is considered made available in 2003 or 2004 before a payment is made and no amount is includible in the gross income of L until distributions commence. The annual installment payable in 2004 will be includible in L's gross income in 2004.

Example 3. (i) *Facts.* The facts are the same as in *Example 1,* except that eligible Plan X also provides that those participants who are receiving distributions in 10 annual installments may, at any time and without restriction, elect to receive a cash out of all remaining installments. Participant M elects to receive a distribution in 10 annual installments commencing in 2004.

(ii) *Conclusion.* M's total account balance, representing the total of the amounts deferred under the plan, is considered made available and is includible in M's gross income in 2004.

Example 4. (i) *Facts.* The facts are the same as in *Example 3,* except that, instead of providing for an unrestricted cashout of remaining payments, the plan provides that participants or beneficiaries who are receiving distributions in 10 annual installments may accelerate the payment of the amount remaining payable to the participant upon the occurrence of an unforeseeable emergency as described in § 1.457–6(c)(1) in an amount not exceeding that described in § 1.457–6(c)(2).

(ii) *Conclusion.* No amount is considered made available to participant M on account of M's right to accelerate payments upon the occurrence of an unforeseeable emergency.

Example 5. (i) *Facts.* Eligible Plan Y of a tax-exempt entity provides that distributions will commence 60 days after a participant's severance from employment unless the participant elects, within a 30-day window period following severance from employment, to defer distributions to a later date (but no later than the year following the calendar year the participant attains age 70½). The plan provides that a participant who has elected to defer distributions to a later date may make an election as to form of distribution at any time prior to the 30th day before distributions are to commence.

(ii) *Conclusion.* No amount is considered made available prior to the date distributions are to commence by reason of a participant's right to defer or make an election as to the form of distribution.

Example 6. (i) *Facts.* The facts are the same as in *Example 1,* except that the plan also permits participants who have made an initial election to defer distribution to make one additional deferral election at any time prior to the date distributions are scheduled to commence. Participant N has a severance from employment at age 50. The next day, during the 30-day period provided in the plan, N elects to receive distribution in the form of 10 annual installment payments

beginning at age 55. Two weeks later, within the 30-day window period, N makes a new election permitted under the plan to receive 10 annual installment payments beginning at age 60 (instead of age 55). When N is age 59, N elects under the additional deferral election provisions, to defer distributions until age 65.

(ii) *Conclusion.* In this example, N's election to defer distributions until age 65 is a valid election. The two elections N makes during the 30-day window period are not additional deferral elections described in paragraph (c)(2)(iii) of this section because they are made before the first permissible payout date under the plan. Therefore, the plan is not precluded from allowing N to make the additional deferral election. However, N can make no further election to defer distributions beyond age 65 (or accelerate distribution before age 65) because this additional deferral election can only be made once.

§ 1.457–8 Funding rules for eligible plans.

(a) *Eligible governmental plans*—(1) *In general.* In order to be an eligible governmental plan, all amounts deferred under the plan, all property and rights purchased with such amounts, and all income attributable to such amounts, property, or rights, must be held in trust for the exclusive benefit of participants and their beneficiaries. A trust described in this paragraph (a) that also meets the requirements of §§ 1.457–3 through 1.457–10 is treated as an organization exempt from tax under section 501(a), and a participant's or beneficiary's interest in amounts in the trust is includible in the gross income of the participants and beneficiaries only to the extent, and at the time, provided for in section 457(a) and §§ 1.457–4 through 1.457–10.

(2) *Trust requirement.* (i) A trust described in this paragraph (a) must be established pursuant to a written agreement that constitutes a valid trust under State law. The terms of the trust must make it impossible, prior to the satisfaction of all liabilities with respect to participants and their beneficiaries, for any part of the assets and income of the trust to be used for, or diverted to, purposes other than for the exclusive benefit of participants and their beneficiaries.

(ii) Amounts deferred under an eligible governmental plan must be transferred to a trust within a period that is not longer than is reasonable for the proper administration of the participant accounts (if any). For purposes of this requirement, the plan may provide for amounts deferred for a participant under the plan to be transferred to the trust within a specified period after the date the amounts would otherwise have been paid to the participant. For example, the plan could provide for amounts deferred under the plan at the election of the participant to be contributed to the trust within 15 business days following the month in which these amounts would otherwise have been paid to the participant.

(3) *Custodial accounts and annuity contracts treated as trusts*—(i) *In general.* For purposes of the trust requirement of this paragraph (a), custodial accounts and annuity contracts described in section 401(f) that satisfy the requirements of this paragraph (a)(3) are treated as trusts under rules similar to the rules of section 401(f). Therefore, the provisions of § 1.401(f)–1(b) will generally apply to determine whether a custodial account or an annuity contract is treated as a trust. The use of a custodial account or annuity contract as part of an eligible governmental plan does not preclude the use of a trust or another custodial account or annuity contract as part of the same plan, provided that all such vehicles satisfy the requirements of section 457(g)(1) and (3) and paragraphs (a)(1) and (2) of this section and that all assets and income of the plan are held in such vehicles.

(ii) *Custodial accounts*—(A) *In general.* A custodial account is treated as a trust, for purposes of section 457(g)(1) and paragraphs (a)(1) and (2) of this section, if the custodian is a bank, as described in section 408(n), or a person who meets the nonbank trustee requirements of paragraph (a)(3)(ii)(B) of this section, and the account meets the requirements of paragraphs (a)(1) and (2) of this section, other than the requirement that it be a trust.

(B) *Nonbank trustee status.* The custodian of a custodial account may be a person other than a bank only if the person demonstrates to the satisfaction of the Commissioner that the manner in which the person will administer the custodial account will be consistent with the requirements of section 457(g)(1) and (3). To do so, the person must demonstrate that the requirements of § 1.408–2(e)(2) through (6) (relating to nonbank trustees) are met. The written application must be sent to the address prescribed by the Commissioner in the same manner as prescribed under § 1.408–2(e). To the extent that a person has already demonstrated to the satisfaction of the Commissioner that the person satisfies the requirements of § 1.408–2(e) in connection with a qualified trust (or custodial account or annuity contract) under section 401(a), that person is deemed to satisfy the requirements of this paragraph (a)(3)(ii)(B).

(iii) *Annuity contracts.* An annuity contract is treated as a trust for purposes of section 457(g)(1) and paragraph (a)(1) of this section if the contract is an annuity contract, as defined in section 401(g), that has been issued by an insurance company qualified to do business in the State, and the contract meets the requirements of paragraphs (a)(1) and (2) of this section, other than the requirement that it be a trust. An annuity contract does not include a life, health or accident, property, casualty, or liability insurance contract.

(4) *Combining assets.* [Reserved]

(b) *Eligible plans maintained by tax-exempt entity*—(1) *General rule.* In order to be an eligible plan of a tax-exempt entity, the plan must be unfunded and plan assets must not be set aside for participants or their beneficiaries. Under section 457(b)(6) and this paragraph (b), an eligible plan of a tax-exempt entity must provide that all amounts deferred under the plan, all property and rights to property (including rights as a beneficiary of a contract providing life insurance protection) purchased with such amounts, and all income attributable to such amounts, property, or rights, must remain (until paid or made available to the participant or beneficiary) solely the property and rights of the eligible employer (without being restricted to the provision of benefits under the plan), subject only to the claims of the eligible employer's general creditors.

(2) *Additional requirements.* For purposes of a paragraph (b)(1) of this section, the plan must be unfunded regardless of whether or not the amounts were deferred pursuant to a salary reduction agreement between the eligible employer and the participant. Any funding arrangement under an eligible plan of a tax-exempt entity that sets aside assets for the exclusive benefit of participants violates this requirement, and amounts deferred are generally immediately includible in the gross income of plan participants and beneficiaries. Nothing in this paragraph (b) prohibits an eligible plan from permitting participants and their beneficiaries to make an election among different investment options available under the plan, such as an election affecting the investment of the amounts described in paragraph (b)(1) of this section.

§ 1.457–9 Effect on eligible plans when not administered in accordance with eligibility requirements.

(a) *Eligible governmental plans.* A plan of a State ceases to be an eligible governmental plan on the first day of the first plan year beginning more than

180 days after the date on which the Commissioner notifies the State in writing that the plan is being administered in a manner that is inconsistent with one or more of the requirements of §§ 1.457–3 through 1.457–8, or 1.457–10. However, the plan may correct the plan inconsistencies specified in the written notification before the first day of that plan year and continue to maintain plan eligibility. If a plan ceases to be an eligible governmental plan, amounts subsequently deferred by participants will be includible in income when deferred, or, if later, when the amounts deferred cease to be subject to a substantial risk of forfeiture, as provided at § 1.457–11. Amounts deferred before the date on which the plan ceases to be an eligible governmental plan, and any earnings thereon, will be treated as if the plan continues to be an eligible governmental plan and will not be includible in participant's or beneficiary's gross income until paid to the participant or beneficiary.

(b) *Eligible plans of tax-exempt entities.* A plan of a tax-exempt entity ceases to be an eligible plan on the first day that the plan fails to satisfy one or more of the requirements of §§ 1.457–3 through 1.457–8, or § 1.457–10. *See* § 1.457–11 for rules regarding the treatment of an ineligible plan.

§ 1.457–10 Miscellaneous provisions.

(a) *Plan terminations and frozen plans*—(1) *In general.* An eligible employer may amend its plan to eliminate future deferrals for existing participants or to limit participation to existing participants and employees. An eligible plan may also contain provisions that permit plan termination and permit amounts deferred to be distributed on termination. In order for a plan to be considered terminated, amounts deferred under an eligible plan must be distributed to all plan participants and beneficiaries as soon as administratively practicable after termination of the eligible plan. The mere provision for, and making of, distributions to participants or beneficiaries upon a plan termination will not cause an eligible plan to cease to satisfy the requirements of section 457(b) or the regulations.

(2) *Employers that cease to be eligible employers*—(i) *Plan not terminated.* An eligible employer that ceases to be an eligible employer may no longer maintain an eligible plan. If the employer was a tax-exempt entity and the plan is not terminated as permitted under a paragraph (a)(2)(ii) of this section, the tax consequences to participants and beneficiaries in the previously eligible (unfunded) plan of an ineligible employer are determined in accordance with either section 451 if the employer becomes an entity other than a State or § 1.457–11 if the employer becomes a State. If the employer was a State and the plan is neither terminated as permitted under paragraph (a)(2)(ii) of this section nor transferred to another eligible plan of that State as permitted under paragraph (b) of this section, the tax consequences to participants in the previously eligible governmental plan of an ineligible employer, the assets of which are held in trust pursuant to § 1.457–8(a), are determined in accordance with section 402(b) (section 403(c) in the case of an annuity contract) and the trust is no longer to be treated as a trust that is exempt from tax under section 501(a).

(ii) *Plan termination.* As an alternative to determining the tax consequences to the plan and participants under paragraph (a)(2)(i) of this section, the employer may terminate the plan and distribute the amounts deferred (and all plan assets) to all plan participants as soon as administratively practicable in accordance with paragraph (a)(1) of this section. Such distribution may include eligible rollover distributions in the case of a plan that was an eligible governmental plan. In addition, if the employer is a State, another alternative to determining the tax consequences under paragraph (a)(2)(i) of this section is to transfer the assets of the eligible governmental plan to an eligible governmental plan of another eligible employer within the same State under the plan-to-plan transfer rules of paragraph (b) of this section.

(3) *Examples.* The provisions of this paragraph (a) are illustrated by the following examples:

Example 1. (i) *Facts.* Employer Y, a corporation that owns a State hospital, sponsors an eligible governmental plan funded through a trust. Employer Y is acquired by a for-profit hospital and Employer Y ceases to be an eligible employer under section 457(e)(1) or § 1.457–2(e). Employer Y terminates the plan and, during the next 6 months, distributes to participants and beneficiaries all amounts deferred that were under the plan.

(ii) *Conclusion.* The termination and distribution does not cause the plan to fail to be an eligible governmental plan. Amounts that are distributed as eligible rollover distributions may be rolled over to an eligible retirement plan described in section 402(c)(8)(B).

Example 2. (i) *Facts.* The facts are the same as in *Example 1,* except that Employer Y decides to continue to maintain the plan.

(ii) *Conclusion.* If Employer Y continues to maintain the plan, the tax consequences to participants and beneficiaries will be determined in accordance with either section 402(b) if the compensation deferred is funded through a trust, section 403(c) if the compensation deferred is funded through annuity contracts, or § 1.457–11 if the compensation deferred is not funded through a trust or annuity contract. In addition, if Employer Y continues to maintain the plan, the trust will no longer be treated as exempt from tax under section 501(a).

Example 3. (i) *Facts.* Employer Z, a corporation that owns a tax-exempt hospital, sponsors an unfunded eligible plan. Employer Z is acquired by a for-profit hospital and is no longer an eligible employer under section 457(e)(1) or § 1.457–2(e). Employer Z terminates the plan and distributes all amounts deferred under the eligible plan to participants and beneficiaries within a one-year period.

(ii) *Conclusion.* Distributions under the plan are treated as made under an eligible plan of a tax-exempt entity and the distributions of the amounts deferred are includible in the gross income of the participant or beneficiary in the year distributed.

Example 4. (i) *Facts.* The facts are the same as in *Example 3,* except that Employer Z decides to maintain instead of terminate the plan.

(ii) *Conclusion.* If Employer Z maintains the plan, the tax consequences to participants and beneficiaries in the plan will thereafter be determined in accordance with section 451.

(b) *Plan-to-plan transfers*—(1) *General rule.* An eligible governmental plan may provide for the transfer of amounts deferred by a participant or beneficiary to another eligible governmental plan if the conditions in paragraph (b)(2), (3), or (4) of this section are met. An eligible plan of a tax-exempt entity may provide for transfers of amounts deferred by a participant to another eligible plan of a tax-exempt entity if the conditions in paragraph (b)(5) of this section are met. In addition, an eligible governmental plan may accept transfers from another eligible governmental plan as described in the first sentence of this paragraph (b)(1), and an eligible plan of a tax-exempt entity may accept transfers from another eligible plan of a tax-exempt entity as described in the preceding sentence. However, a State may not transfer the assets of its eligible governmental plan to a tax-exempt entity's eligible plan and the plan of a tax-exempt entity may not accept such a transfer. Similarly, a tax-exempt entity may not transfer the assets of its eligible plan to an eligible governmental plan and an eligible governmental plan may not accept such a transfer. In addition, if the conditions in paragraph (b)(4) of this section (relating to permissive past service credit and repayments under section 415) are met, an eligible governmental plan of a State may provide for the transfer of amounts

deferred by a participant or beneficiary to a qualified plan (under section 401(a)) maintained by a State. However, a qualified plan may not transfer assets to an eligible governmental plan or to an eligible plan of a tax-exempt entity, and an eligible governmental plan or the plan of a tax-exempt entity may not accept such a transfer.

(2) *Requirements for post-severance plan-to-plan transfers among eligible governmental plans.* A transfer under paragraph (b)(1) of this section from an eligible governmental plan to another eligible governmental plan is permitted if the following conditions are met—

(i) The transferor plan provides for transfers;

(ii) The receiving plan provides for the receipt of transfers;

(iii) The participant or beneficiary whose amounts deferred are being transferred will have an amount deferred immediately after the transfer at least equal to the amount deferred with respect to that participant or beneficiary immediately before the transfer; and

(iv) In the case of a transfer for a participant, the participant has had a severance from employment with the transferring employer and is performing services for the entity maintaining the receiving plan.

(3) *Requirements for plan-to-plan transfers of all plan assets of eligible governmental plan.* A transfer under paragraph (b)(1) of this section from an eligible governmental plan to another eligible governmental plan is permitted if the following conditions are met—

(i) The transfer is from an eligible governmental plan to another eligible governmental plan within the same State;

(ii) All of the assets held by the transferor plan are transferred;

(iii) The transferor plan provides for transfers;

(iv) The receiving plan provides for the receipt of transfers;

(v) The participant or beneficiary whose amounts deferred are being transferred will have an amount deferred immediately after the transfer at least equal to the amount deferred with respect to that participant or beneficiary immediately before the transfer; and

(vi) The participants or beneficiaries whose deferred amounts are being transferred are not eligible for additional annual deferrals in the receiving plan unless they are performing services for the entity maintaining the receiving plan.

(4) *Requirements for plan-to-plan transfers among eligible governmental plans of the same employer.* A transfer under paragraph (b)(1) of this section from an eligible governmental plan to another eligible governmental plan is permitted if the following conditions are met—

(i) The transfer is from an eligible governmental plan to another eligible governmental plan of the same employer (and, for this purpose, the employer is not treated as the same employer if the participant's compensation is paid by a different entity);

(ii) The transferor plan provides for transfers;

(iii) The receiving plan provides for the receipt of transfers;

(iv) The participant or beneficiary whose amounts deferred are being transferred will have an amount deferred immediately after the transfer at least equal to the amount deferred with respect to that participant or beneficiary immediately before the transfer; and

(v) The participant or beneficiary whose deferred amounts are being transferred is not eligible for additional annual deferrals in the receiving plan unless the participant or beneficiary is performing services for the entity maintaining the receiving plan.

(5) *Requirements for post-severance plan-to-plan transfers among eligible plans of tax-exempt entities.* A transfer under paragraph (b)(1) of this section from an eligible plan of a tax-exempt employer to another eligible plan of a tax-exempt employer is permitted if the following conditions are met—

(i) The transferor plan provides for transfers;

(ii) The receiving plan provides for the receipt of transfers;

(iii) The participant or beneficiary whose amounts deferred are being transferred will have an amount deferred immediately after the transfer at least equal to the amount deferred with respect to that participant or beneficiary immediately before the transfer; and

(iv) In the case of a transfer for a participant, the participant has had a severance from employment with the transferring employer and is performing services for the entity maintaining the receiving plan.

(6) *Treatment of amount transferred following a plan-to-plan transfer between eligible plans.* Following a transfer of any amount between eligible plans under paragraphs (b)(1) through (b)(5) of this section—

(i) The transferred amount is subject to the restrictions of § 1.457–6 (relating to when distributions are permitted to be made to a participant under an eligible plan) in the receiving plan in the same manner as if the transferred amount had been originally been deferred under the receiving plan if the participant is performing services for the entity maintaining the receiving plan, and

(ii) In the case of a transfer between eligible plans of tax-exempt entities, except as otherwise determined by the Commissioner, the transferred amount is subject to § 1.457–7(c)(2) (relating to when amounts are considered to be made available under an eligible plan of a tax-exempt entity) in the same manner as if the elections made by the participant or beneficiary under the transferor plan had been made under the receiving plan.

(7) *Examples.* The provisions of paragraphs (b)(1) through (6) of this section are illustrated by the following examples:

Example 1. (i) *Facts.* Participant A, the president of City X's hospital, has accepted a position with another hospital which is a tax-exempt entity. A participates in the eligible governmental plan of City X. A would like to transfer the amounts deferred under City X's eligible governmental plan to the eligible plan of the tax-exempt hospital.

(ii) *Conclusion.* City X's plan may not transfer A's amounts deferred to the tax-exempt employer's eligible plan. In addition, because the amounts deferred would no longer be held in trust for the exclusive benefit of participants and their beneficiaries, the transfer would violate the exclusive benefit rule of section 457(g) and § 1.457–8(a).

Example 2. (i) *Facts.* County M, located in State S, operates several health clinics and maintains an eligible governmental plan for employees of those clinics. One of the clinics operated by County M is being acquired by a hospital operated by State S, and employees of that clinic will become employees of State S. County M permits those employees to transfer their balances under County M's eligible governmental plan to the eligible governmental plan of State S.

(ii) *Conclusion.* If the eligible governmental plans of County M and State S provide for the transfer and acceptance of the transfer (and the other requirements of paragraph (b)(1) of this section are satisfied), then the requirements of paragraph (b)(2) of this section are satisfied and, thus, the transfer will not cause either plan to violate the requirements of section 457 or these regulations.

Example 3. (i) *Facts.* City Employer Z, a hospital, sponsors an eligible governmental plan. City Employer Z is located in State B. All of the assets of City Employer Z are being acquired by a tax-exempt hospital. City Employer Z, in accordance with the plan-to-plan transfer rules of paragraph (b) of this section, would like to transfer the total amount of assets deferred under City Employer Z's eligible governmental plan to the acquiring tax-exempt entity's eligible plan.

(ii) *Conclusion.* City Employer Z may not permit participants to transfer the amounts to

the eligible plan of the tax-exempt entity. In addition, because the amounts deferred would no longer be held in trust for the exclusive benefit of participants and their beneficiaries, the transfer would violate the exclusive benefit rule of section 457(g) and § 1.457–8(a).

Example 4. (i) *Facts.* The facts are the same as in *Example 3*, except that City Employer Z, instead of transferring all of its assets to the eligible plan of the tax-exempt entity, decides to transfer all of the amounts deferred under City Z's eligible governmental plan to the eligible governmental plan of County B in which City Z is located. County B's eligible plan does not cover employees of City Z, but is willing to allow the assets of City Z's plan to be transferred to County B's plan, a related state government entity, also located in State B.

(ii) *Conclusion.* If City Employer Z's (transferor) eligible governmental plan provides for such transfer and the eligible governmental plan of County B permits the acceptance of such a transfer (and the other requirements of paragraph (b)(1) of this section are satisfied), then the requirements of paragraph (b)(3) of this section are satisfied and, thus, City Employer Z may transfer the total amounts deferred under its eligible governmental plan, prior to termination of that plan, to the eligible governmental plan maintained by County B. However, the participants of City Employer Z whose deferred amounts are being transferred are not eligible to participate in the eligible governmental plan of County B, the receiving plan, unless they are performing services for County B.

Example 5. (i) *Facts.* State C has an eligible governmental plan. Employees of City U in State C are among the eligible employees for State C's plan and City U decides to adopt another eligible governmental plan only for its employees. State C decides to allow employees to elect to transfer all of the amounts deferred for an employee under State C's eligible governmental plan to City U's eligible governmental plan.

(ii) Conclusion. If State C's (transferor) eligible governmental plan provides for such transfer and the eligible governmental plan of City U permits the acceptance of such a transfer (and the other requirements of paragraph (b)(1) of this section are satisfied), then the requirements of paragraph (b)(4) of this section are satisfied and, thus, State C may transfer the total amounts deferred under its eligible governmental plan to the eligible governmental plan maintained by City U.

(8) *Purchase of permissive past service credit by plan-to-plan transfers from an eligible governmental plan to a qualified plan*—(i) *General rule.* An eligible governmental plan of a State may provide for the transfer of amounts deferred by a participant or beneficiary to a defined benefit governmental plan (as defined in section 414(d)), and no amount shall be includible in gross income by reason of the transfer, if the conditions in paragraph (b)(8)(ii) of this section are met. A transfer under this paragraph (b)(8) is not treated as a distribution for purposes of § 1.457–6. Therefore, such a transfer may be made before severance from employment.

(ii) *Conditions for plan-to-plan transfers from an eligible governmental plan to a qualified plan.* A transfer may be made under this paragraph (b)(8) only if the transfer is either—

(A) For the purchase of permissive past service credit (as defined in section 415(n)(3)(A)) under the receiving defined benefit governmental plan; or

(B) A repayment to which section 415 does not apply by reason of section 415(k)(3).

(iii) *Example.* The provisions of this paragraph (b)(8) are illustrated by the following example:

Example. (i) *Facts.* Plan X is an eligible governmental plan maintained by County Y for its employees. Plan X provides for distributions only in the event of death, an unforeseeable emergency, or severance from employment with County Y (including retirement from County Y). Plan S is a qualified defined benefit plan maintained by State T for its employees. County Y is within State T. Employee A is an employee of County Y and is a participant in Plan X. Employee A previously was an employee of State T and is still entitled to benefits under Plan S. Plan S includes provisions allowing participants in certain plans, including Plan X, to transfer assets to Plan S for the purchase of past service credit under Plan S and does not permit the amount transferred to exceed the amount necessary to fund the benefit resulting from the past service credit. Although not required to do so, Plan X allows Employee A to transfer assets to Plan S to provide a past service benefit under Plan S.

(ii) *Conclusion.* The transfer is permitted under this paragraph (b)(8).

(c) *Qualified domestic relations orders under eligible plans*—(1) *General rule.* An eligible plan does not become an ineligible plan described in section 457(f) solely because its administrator or sponsor complies with a qualified domestic relations order as defined in section 414(p), including an order requiring the distribution of the benefits of a participant to an alternate payee in advance of the general rules for eligible plan distributions under § 1.457–6. If a distribution or payment is made from an eligible plan to an alternate payee pursuant to a qualified domestic relations order, rules similar to the rules of section 402(e)(1)(A) shall apply to the distribution or payment.

(2) *Examples.* The provisions of this paragraph (c) are illustrated by the following examples:

Example 1. (i) *Facts.* Participant C and C's spouse D are divorcing. C is employed by State S and is a participant in an eligible plan maintained by State S. C has an account valued at $100,000 under the plan. Pursuant to the divorce, a court issues a qualified domestic relations order on September 1, 2003 that allocates 50 percent of C's $100,000 plan account to D and specifically provides for an immediate distribution to D of D's share within 6 months of the order. Payment is made to D in January of 2004.

(ii) *Conclusion.* State S's eligible plan does not become an ineligible plan described in section 457(f) and § 1.457–11 solely because its administrator or sponsor complies with the qualified domestic relations order requiring the immediate distribution to D in advance of the general rules for eligible plan distributions under § 1.457–6. In accordance with section 402(e)(1)(A), D (not C) must include the distribution in gross income. The distribution is includible in D's gross income in 2004. If the qualified domestic relations order were to provide for distribution to D at a future date, amounts deferred attributable to D's share will be includible in D's gross income when paid to D.

Example 2. (i) *Facts.* The facts are the same as in *Example 1*, except that S is a tax-exempt entity, instead of a State.

(ii) *Conclusion.* State S's eligible plan does not become an ineligible plan described in section 457(f) and § 1.457–11 solely because its administrator or sponsor complies with the qualified domestic relations order requiring the immediate distribution to D in advance of the general rules for eligible plan distributions under § 1.457–6. In accordance with section 402(e)(1)(A), D (not C) must include the distribution in gross income. The distribution is includible in D's gross income in 2004, assuming that the plan did not make the distribution available to D in 2003. If the qualified domestic relations order were to provide for distribution to D at a future date, amounts deferred attributable to D's share would be includible in D's gross income when paid or made available to D.

(d) *Death benefits and life insurance proceeds.* A death benefit plan under section 457(e)(11) is not an eligible plan. In addition, no amount paid or made available under an eligible plan as death benefits or life insurance proceeds is excludable from gross income under section 101.

(e) *Rollovers to eligible governmental plans*—(1) *General rule.* An eligible governmental plan may accept contributions that are eligible rollover distributions (as defined in section 402(c)(4)) made from another eligible retirement plan (as defined in section 402(c)(8)(B)) if the conditions in paragraph (e)(2) of this section are met. Amounts contributed to an eligible governmental plan as eligible rollover distributions are not taken into account for purposes of the annual limit on annual deferrals by a participant in § 1.457–4(c) or § 1.457–5, but are otherwise treated in the same manner as amounts deferred under section 457 for purposes of §§ 1.457–3 through 1.457–9 and this section.

(2) *Conditions for rollovers to an eligible governmental plan.* An eligible governmental plan that permits eligible rollover distributions made from another eligible retirement plan to be paid into the eligible governmental plan is required under this paragraph (e)(2) to provide that it will separately account for any eligible rollover distributions it receives. A plan does not fail to satisfy this requirement if it separately accounts for particular types of eligible rollover distributions (for example, if it maintains a separate account for eligible rollover distributions attributable to annual deferrals that were made under other eligible governmental plans and a separate account for amounts attributable to other eligible rollover distributions), but this requirement is not satisfied if any such separate account includes any amount that is not attributable to an eligible rollover distribution.

(3) *Example.* The provisions of this paragraph (e) are illustrated by the following example:

Example. (i) *Facts.* Plan T is an eligible governmental plan that provides that employees who are eligible to participate in Plan T may make rollover contributions to Plan T from amounts distributed to an employee from an eligible retirement plan. An eligible retirement plan is defined in Plan T as another eligible governmental plan, a qualified section 401(a) or 403(a) plan, or a section 403(b) contract, or an individual retirement arrangement (IRA) that holds such amounts. Plan T requires rollover contributions to be paid by the eligible retirement plan directly to Plan T (a direct rollover) or to be paid by the participant within 60 days after the date on which the participant received the amount from the other eligible retirement plan. Plan T does not take rollover contributions into account for purposes of the plan's limits on amounts deferred that conform to § 1.457–4(c). Rollover contributions paid to Plan T are invested in the trust in the same manner as amounts deferred under Plan T and rollover contributions (and earnings thereon) are available for distribution to the participant at the same time and in the same manner as amounts deferred under Plan T. In addition, Plan T provides that, for each participant who makes a rollover contribution to Plan T, the Plan T record-keeper is to establish a separate account for the participant's rollover contributions. The record-keeper calculates earnings and losses for investments held in the rollover account separately from earnings and losses on other amounts held under the plan and calculates disbursements from and payments made to the rollover account separately from disbursements from and payments made to other amounts held under the plan.

(ii) *Conclusion.* Plan T does not lose its status as an eligible governmental plan as a result of the receipt of rollover contributions. The conclusion would not be different if the Plan T record-keeper were to establish two separate accounts, one of which is for the participant's rollover contributions attributable to annual deferrals that were made under an eligible governmental plan and the other of which is for other rollover contributions.

(f) *Deemed IRAs under eligible governmental plans.* See regulations under section 408(q) for guidance regarding the treatment of separate accounts or annuities as individual retirement plans (IRAs). *§ 1.457–11 Tax treatment of participants if plan is not an eligible plan.*

(a) *In general.* Under section 457(f), if an eligible employer provides for a deferral of compensation under any agreement or arrangement that is an ineligible plan—

(1) Compensation deferred under the agreement or arrangement is includible in the gross income of the participant or beneficiary for the first taxable year in which there is no substantial risk of forfeiture (within the meaning of section 457(f)(3)(B)) of the rights to such compensation;

(2) If the compensation deferred is subject to a substantial risk of forfeiture, the amount includible in gross income for the first taxable year in which there is no substantial risk of forfeiture includes earnings thereon to the date on which there is no substantial risk of forfeiture;

(3) Earnings credited on the compensation deferred under the agreement or arrangement that are not includible in gross income under paragraph (a)(2) of this section are includible in the gross income of the participant or beneficiary only when paid or made available to the participant or beneficiary, provided that the interest of the participant or beneficiary in any assets (including amounts deferred under the plan) of the entity sponsoring the agreement or arrangement is not senior to the entity's general creditors; and

(4) Amounts paid or made available to a participant or beneficiary under the agreement or arrangement are includible in the gross income of the participant or beneficiary under section 72, relating to annuities.

(b) *Exceptions.* Paragraph (a) of this section does not apply with respect to—

(1) A plan described in section 401(a) which includes a trust exempt from tax under section 501(a);

(2) An annuity plan or contract described in section 403;

(3) That portion of any plan which consists of a transfer of property described in section 83;

(4) That portion of any plan which consists of a trust to which section 402(b) applies; or

(5) A qualified governmental excess benefit arrangement described in section 415(m).

(c) *Amount included in income.* The amount included in gross income on the applicable date under paragraphs (a)(1) and (a)(2) of this section is equal to the present value of the compensation (including earnings to the extent provided in paragraph (a)(2) of this section) on that date. For purposes of applying section 72 on the applicable date under paragraphs (a)(3) and (4) of this section, the participant is treated as having paid investment in the contract (or basis) to the extent that the deferred compensation has been taken into account by the participant in accordance with paragraphs (a)(1) and (a)(2) of this section.

(d) *Coordination of section 457(f) with section 83*— (1) *General rules.* Under paragraph (b)(3) of this section, section 457(f) and paragraph (a) of this section do not apply to that portion of any plan which consists of a transfer of property described in section 83. For this purpose, a transfer of property described in section 83 means a transfer of property to which section 83 applies. Section 457(f) and paragraph (a) of this section do not apply if the date on which there is no substantial risk of forfeiture with respect to compensation deferred under an agreement or arrangement that is not an eligible plan is on or after the date on which there is a transfer of property to which section 83 applies. However, section 457(f) and paragraph (a) of this section apply if the date on which there is no substantial risk of forfeiture with respect to compensation deferred under an agreement or arrangement that is not an eligible plan precedes the date on which there is a transfer of property to which section 83 applies. If deferred compensation payable in property is includible in gross income under section 457(f), then, as provided in section 72, the amount includible in gross income when that property is later transferred or made available to the service provider is the excess of the value of the property at that time over the amount previously included in gross income under section 457(f).

(2) *Examples.* The provisions of this paragraph (d) are illustrated in the following examples:

Example 1. (i) *Facts.* As part of an arrangement for the deferral of compensation, an eligible employer agrees on December 1, 2002 to pay an individual rendering services for the eligible employer a specified dollar amount on January 15, 2005. The arrangement provides for the payment to be made in the form of property having a fair market value equal to the specified dollar

amount. The individual's rights to the payment are not subject to a substantial risk of forfeiture (within the meaning of section 457(f)(3)(B)).

(ii) *Conclusion.* In this *Example 1*, because there is no substantial risk of forfeiture with respect to the agreement to transfer property in 2005, the present value (as of December 1, 2002) of the payment is includible in the individual's gross income for 2002. Under paragraph (a)(4) of this section, when the payment is made on January 15, 2005, the amount includible in the individual's gross income is equal to the excess of the fair market value of the property when paid, over the amount that was includible in gross income for 2002 (which is the basis allocable to that payment).

Example 2. (i) *Facts.* As part of an arrangement for the deferral of compensation, individuals A and B rendering services for a tax-exempt entity each receive in 2010 property that is subject to a substantial risk of forfeiture (within the meaning of section 457(f)(3)(B) and within the meaning of section 83(c)(1)). Individual A makes an election to include the fair market value of the property in gross income under section 83(b) and individual B does not make this election. The substantial risk of forfeiture for the property transferred to individual A lapses in 2012 and the substantial risk of forfeiture for the property transferred to individual B also lapses in 2012. Thus, the property transferred to individual A is included in A's gross income for 2010 when A makes a section 83(b) election and the property transferred to individual B is included in B's gross income for 2012 when the substantial risk of forfeiture for the property lapses.

(ii) *Conclusion.* In this *Example 2*, in each case, the compensation deferred is not subject to section 457(f) or this section because section 83 applies to the transfer of property on or before the date on which there is no substantial risk of forfeiture with respect to compensation deferred under the arrangement.

Example 3. (i) *Facts.* In 2004, Z, a tax-exempt entity, grants an option to acquire property to employee C. The option lacks a readily ascertainable fair market value, within the meaning of section 83(e)(3), has a value on the date of grant equal to $100,000, and is not subject to a substantial risk of forfeiture (within the meaning of section 457(f)(3)(B) and within the meaning of section 83(c)(1)). Z exercises the option in 2012 by paying an exercise price of $75,000 and receives property that has a fair market value (for purposes of section 83) equal to $300,000.

(ii) *Conclusion.* In this *Example 3*, under section 83(e)(3), section 83 does not apply to the grant of the option. Accordingly, C has income of $100,000 in 2004 under section 457(f). In 2012, C has income of $125,000, which is the value of the property transferred in 2012, minus the allocable portion of the basis that results from the $100,000 of income in 2004 and the $75,000 exercise price.

Example 4. (i) *Facts.* In 2010, X, a tax-exempt entity, agrees to pay deferred compensation to employee D. The amount payable is $100,000 to be paid 10 years later in 2020. The commitment to make the $100,000 payment is not subject to a substantial risk of forfeiture. In 2010, the present value of the $100,000 is $50,000. In 2018, X transfers to D property having a fair market value (for purposes of section 83) equal to $70,000. The transfer is in partial settlement of the commitment made in 2010 and, at the time of the transfer in 2018, the present value of the commitment is $80,000. In 2020, X pays D the $12,500 that remains due.

(ii) *Conclusion.* In this *Example 4*, D has income of $50,000 in 2010. In 2018, D has income of $30,000, which is the amount transferred in 2018, minus the allocable portion of the basis that results from the $50,000 of income in 2010. (Under section 72(e)(2)(B), income is allocated first. The income is equal to $30,000 ($80,000 minus the $50,000 basis), with the result that the allocable portion of the basis is equal to $40,000 ($70,000 minus the $30,000 of income).) In 2020, D has income of $2,500 ($12,500 minus $10,000, which is the excess of the original $50,000 basis over the $40,000 basis allocated to the transfer made in 2018).

§ 1.457–12 Effective dates.

(a) *General effective date.* Except as otherwise provided in this section, §§ 1.457–1 through 1.457–11 apply for taxable years beginning after December 31, 2001.

(b) *Transition period for eligible plans to comply with EGTRRA.* For taxable years beginning after December 31, 2001, and before January 1, 2004, a plan does not fail to be an eligible plan as a result of requirements imposed by the Economic Growth and Tax Relief Reconciliation Act of 2001 (115 Stat. 385) (EGTRRA) (Public Law 107–16) June 7, 2001, if it is operated in accordance with a reasonable, good faith interpretation of EGTRRA.

(c) *Special rule for distributions from rollover accounts.* The last sentence of § 1.457–6(a) (relating to distributions of amounts held in a separate account for eligible rollover distributions) applies for taxable years beginning after December 31, 2003.

(d) *Special rule for options.* Section 1.457–11(d) does not apply with respect to an option without a readily ascertainable fair market value (within the meaning of section 83(e)(3)) that was granted on or before May 8, 2002.

(e) *Special rule for qualified domestic relations orders.* Section 1.457–10(c) (relating to qualified domestic relations orders) applies for transfers, distributions, and payments made after December 31, 2001.

PART 602—OMB CONTROL NUMBERS UNDER THE PAPERWORK REDUCTION ACT

■ **Par. 4.** The authority citation for part 602 continues to read as follows:

Authority: 26 U.S.C. 7805.

■ **Par. 5.** In § 602.101, paragraph (b) is amended by adding an entry in numerical order to the table to read as follows:

§ 602.101 OMB Control numbers.

* * * * *

(b) * * *

CFR part or section where identified and described	Current OMB control No.
* * * * *	
1.457–8	1545–1580
* * * * *	

Robert E. Wenzel,

Deputy Commissioner for Services and Enforcement.

Approved: July 2, 2003.

Pamela F. Olson,

Assistant Secretary of Treasury (Tax Policy)

[FR Doc. 03–17523 Filed 7–10–03; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

31 CFR Part 50

RIN 1505–AA96

Terrorism Risk Insurance Program

AGENCY: Departmental Offices, Treasury.

ACTION: Final rule.

SUMMARY: The Department of the Treasury (Treasury) is issuing this rule in final form as part of its implementation of Title I of the Terrorism Risk Insurance Act of 2002 (Act). That Act established a temporary Terrorism Risk Insurance Program (Program) under which the Federal Government will share the risk of insured loss from certified acts of terrorism with commercial property and casualty insurers until the Program sunsets on December 31, 2005. Treasury published an interim final rule with a request for comment on February 28, 2003. That rule set forth the purpose and scope of the Program and key definitions that Treasury will use in implementing the Program. It was the first in a series of regulations that Treasury will be issuing to implement the Program. This final rule generally adopts the interim final rule, but makes revisions in the definition of ''affiliate'' and certain other changes described in the preamble.

DATES: This final rule is effective July 11, 2003.

FOR FURTHER INFORMATION CONTACT: Mario Ugoletti, Deputy Director, Office of Financial Institutions Policy (202) 622–2730, or Martha Ellett or Cynthia Reese, Attorney-Advisors, Office of the Assistant General Counsel (Banking & Finance), (202) 622–0480 (not toll-free numbers).

SUPPLEMENTARY INFORMATION:

I. Background

A. Terrorism Risk Insurance Act of 2002

On November 26, 2002, President Bush signed into law the Terrorism Risk Insurance Act of 2002 (Public Law 107–297, 116 Stat. 2322). The Act was effective immediately. Title I of the Act establishes a temporary federal program of shared public and private compensation for insured commercial property and casualty losses resulting from an act of terrorism as defined in the Act and certified by the Secretary of the Treasury, in concurrence with the Secretary of State and the Attorney General. The Act authorizes Treasury to administer and implement the Terrorism Risk Insurance Program, including the issuance of regulations and procedures. The Program will sunset on December 31, 2005.

The Act's purposes are to address market disruptions, ensure the continued widespread availability and affordability of commercial property and casualty insurance for terrorism risk and to allow for a transition period for the private markets to stabilize and build capacity while preserving State insurance regulation and consumer protections. The amount of Federal payment for an insured loss resulting from an act of terrorism is to be determined based upon the insurance company deductibles and excess loss sharing with the Federal Government, as specified by the Act. Thus, the Program provides a Federal reinsurance backstop for a temporary period of time. The Act also provides Treasury with authority to recoup Federal payments made under the Program through policyholder surcharges, up to a maximum annual limit.

Each entity that meets the definition of ''insurer'' (well over 2000 firms) must participate in the Program. From the date of enactment of the Act through the last day of Program Year 2 (December 31, 2004), insurers under the Program must ''make available'' terrorism risk insurance in their commercial property and casualty insurance policies and the coverage must not differ materially from the terms, amounts and other coverage limitations applicable to commercial property and casualty losses arising from events other than acts of terrorism. The Act permits Treasury to extend the ''make available'' requirement into Program Year 3, based on an analysis of factors referenced in the study required by section 108(d)(1) of the Act, and not later than September 1, 2004. An insurer's deductible increases each year of the Program, thereby reducing the Federal government's involvement prior to sunset of the Program. An insurer's deductible is based on ''direct earned premiums'' over a statutory Transition Period and the three Program Years. Once an insurer has met its deductible, the Federal payments cover 90 percent of insured losses above the deductible, subject to an aggregate annual cap of $100 billion. The Act prohibits duplicative payments for insured losses that have been covered under any other Federal program.

As conditions for federal payment under the Program, insurers must provide clear and conspicuous disclosure to the policyholders of the premium charged for insured losses covered by the Program, and must submit a claim and certain certifications to Treasury. Treasury will be prescribing claims procedures at a later date.

The Act also contains specific provisions designed to manage litigation arising from or relating to a certified act of terrorism. Section 107 creates an exclusive federal cause of action, provides for claims consolidation in federal court and contains a prohibition on Federal payments for punitive damages under the Program. This section also provides the United States with the right of subrogation with respect to any payment or claim paid by the United States under the Program.

B. The Interim Final Rule

The interim final rule established Subpart A of a new Part 50 in Title 31 of the Code of Federal Regulations. Subpart A of new Part 50 contains certain general provisions and definitions of Program terms. The definitions contained in the interim final rule provide the foundation for participation by insurers under the Federal reinsurance Program created by the Act.

Some of the definitions in the interim final rule were taken virtually verbatim from the Act because they do not need further clarification. For other definitions, the interim final rule generally incorporated previously issued interim guidance provided by Treasury as it pertains to Program terms, for example, the terms ''insurer,'' ''affiliate,'' ''property and casualty insurance'' and ''direct earned premium.'' Such interim guidance was published at 67 FR 76206 (December 11, 2002), 67 FR 78864 (December 26, 2002) and 68 FR 4544 (January 29, 2003). In several areas, the interim final rule made clarifying modifications to, or supplemented, the previously issued interim guidance.

In implementing the Program, Treasury has been guided by several goals. First, we strive to implement the Act in a transparent and effective manner that treats comparably those insurers required to participate in the Program and that provides necessary information to policyholders in a useful and efficient manner. Second, Treasury seeks to rely as much as possible on the State insurance regulatory structure. In that regard, Treasury is closely coordinating with the National Association of Insurance Commissioners (NAIC) in implementing definitional and other aspects of the Program. Third, to the extent possible within statutory constraints, Treasury seeks to allow insurers to participate in the Program in a manner consistent with their normal course of business. Finally, given the temporary and transitional nature of the Program, Treasury is guided by the Act's goal for insurers to develop their own capacity, resources and mechanisms for terrorism risk insurance coverage when the Program expires.

II. Summary of Comments and Final Rule

Treasury received over 40 comments on the interim final rule. Comments were submitted by insurance companies, industry trade associations, the NAIC, two cities, and by two members of Congress. After review and careful consideration of these comments, as well as additional research and consultation with the NAIC, Treasury is now promulgating a final rule concerning TRIA definitions. In general, the final rule reflects the interim final rule. However, revisions and clarifications were made in several areas, based on comments received. For example, revisions were made to the rebuttable presumptions to controlling influence determinations under the definition of ''affiliate,'' and clarifications were made to the definitions of ''direct earned premium'' and ''commercial property and casualty insurance.'' The final rule, including changes and clarifications, is discussed in the summary below.

A. ''Act of Terrorism'' (Section 50.5.b)

The interim final rule incorporated the statutory definition of ''act of terrorism'' found in section 102(1) of the Act. In that regard, the interim final rule provides that an ''act of terrorism'' for

purposes of the Program must be certified by the Treasury Secretary, in concurrence with the Secretary of State and the Attorney General of the United States, and must fall within other statutory parameters. The requirements in clauses (i)–(iv) of section 102(1)(A) are conjunctive. An act of terrorism, if it also meets the limitations in section 102(1)(B), may be certified if it: is violent or dangerous to human life, property or infrastructure; and has resulted in damage within the United States, or outside the United States in the case of certain air carriers or vessels or if on the premises of a U.S. mission; and has been committed by individual(s) on behalf of any foreign person or foreign interest, as part of an effort to coerce the U.S. civilian population or to influence the policy or affect the conduct of the U.S. government by coercion. Therefore, acts of domestic civil disturbance would not be covered by the Act's definition of ''act of terrorism'' or by the Program.

Section 102(1)(B) limits the Secretary's ability to certify an act if committed as part of a course of war declared by Congress, (except for workers'compensation coverage), or if property and casualty insurance losses resulting from the act, in the aggregate, do not exceed a $5,000,000 *de minimis* threshold. With regard to the first limitation, one commenter raised a question concerning the effect of a declaration of war on an act of terrorism certification. While it is not possible for a regulation to address all potential situations surrounding an act of terrorism determination under the Program, it is Treasury's view that the war exclusion in the Act applies only to acts of terrorism committed in connection with a formal, congressionally declared war. While the phrase ''war declared by the Congress'' is not defined in the Act, Article I, section 8, clause 11 of the Constitution grants Congress the exclusive authority to declare war. Congress has done so on five occasions, the most recent of which occurred in 1941 at the outset of World War II. Most other American military actions have been conducted pursuant to constitutional authorities of the President connected with his role as commander-in-chief, and while many of these have also enjoyed explicit Congressional support, they have not been authorized by a formal declaration of war. For example, the ''Authorization for Use of Military Force Against Iraq Resolution of 2002,'' (P.L. 107–243) gave the President authority to conduct military operations, but is not a formal declaration of war.

With regard to the second statutory limitation on an act of terrorism certification, one commenter asked whether the $5,000,000 threshold loss has to be suffered by one insured policyholder. The Act, as reflected in the interim final rule, provides that the *de minimis* threshold is based on loss ''in the aggregate''. One certified act of terrorism could result in insured losses from several policyholders, none of which alone would amount to $5,000,000, but, in the aggregate, would be in excess of that amount.

Section 106(a)(2) of the Act provides that the Act's definition is the exclusive definition of the term ''act of terrorism'' for purposes of compensation for insured losses under the Act. In addition, section 102(1)(C) of the Act provides that the Secretary's determination or certification with regard to whether an act is an act of terrorism for purposes of the Program is final and is not subject to judicial review.

One commenter urged Treasury to establish a time frame within which the Secretary would be required to make a determination or certification that an ''act of terrorism'' had occurred in order to better assist insurers in responding to inquiries and claims from their policyholders. Treasury understands the desire for certainty of those in the industry who would advocate a definite time frame, and intends to make its determination as promptly as possible after obtaining and evaluating the facts surrounding a possible act of terrorism. However, there is no way to predict future events and ascertain a time frame that would be appropriate for all potential situations. Facts could be immediately available and, after consultation, present a clear basis for a quick determination by the Secretary; conversely, a determination could require more time to gather information and conduct an analysis of the act. Given this inherent uncertainty and the significance of an act of terrorism determination to all aspects of the Program, Treasury does not believe that it would be in the public interest to establish in advance a regulatory time frame that may later prove to be inappropriate or unattainable.

B. ''Affiliate'' Including ''Control'' (Section 50.5(c))

Approximately one-third of the comments submitted to Treasury on the interim final rule raised questions or concerns with regard to the definition of ''affiliate'', which includes the definition of ''control'' in section 50.5(c). Most of these comments raised questions with either procedural or substantive aspects of the rebuttable presumptions of controlling influence in this section. After careful consideration of the comments and further consultation with the NAIC, Treasury has made several revisions in the final rule to address these comments. The regulatory definitions and changes to the interim final rule are set forth below.

Section 102(6) of the Act defines an ''insurer'' to include ''any affiliate thereof.'' The definitions of ''affiliate'' and ''control'' are intertwined in the Act. Section 102(2) defines ''affiliate'' to mean ''with respect to any insurer, an entity that controls, is controlled by, or is under common control with the insurer.'' Pursuant to Section 102(3) of the Act, ''control'' exists if

- an entity directly or indirectly or acting through 1 or more other persons owns, controls, or has power to vote 25 percent or more of any class of voting securities of the other entity; or
- an entity controls in any manner the election of a majority of the directors or trustees of the other entity; or
- the Secretary determines, after notice and opportunity for hearing, that the entity directly or indirectly exercises a controlling influence over the management or policies of the other entity.

Section 50.5(c) of the interim final rule generally incorporates and combines the related statutory definitions of ''affiliate'' and ''control.'' In addition, the interim final rule provides that an affiliate must itself meet the definition of ''insurer'' to participate in the Program. (See part E of this preamble for further discussion of ''insurer'' definition.) The definitions of affiliate and control are integral to Treasury's implementation of the Program. As discussed further in parts C and F of this preamble, affiliated insurers are treated collectively as one entity by Treasury for purposes of calculating direct earned premiums and an insurer deductible under the Program. Three comments objected to this consolidated treatment as not equitable. However, as noted in the preamble to the interim final rule, this consolidated treatment is in accord with the Act's legislative history and the clear intent of Congress. The Conference Report states that the terms ''affiliate'' and ''control'' were meant ''to ensure that affiliated insurers are treated as a consolidated entity for calculating direct earned premiums.'' H.R. Conf. Rep. No. 107–779 (2002).

Therefore, for example, if an insurance company meets the definition of an ''insurer'' under section 102(6) as implemented by Treasury, and three out

of four of the companies it controls also meet the Act's definition of ''insurer,'' then the parent company and the three companies it controls that meet the Act's definition of ''insurer'' (the parent company's affiliates) will be treated by Treasury collectively as one insurer for purposes of calculating direct earned premiums and calculating the insurer deductible under the Program. The company that does not meet the definition of ''insurer'' is not included in the Program.

In addition, if an entity is under common control with an insurer, and that entity also meets the definition of ''insurer'' under Section 102(6) of the Act as implemented by Treasury, then the two insurers are ''affiliates'' and Treasury will treat them collectively as one ''insurer'' for the Program purposes of consolidating direct earned premiums and calculating the insurer deductible. If their parent company does not meet the definition of ''insurer'' under the Act, then it is not included in the Program.

Control

The statutory definition of ''control'' in section 102(3) contains three categories. Section 102(3)(A) and (B) establish conclusive control under certain circumstances for purposes of the Program. The conclusive control provisions of the Act are contained in the definition of ''affiliate'' in the interim final rule at section 50.5(c)(2)(i) and (ii). If a relationship between or among insurers does not fit within the conclusive control provisions, control may still exist for purposes of the Program if Treasury determines, pursuant to section 102(3)(C), that an entity directly or indirectly exercises a controlling influence over the management or policies of another entity. Section 102(3)(C) is contained in the interim final rule at section 50.5(c)(2)(iii). In making a determination of whether controlling influence exists among insurers, section 102(3)(C) of the Act requires Treasury to provide notice and an opportunity for a hearing.

The Act's definition of control in section 102(3)(A), (B) and (C) is almost identical to the definition of ''control'' contained in the Bank Holding Company Act (BHCA) at 12 U.S.C. 1841(a)(2) and in the Savings and Loan Holding Company Act (SLHCA) at 12 U.S.C. 1467a, except that the Act does not contain a presumption of no control for holding less than 5 percent of any class of voting securities, nor does the Act provide any of the other explicit statutory exemptions that are provided in the BHCA and SLHCA. The Act's definition of control is also similar to the definition of control in the NAIC's Model Insurance Company Holding Company Act (Model Act) except that the Model Act contains a presumption of control if an entity owns 10 percent of the voting securities of an insurance company instead of the 25 percent conclusive control threshold that is contained in the Act (and in the BHCA and the SLHCA).

Owns, Controls or has the Power to Vote 25 Percent or More of Voting Securities

Under Section 102(3)(A) of the Act, ''an entity has 'control' over another entity if the entity directly or indirectly or acting through 1 or more persons owns, controls or has the power to vote 25 percent or more of any class of voting securities of the other entity.'' The interim final rule incorporates this statutory definition, but uses the word ''insurer'' instead of ''entity'' to clarify that the definition of control does not include entities that are not insurers.

One commenter asked for clarification that an affiliate itself must be an insurer to be treated as part of a consolidated entity with a related insurer. In view of the congressional intent that affiliated insurers be treated as a consolidated entity for purposes of calculating direct earned premiums, there is no reason to include non-insurer entities in the definition of ''affiliate'' because these entities do not have ''direct earned premiums'' as defined in the Act. Viewing a group of affiliates with both insurer and non-insurer entities, the direct earned premiums for the group should be no different whether or not the non-insurers are included in the group. For this reason, Treasury has decided to interpret the Act as generally excluding non-insurers from the definitions of affiliate and control at this time. Treasury could revisit this issue if it finds evidence that other corporate structures or arrangements are being used to thwart the goals and purposes of the Program.

Five insurance industry commenters took the position that ownership of 25 percent or more of the voting securities of an insurer should not automatically result in control. These commenters asserted that Treasury could and should by regulation change this statutory limit. One commenter referenced the NAIC Model Act language in support of creating a regulatory presumption. As noted above, unlike section 102(3)(A), the NAIC Model Act contains a 10 percent statutory presumption not a threshold of conclusive control. Several of these commenters stated that a 25 percent or more conclusive control limit could adversely affect the availability and affordability of coverage, and in particular, would have an adverse effect on their own companies if they were required to aggregate direct earned premiums. These commenters suggested various alternatives for Treasury to use instead of the 25 percent statutory limit. These included substituting other regulatory factors for the 25 percent limit and accepting a state determinations of ''no control'' based on state law even where there is ownership of more than 25 percent.

Consistent with the statutory language in section 102(3)(A) and with other statutes containing similar language, Treasury interprets the 25 percent or more direct or indirect ownership of any class of voting securities to be an objective standard establishing conclusive control. Under the plain language of the statute, the 25 percent voting securities threshold is not a presumption, and is not subject to rebuttal. We also note that in addressing the rebuttable presumptions in the interim final rule in connection with section 102(3)(C), several commenters characterized the ownership of 25 percent or more of any class of voting securities threshold in section 102(3)(A), as well as the control provision in section 102(3)(B), as objective standards. For these reasons, Treasury has not made any change in the final rule to the 25 percent threshold in section 50.5(c)(2)(ii) of the interim final rule.

Controls the Election of a Majority of the Directors or Trustees

The interim final rule provides that an insurer controls another insurer for purposes of the Program if the insurer controls in any manner the election of a majority of the directors or trustees of the other insurer. In general, this regulatory provision incorporates the statutory language in section 102(3)(B). For the reasons stated above in connection with section 102(3)(A), Treasury interprets the section 102(3)(B) as another objective standard that establishes conclusive control for purposes of the Act. This standard is not a presumption and is not subject to rebuttal.

Controlling Influence and Rebuttable Presumptions

In addition to the conclusive control provisions in section 102(3)(A) and (B), the Act defines control to exist if, ''the Secretary determines, after notice and opportunity for hearing, that the entity directly or indirectly exercises a controlling influence over the management or policies of the other entity.'' Section 102(3)(C). In the interim

final rule, Treasury established several rebuttable presumptions for the purposes of a determination of controlling influence: (1) If a State has determined that an insurer controls another insurer; (2) if an insurer provides 25 percent or more of another insurer's capital (in the case of a stock insurer), policyholder surplus (in the case of a mutual insurer), or corporate capital (in the case of other entities that qualify as insurers); or (3) if an insurer, at any time during a Program Year, supplies 25 percent or more of the underwriting capacity for that year to an insurer that is a syndicate consisting of a group including incorporated and individual unincorporated underwriters.

Section 50.5(c)(4) of the interim final rule provided an insurer with an opportunity for an informal hearing to rebut a controlling influence presumption through written submissions and, in addition in Treasury's discretion, by an informal oral presentation. Treasury subsequently issued a notice on March 25, 2003 (68 FR 15039, March 27, 2003, ''Interim Guidance IV'') providing further guidance on the procedure for rebutting a presumption of controlling influence.

In establishing several rebuttable presumptions in Section 50.5(c)(3) of the interim final rule, Treasury had two key goals. One was to provide additional transparency about the factors that Treasury considers indicative of controlling influence to provide greater certainty to insurers prior to a final determination of control and thereby facilitate the calculation of insurer deductibles prior to presentment of a claim.

The second was to enhance administrative efficiency given available time and other resources in this temporary Program.

With regard to the second goal, we point out that, in the Act, Congress established a temporary backstop program with the expectation that Treasury would not build a large bureaucratic program structure, but instead would leverage off of the state insurance regulatory structure, where possible and appropriate. Unlike state insurance commissioners, or state or federal bank examiners, Treasury does not conduct regular on-site examinations of Program participants, nor does it routinely review acquisitions, mergers or other transactions of such insurers. Thus, Treasury does not have ready access to detailed information on the control relationships of insurers that is generally available to regulators that implement the control provisions of the BHCA, the SLHCA, or state insurance law.

At this point, it is unclear to Treasury how many insurers fall outside section 102(3)(A) and (B) but may come within the controlling influence category. Rejecting the imposition of significant new regulatory reporting requirements on the property and casualty insurance industry, Treasury decided to utilize regulatory presumptions to accomplish these two goals and to implement the controlling influence provisions.

Treasury received 6 comments, from insurers and from a large insurance industry trade group, taking exception to the rebuttable presumptions as presented in the interim final rule. These commenters objected on procedural and substantive grounds. In addition, one commenter supported, in principle, the rebuttable presumption process.

Most of these commenters objected to the reliance on a state law determination of control in the first rebuttable presumption in the interim final rule. They contended that exclusive reliance on a state law determination, for purposes of a rebuttable presumption, was inappropriate given the varying state standards and the differences between the Act's definition of ''control'', and the definition of ''control'' in the NAIC Model Law used by most states. Several commenters suggested that Treasury utilize specific guidelines or standards (such as the existence of a management agreement) instead of rebuttable presumptions.

After consideration of these comments and the stated administrative goals, Treasury has decided to retain the use of rebuttable presumptions, with modifications. Use of the rebuttable presumptions provides increased certainty and transparency to insurers and others of the factors that Treasury considers indicative of a controlling influence. Rebuttable presumptions have been and are used successfully by other agencies in implementing nearly identical statutory definitions of ''control.'' Rebuttable presumptions also aid efficient implementation of the controlling influence determination process, given that Treasury does not have ready access to relevant information about the financial, managerial, policymaking and corporate structures of insurers. Moreover, a rebuttable presumption is not a final determination of controlling influence by Treasury. Under the final rule, insurers subject to rebuttable presumptions, and others that do not fall within the conclusive control provisions and wish to have a final determination of controlling influence, all have an opportunity for a hearing. Based upon the comments, and further consultation with NAIC, Treasury is revising the rebuttable presumptions to provide more detail and transparency concerning factors that Treasury will consider indicative of controlling influence and is using these factors in the rebuttable presumptions. For example, in response to several comments, no rebuttable presumption relies exclusively on a state law determination of control in the absence of the existence of at least one of the listed control factors. The final rule also adds the existence of at least one of the control factors to the other two presumptions (which are based on the provision of 25 percent corporate capital/ policyholder surplus, or the provision of 25 percent underwriting capacity to another insurer).

In the final rule, if an insurer does not come within the conclusive control provisions of section 102(3)(A) or (B) (section 50.5(c)(2)(i) or (ii) of the final rule), but at least two of the following control factors exists, then Treasury will presume controlling influence exists prior to a final determination unless and until rebutted by the insurer:

- The insurer is one of the two largest shareholders of any class of voting stock;
- The insurer holds more than 35 percent of the combined debt securities and equity of the other insurer;
- The insurer is party to an agreement pursuant to which the insurer possesses a material economic stake in another insurer resulting from a profit-sharing arrangement, use of common names, facilities or personnel, or the provision of essential services to another insurer;
- The insurer is party to an agreement that enables the insurer to influence a material aspect of the management or policies of another insurer;
- The insurer would have the ability, other than through the holding of revocable proxies, to direct the votes of more than 25 percent of the other insurer's voting stock in the future upon the occurrence of an event;
- The insurer has the power to direct the disposition of more than 25 percent of a class of voting stock in a manner other than a widely dispersed or public offering;
- The insurer and/or the insurer's representative or nominee constitute more than one member of the other insurer's board of directors;
- The insurer or its nominee or an officer of the insurer serves as the chairman of the board, chairman of the

executive committee, chief executive officer, chief operating officer, chief financial officer or in any position with similar policymaking authority in another insurer;

In addition, if a State has determined that an insurer controls another insurer, and at least one of the factors listed above exists, then Treasury will presume controlling influence exists unless and until rebutted by the insurer.

Further, if an insurer provides 25 percent or more of another insurer's capital in the case of a stock insurer, policyholder surplus (in the case of a mutual insurer) or corporate capital (in the case of other entities that qualify as insurers), and at least one of the factors listed above exists, then Treasury will presume a controlling influence exists unless and until rebutted by the insurer.

Finally, if an insurer, at anytime during the Program Year, supplies 25 percent or more of the underwriting capacity for that year to an insurer that is a syndicate consisting of a group including incorporated and individual unincorporated underwriters, and at least one of the factors in the above list exists, then Treasury will presume a controlling influence unless and until rebutted by the insurer.

A few of the commenters objected to the second and third rebuttable presumptions in the interim final rule as inconsistent with the conclusive control provisions in section 102(3)(A) and (B). As a general matter, Treasury is directed by the Act to treat insurers comparably under the Program. Treasury views the provision by an insurer of 25 percent of an insurer's corporate capital (or policyholder surplus), or supplying of 25 percent of an insurer's underwriting capacity for the Program Year, to indicate the functional equivalent of ownership of 25 percent of voting securities. As the administrator of the Program, Treasury also seeks to prevent loopholes in the regulations and elsewhere that may create opportunities to avoid or greatly minimize an insurer deductible merely on the basis of an insurer's unusual corporate structure or arrangement where, in effect, the insurer exercises a controlling influence over another insurer in the same or similar manner as the more traditional corporate structures of other insurers. The controlling influence determination authority in section 102(3)(C) aids Treasury's efforts to treat insurers comparably and helps preserve the goals and effectiveness of the Program. As described below, the final rule provides insurers with an opportunity for a hearing and a final determination on controlling influence.

Opportunity for Hearing

Section 102(3)(C) of the Act authorizes Treasury to make a determination that an insurer directly or indirectly exercises a controlling influence over the management or policies of another insurer, after notice and opportunity for hearing. The statutory language providing an opportunity for hearing does not require a formal hearing on the record. In the interim final rule, Treasury provided an opportunity for an informal hearing to any insurer that (1) does not come within the conclusive control provisions of section 102(3)(A) or (B) and (2) wanted to rebut a presumption of controlling influence. The informal hearing procedure requires an insurer to provide Treasury with relevant facts and circumstances concerning the relationship and in support of the insurer's contention that no controlling influence exists. The procedure also allows a supplementary oral presentation by the insurer, if deemed necessary by Treasury. Based on the information provided by the insurer, including any oral presentation, the factors listed in the regulation and other relevant facts and circumstances, Treasury would then make a final determination of whether a controlling influence exists.

A few commenters contended that Section 554 of the Administrative Procedure Act (''APA''), 5 U.S.C. § 554, requires Treasury to hold a formal hearing for insurers challenging determinations of entity control under section 102(3) of the Act. We do not agree. The APA's formal hearing requirements apply when a hearing on the record is required by statute. ''While the exact phrase 'on the record' is not an absolute prerequisite to the application of formal hearing procedures, the Supreme Court has made clear that these provisions do not apply, unless Congress has clearly indicated that the 'hearing' required by the statute must be trial-type hearing on the record.'' *U.S. Lines Inc.* v. *Federal Maritime Commission,* 584 F. 2d 519 (D.C. Cir 1978) (citing *United State* v. *Florida East Coast R. Co.,* 410 U.S. 224, 234–38 (1973)). The D.C. Circuit added that, in that case, the statute did not provide for a hearing ''on the record,'' and nothing in the terms of the statute or in its legislative history indicated that a trial-type hearing was intended. *Id.* Similarly, section 102(3)(C) of the Act does not require a hearing on the record and nothing in the language or history of the Act indicates that Congress intended Treasury to establish procedures and apparatus for formal trial-type hearings on the issue of controlling influence for purposes of this temporary Program.

In response to the comments received, the final rule revises the interim final rule to provide greater transparency in the controlling influence determination process. The final rule includes regulatory notice of specific factors that Treasury considers indicative of a controlling influence, and the rebuttable presumptions in the interim final rule are revised to avoid reliance on state law determinations without other indicia of control. The final rule affords insurers an opportunity to request an informal hearing in which an insurer may submit all relevant information on the issue of controlling influence, whether to rebut a presumption or to otherwise obtain a final controlling influence determination from Treasury. As in the interim final rule, the final rule allows an oral presentation, where deemed necessary by Treasury to supplement the written submission. Treasury will base its final determination on the factors set forth in the final rule, on information provided to Treasury by the insurer and on other relevant facts and circumstances. Although the final rule sets no deadline for an insurer to request a hearing, Treasury encourages insurers that do not come within the conclusive control provisions but that are in a relationship or arrangement in which the control factors apply or exist to request a hearing as soon as possible if they wish to rebut the regulatory presumptions of controlling influence and obtain a final determination from Treasury of whether the relationship involves a controlling influence (and therefore control).

Separately from the issuance of the interim final rule, Treasury solicited comment on a pro rata allocation method for control determinations under section 102(3)(C) of the Act, in situations in which multiple insurers each provide 25 percent or more of the capital of a stock insurer, policyholder surplus of a mutual insurer or corporate capital of other entities that meet the definition of insurer under the Act and in the interim final rule. The pro rata approach under consideration by Treasury would allocate premium on a pro rata basis in situations where there are multiple 25 percent owners. This approach is still under consideration by Treasury and may be proposed in connection with claims procedures.

Treasury anticipates proposing within claims procedures at a later date that the controlling insurer will be the insurer that will be required to file any claim with Treasury for Federal payment under the Program and that this insurer

will receive the Federal payment that is to be distributed within the consolidated insurer group in accordance with distribution of risk within the consolidated insurer group.

Treasury also solicited comment on various means to ensure the prompt distribution of the federal payment as appropriate to ensure that the purposes of the Program are not thwarted or evaded, and that the ultimate risk bearing entities are treated in an equitable manner, within the Act's requirements. Treasury will propose means of distribution of the federal payment in connection with the claims procedures at a later date.

C. Direct Earned Premium (Section 50.5.d) and Property and Casualty Insurance (Section 50.5.l)

The Act requires that ''commercial property and casualty insurance'' that falls within the scope of ''insured loss'' and that is written by an ''insurer,'' is part of the Program, and thus eligible for Federal payments and also subject to other provisions of the Act. Losses arising from a certified act of terrorism that do not meet these requirements are not eligible for Federal payments under the Program. For those losses that are eligible, the amount of Federal payment that an insurer may receive is subject to the insurer's ''insurer deductible,'' which is determined by a calculation based on the insurer's ''direct earned premium''.

In the interim final rule, Treasury initially looked to the Act's definition to ascertain the scope of commercial property and casualty insurance for purposes of the Program. Section 102(12) of the Act expressly includes several lines of insurance: excess insurance, workers' compensation insurance and surety insurance. It also expressly excludes several additional lines of insurance: (i) Federal crop insurance issued or reinsured under the Federal Crop Insurance Act or any other type of crop or livestock insurance that is privately issued or reinsured; (ii) private mortgage insurance as defined in the Homeowners Protection Act or title insurance; (iii) financial guaranty insurance issued by monoline financial guaranty insurance corporations; (iv) insurance for medical malpractice; (v) health or life insurance including group life insurance; (vi) flood insurance provided under the National Flood Insurance Act of 1968; and (vii) reinsurance or retrocessional reinsurance.

In addition to these specific statutory inclusions and exclusions, Treasury needed to develop a uniform regulatory definition of commercial property and casualty insurance for purposes of the Program. Insurance is generally regulated by State law in the United States. After consulting with the NAIC and others, Treasury found no uniform or consistent definition of ''commercial property and casualty insurance'' among the States that could provide guidance or be used for purposes of the Program. In some States, a line of insurance may be considered as commercial; and, in other States, the same line of insurance may be considered as a personal line.

The closest reference point that Treasury found for a uniform definition was the NAIC's Annual Statement's Exhibit of Premiums and Losses (''Statutory Page 14''). Therefore, the interim final rule incorporated the interim guidance issued at 67 FR 76206 that designated those commercial lines reported on specified lines of Statutory Page 14 as commercial property and casualty lines of coverage to be included in the Program (subject to the Act's specific inclusions and exclusions). The lines so specified were: Line 1 (Fire); Line 2.1 (Allied Lines); Line 3 (Farmowners Multiple Peril); Line 5.1 (Commercial Multiple Peril—non-liability portion); Line 5.2 (Commercial Multiple Peril—liability portion); Line 8 (Ocean Marine); Line 9 (Inland Marine); Line 16 (Workers' Compensation); Line 17 (Other Liability); Line 18 (Products Liability); Line 19.3 (Commercial Auto No Fault—personal injury protection); Line 19.4 (Other Commercial Auto Liability); Line 21.2 (Commercial Auto Physical Damage); Line 22 (Aircraft—all perils); Line 24 (Surety); Line 26 (Burglary and Theft); and Line 27 (Boiler and Machinery). In making this determination Treasury considered the Act's definition of ''commercial property and casualty insurance'' and how it relates to the lines of coverage listed on Statutory Page 14, the Program structure, and what would be necessary to effectively administer the Program. In developing the interim final rule, Treasury consulted with the NAIC and others regarding State law and premium reports filed with insurance regulators in the respective States and with the NAIC.

Section 102(4) of the Act defines ''direct earned premium'' to mean direct earned premium (DEP) for property and casualty insurance issued by any ''insurer'' for losses within the scope of ''insured loss.'' The interim final rule also clarified that premium information on the specified lines of Statutory Page 14 should be included in calculating an insurer's DEP *only to the extent that coverage under the Program is provided for commercial property and casualty exposures.* Therefore, policies (or portions of policies) not eligible for Federal payments under the Program, such as personal lines or other lines of coverage (such as medical malpractice) specifically excluded by the Act, should not go into the calculation of an insurer's DEP. Treasury's approach is designed to maintain a close correlation between the lines of commercial property and casualty insurance eligible for the Federal payments under the Program, and the amount of premiums for those coverages that actually go into calculating an insurer's DEP under the Program.

Many policies have combined risk coverage (hybrid policies). Under some hybrid policies, some of the risks or lines are covered by the definition of commercial property and casualty insurance under the Program and some are not covered. To address these situations, the interim final rule allows (but does not require) an insurer to allocate a portion of the premium (*i.e.* that portion for covered lines or risks) in calculating an insurer's DEP under the Program. If an insurer does not choose to allocate its hybrid policy premiums in this manner, then the entire DEP reported on the specific lines of Statutory Page 14 must go into its DEP calculation, and also, potentially, into the recoupment base for that insurer. Treasury has not yet issued rules or procedures governing any potential recoupment under section 103(e)(7) of the Act or concerning the surcharges required by section 103(e)(8) of the Act. However, it is Treasury's expectation that an insurer's policies (or portions of policies) that go into calculating an insurer's DEP would be the same policies (or portions of policies) that go into determining an insurer's recoupment base.

Instead of issuing a new reporting requirement or mandating a specific allocation formula for hybrid policies, Treasury has suggested several methods that insurers may use in adjusting and calculating their DEP under the Program:

(1) For policies with predominant personal line coverages, but where the premiums might also cover a portion for coverage of commercial risks, Treasury indicated that a policy would be considered personal, and not included in DEP, if the commercial portion was incidental (less than 25 percent of the total premium). If the commercial coverage portion represented more than 25 percent of the total premium, then the company should allocate the appropriate portion of the premium as commercial to be included in DEP.

(2) For policies written by insurers required to participate in the Program, but for which the premiums are not reported on Statutory Page 14 (*e.g.* certain county or town

mutuals), the interim final rule suggested other methods by which adjustments could be made by the insurer to calculate its DEP. Specific methods were suggested in the interim final rule for county or town mutual insurers, eligible surplus line insurers, and federally approved insurers.

Included Versus Excluded Lines of Coverage in General

Several commenters were uncertain about whether the interim final rule's list of commercial lines as reported on the specified lines of Statutory Page 14 was exclusive or merely illustrative. Their uncertainty appears to arise from use of the word ''includes'' in section 50.5(l) of the interim final rule that property and casualty insurance (''includes commercial lines within the following lines of insurance.'') These commenters suggested that Treasury clarify whether it intended for the list to be exclusive, or identify those lines of business that are excluded.

As previously noted, Treasury consulted with the NAIC and others concerning the definition of commercial property and casualty insurance. Finding no uniform or consistent definition of the term, Treasury determined that the NAIC's Statutory Page 14, provided the best available point of reference—not only for identifying the lines of coverage for the Program, but also for guidance in determining an insurer's DEP for those lines of coverage. Treasury intended that the list of specified lines on Statutory Page 14 would be exclusive, and premiums reported on other lines would not be part of the Program. The final rule revises the previous language to clarify this.

In its comment on the interim final rule, the NAIC suggested Treasury should add the following language from the Act: ''* * * or any other type of crop or livestock insurance that is privately issued or reinsured'' to section 50.5(l)(2)(i) of the interim final rule. The NAIC commented that such an addition would prevent any uncertainty concerning the treatment of crop or livestock coverage that is not part of the Program.

In developing the interim final rule, Treasury understood based on available information that privately issued or reinsured crop or livestock insurance was reported under Multiple Peril Crop insurance on Line 2.2 of Statutory Page 14. It is now Treasury's understanding, based on additional information from the NAIC, that privately issued or reinsured crop or livestock insurance is generally reported as Allied Lines insurance on Line 2.1 of Statutory Page 14. Therefore, in the final rule, Treasury has added the specific statutory language and the appropriate reporting lines of Statutory Page 14 to section 50.5(l)(2)(i) of the final rule.

The Act and interim final rule exclude Federal flood insurance which is a line of single peril natural disaster insurance. Similarly, the interim final rule excluded earthquake insurance reported on Statutory Page 14. Treasury received no comments on the interim final rule regarding the treatment of any single peril natural disaster insurance. However, in light of information subsequently received in response to Treasury's proposed rule concerning state residual market insurance entities, Treasury is considering issuing a proposed rule specifically requesting comment on the inclusion or exclusion in the Program definition of commercial property and casualty insurance of other single peril natural disaster insurance, such as stand alone, single peril wind insurance, if reported on included lines of Statutory Page 14.

Personal Lines

One commenter asserted that Treasury's determination that commercial coverage is incidental if its applicable premium is less than 25 percent of a hybrid personal/commercial lines policy premium would have adverse effects, suggesting that this could cause insurers to force incidental coverages off such personal policies, such as Homeowners insurance. Others commented that the incidental rule should only be used as a threshold calculation, or that insurers should be allowed to allocate personal/commercial hybrid policy premiums according to their normal business methods and procedures. One commenter contended that Homeowners policies should not be included in the Program regardless of the percentage of commercial premium, and that allocation of commercial/personal premium would not be appropriate for Farmowners or Farm Properties policies since they are both considered by some states to be commercial lines.

As discussed above, Treasury has suggested methods for the allocation of commercial portions of premiums in hybrid policies in an attempt to aid insurers by simplifying the adjustment and calculation of an insurer's DEP. If the appropriate premium was included in the DEP and the other required conditions for Federal payment are met, commercial portions of hybrid policies are covered by the Program. The 25 percent incidental provision was included in the interim final rule by Treasury to provide a threshold, so that those insurers that did not want to calculate an actual allocation of premiums on small incidental amounts of coverage, and did not intend to perfect their right to recover Federal payment on claims paid on such incidental commercial coverage, could then exclude those premiums from their DEP calculation if they wished to do so. In order to clarify this in the final rule, and to make it clear that an insurer can chose to allocate premiums below that amount, Treasury has modified the language in section 50.5(d)(1)(i–iv) of the interim final rule.

Personal Versus Commercial Lines

Four commenters asked for clarification with regard to whether coverage for one to four family rental units is personal or commercial insurance. One pointed out that such coverage is generally written under a Dwelling Properties insurance policy (which is considered to be a personal line). However, in other situations, under four family rental units are written as a commercial coverage. Treasury's designation in section 50.5(l)(1) of the interim final rule of the specific lines of commercial coverage from Statutory Page 14 was made, in part, to provide greater clarity for insurers in cases where various States may not treat certain types of coverage consistently as commercial coverage. In general, it is our understanding that premium income for one to four family rental unit insurance coverage generated from policies insuring property owned for business purposes (e.g. to generate income for the property owner) is reported on Lines 1 (Fire) 2.1 (Allied Lines) and 17 (Other Liability) of Statutory Page 14. Based on section 50.5(l)(1) of the final rule, such insurance coverage would be considered commercial property and casualty insurance coverage that is included in the Program. Treasury also addressed the issue of personal lines in the context of adjustments to DEP in section 50.5(d)(1) of the interim final rule and through adjustments to that section in the final rule. To the extent that one to four family rental units have a personal coverage component, the suggested methods of adjusting and calculating the appropriate DEP may be used by an insurer.

Another commenter stated that farm residences should be considered commercial. For purposes of the Program, Treasury does not agree, but considers any owner occupied residence to be basically a personal coverage. Therefore, where a farm residence is covered in a hybrid farm policy, the suggested methods of adjusting and

calculating the appropriate DEP can be utilized.

Other Non-Covered Lines

One commenter suggested that Treasury consider extending the commercial/personal allocation to other hybrid contracts containing premiums for excluded lines of coverage such as Medical Malpractice in combination with Hospital General Liability coverage. Such insurance lines are not within the scope of the definition of commercial property and casualty insurance of the Act and are not included in the Program. Therefore, premiums in hybrid policies applicable to those exceptions do not need to be included in an insurer's DEP. Any allocation of premium for such exclusions should be calculated by insurers either using methods suggested by Treasury, or other similar methods in accordance with the insurer's normal business methods and procedures.

Another commenter suggested that Treasury should exclude premiums reported on the specified lines on Statutory Page 14, but earned from retroactive insurance programs such as certain Novations, Adverse Development Cover, or Loss Portfolio Transfer Programs. Retroactive insurance is insurance covering only events that occurred prior to the inception date of the policy, but there appears to be no differentiation in the Statutory Page 14 reporting to indicate that such premiums relate to risks from prior years. Treasury takes the position that such retroactive premiums are not within the time period of the definition of ''insured losses'' if they are associated with losses that occurred prior to enactment and the effective date of the Act (November 26, 2002). Such premium income may be removed in an insurer's calculation of its DEP. Treasury has modified the language in the final rule (section 50.5(d)(1)(i–iv) of the interim final rule) to clarify the nature of the allocation provisions with regard to hybrid policies and other policies with coverage of losses outside the scope of insured losses under the Program.

Fidelity Insurance

Treasury did not include Line 23 (Fidelity) of Statutory Page 14 in its list of specified lines considered to be commercial ''property and casualty insurance'' covered under the Act in its initial interim guidance or in its interim final rule. Comments were received from five different commenters, two in support of Treasury's position, and three in opposition.

One of the commenters advocating the inclusion of fidelity insurance argued that it can also have a distinct property component as in cases where coverage is provided for the destruction of money and securities, such as those held in bank or corporate vaults. The commenter pointed out that it had losses associated with fidelity policies arising from the September 11 terrorist attacks totaling some $20 million due to the destruction of cash on the premises of its insured. Another commenter emphasized that fidelity has always been considered by state regulators, insurers, and policyholders to be a commercial property and casualty line.

Those opposed to the inclusion of fidelity insurance contend that it is a line of insurance that by itself faces low exposure to terrorism losses. One commenter had indicated previously that it had provided terrorism coverage for all of its fidelity policies prior to the Act, but needed to confirm whether fidelity insurance was covered under the Program in order to know how much reinsurance coverage would be needed to cover its deductible exposure. Commenters also pointed out that if Treasury were to reverse itself and now include fidelity insurance as a covered line, problems associated with the timing of the disclosure requirements and other issues would need to be addressed.

After considering the comments, Treasury has determined that fidelity insurance is not covered under the Act, and thus has not inserted Line 23 (Fidelity) in the specified lines on Statutory Page 14 that make up commercial property and casualty insurance covered under the Act. In making the overall determination of what lines of coverage are included and excluded in the definition of property and casualty insurance, Treasury relied on specific guidance provided by Congress in section 102(12) of the Act. Section 102(12)(A) expressly includes excess insurance, workers' compensation insurance, and surety insurance. Traditional surety insurance and fidelity insurance share a similar characteristic in that they guarantee against losses associated with the performance of third parties. Treasury maintains the position that if Congress had intended fidelity insurance to be covered, it would have specifically included it as it did surety insurance. Treasury relied on a similar rationale for excluding group accident coverage, a line of coverage that shares some of the same risk characteristics as workers' compensation coverage, from the list of specified lines on Statutory Page 14 that make up commercial property and casualty insurance covered under the Act.

Through the comment process, Treasury has been made aware that the traditional fidelity insurance coverage has been expanded in recent years by some insurers to include coverage to non-employee ''insiders,'' as well as to property coverage for loss of firm assets, including cash, due to crime. Although Treasury is making no change to the interim final rule definition with regard to fidelity in the final rule, Treasury will continue to evaluate this wrap-around or hybrid-type coverage which could include other types of coverage that are generally covered by the Act, but not reported as such. In this regard, Treasury will evaluate whether and how the designation of included and excluded lines has affected the availability of coverage for terrorism insurance risk, and whether any further change in the Program might be warranted.

Other DEP-Related Comments

On behalf of county or town mutual insurers that do not report on Statutory Page 14, one commenter suggested that Treasury's suggestion that they convert direct premium or other types of payments such as assessments or contributions into DEP, would lead to inconsistencies in the Program because states have varying reporting requirements. The result would be that DEPs would vary significantly from state to state, which would be ''bad from a public policy perspective, but leaves insurers on uncertain ground despite their best good faith efforts at compliance.'' Treasury has consulted with the NAIC on this issue and we understand that the NAIC plans to develop a recommended conversion method that States in turn could recommend to county or town mutual insurers.

Another commenter requested that Treasury give insurers assurance that ''fronted'' premiums received by an insurer would not be included in DEP and thus raise its deductible, if the insurer assuming the risk (captive or otherwise) is also an insurer under the Program. The commenter explained that ''fronting'' is a credit enhancement procedure that is sometimes employed by business customers and their insurers to expand available insurance capacity, and is recognized by state regulators. However, fronting arrangements are not addressed in the Act, and the Act does not appear to provide any basis to exclude ''fronted'' premiums from DEP. If one insurer ''fronts'' for another by receiving premiums but passes the risk to another,

it remains the ''insurer'' under the Act and the premiums it receives become part of its DEP. This is not unlike situations where primary insurers report DEP on policies that they subsequently reinsure, and reinsurance is specifically excluded from the Act. Therefore, Treasury will not provide assurance that fronted premiums will not be included in DEP.

D. Insured Loss (Section 50.5.e)

Treasury incorporated the statutory definition of ''insured loss'' found in section 102(5) of the Act in section 50.5(e)(1) of the interim final rule. Section 50.5(e)(2) of the interim final rule clarified the meaning of insured loss as it relates to section 102(5)(B) of that Act as follows:

(i) A loss that occurs to an air carrier (as defined in 49 U.S.C. 40102), to a United States flag vessel, or a vessel based principally in the United States, on which United States income tax is paid and whose insurance coverage is subject to regulation in the United States, is not an insured loss under section 102(5)(B) of the Act unless it is incurred by the air carrier or vessel outside the United States.

(ii) An insured loss to an air carrier or vessel outside the United States under section 102(5)(B) of the Act does not include losses covered by third party insurance contracts that are separate from the insurance coverage provided to the air carrier or vessel.

One commenter took exception to Treasury's clarification that such extraterritorial insured third party losses to United States air carriers and vessels are not insured losses, and cited legislative history of the Act to indicate an intent on the part of Congress to provide extraterritorial coverage to United States air carriers and vessels without limitation.

After reviewing the comments including the legislative history cited by the commenter, Treasury has determined not to change the position it took in the interim final rule. Therefore, for purposes of the Program, an insured loss is ''any'' loss, including a third party liability loss, if it occurs within the geographic boundaries of the United States; but, if the loss occurs outside of the geographic boundaries of the United States (extraterritorial) to a United States air carrier or vessel, then only that portion of the loss ''to'' that air carrier or vessel is an insured loss eligible for the backstop. To further clarify, ''to'' in this context means insured losses that are incurred by United States air carriers and vessels (*e.g.,* through United States air carriers' or vessels' property and liability insurance coverage), not losses that are incurred by other entities that are covered by third party insurance contracts that are separate from the insurance coverage provided to the air carrier or vessel.

Treasury's position is consistent with how third party liability losses are generally treated under the Program (including how such losses are treated for foreign air carriers and foreign flag vessels) in that such losses would be considered insured losses if they are incurred within the geographic scope of the United States. The extension of coverage provided to United States air carriers and vessels under the Act is related directly to those entities and their potential insurance exposures, which are fully covered under the interim final rule. Treasury does not believe that granting broader third party indemnification on an extraterritorial basis and creating greater exposure for United States taxpayers is consistent with congressional intent for the Program.

E. Insurer (Section 50.5.f)

The interim final rule incorporated the statutory definition of ''insurer'' as generally reflected in previously issued interim guidance that was published at 67 FR 78864. In accordance with section 103(a)(3) of the Act, each entity that meets the definition of ''insurer'' under the Act as implemented by Treasury must participate in the Program. To participate in the Program, an entity, including an ''affiliate'' of an insurer (see further discussion in part B of this preamble), must itself meet all of the requirements of section 102(6)(A) and (B) and, as the Treasury may prescribe, (C). This means that to be an insurer, an entity must: (1) Fall within one of the categories in section 102(6)(A) described below; (2) receive direct earned premiums as required by section 102(6)(B); and (3) meet any additional criteria established by Treasury pursuant to section 102(6)(C).

The categories of insurers in Section 102(6)(A) that were directly addressed in the interim final rule include:

(i) Licensed or admitted to engage in the business of providing primary or excess insurance in any State (''State'' includes the District of Columbia and territories of the United States);

(ii) Not so licensed or admitted, but is an eligible surplus line carrier listed on the Quarterly Listing of Alien Insurers of the National Association of Insurance Commissioners;

(iii) Approved for the purpose of offering property and casualty insurance by a Federal agency in connection with maritime, energy or aviation activity; and

(iv) A State residual market insurance entity or State workers' compensation fund.

The interim final rule provides that an entity that falls within two categories will be considered by Treasury to fall within the first category that it meets under section 102(6)(A)(i)–(iv). All entities that are licensed or admitted by a State's insurance regulatory authority, such as captive insurers, risk retention groups, and farm and county mutuals, fall under section 102(6)(A)(i).

The interim final rule also specified that the scope of insurance coverage (insured losses) under the Program for federally approved insurers under section 102(6)(A)(iii) is only to the extent of federal approval of the commercial property and casualty insurance coverage approved by the Federal agency in connection with maritime, energy or aviation activity. Therefore, insured losses under other insurance coverage that may be offered by a federally approved insurer under section 102(6)(A)(iii) would not be covered by the Program.

In addition to falling within a category in section 102(6)(A), an ''insurer'' must meet the requirements in section 102(6)(B) unless statutorily excepted. Therefore, an ''insurer'' must receive ''direct earned premiums'' (as defined) on any type of commercial property and casualty insurance (as defined). In addition, an ''insurer'' must meet any additional criteria prescribed by Treasury under section 102(6)(C). The interim final rule did not prescribe additional criteria under section 102(6)(C). However, under a separate notice of proposed rulemaking published at 68 FR 9814 Treasury solicited public comment on whether the Secretary should prescribe other criteria for certain insurers pursuant to the authority provided by section 102(6)(C) and, if so, what criteria Treasury should prescribe.

Captive Insurers

Treasury received six comments that addressed the treatment of captive insurers under the Program. The majority of these objected to Treasury's mandatory inclusion of captive insurers as a State licensed or approved insurer under Section 102(6)(A)(i). These commenters suggested that captives should be allowed to opt-in to the Program as opposed to being mandatory participants. In support of this position, commenters offered the following points: many captive insurers were created to operate outside of the traditional insurance marketplace, and thus they should not be treated as other insurance companies; some types of commercial coverage provided by

captive insurers may have little or no exposure to terrorism risk, thus captive insurers should not be subject to the Act's potential recoupment provisions; and mandatory participation requirements for captives, in particular the Act's potential recoupment provisions, could negatively affect the formation of domestic captives as companies may find setting up off-shore captives to be advantageous.

Treasury received one comment letter in support of treating State licensed or admitted captive insurers as mandatory participants under the Program. Treasury also received a comment letter from the NAIC that described a split view on the part of State regulators over mandatory participation requirements for state-licensed or admitted captive insurers. Although the NAIC's comments included some of the points noted above, the NAIC also acknowledged that allowing opt-in treatment for captive insurers could allow for adverse selection and could set a bad precedent as other entities would seek similar treatment. In addition, the NAIC noted that ''when pressed for a decision regarding whether a complete inclusion is better than a complete exclusion for captives, regulators generally agree that inclusion is preferable.''

Treasury disagrees with the suggestion in some comments that captive insurers should be provided with opt-in treatment. Requiring mandatory participation for State licensed or admitted captive insurers is in accord with the plain language of section 102(6)(A)(i) where no distinction is made regarding types of State licensed or admitted insurers. This treatment also furthers other statutory objectives such as ensuring that policyholders have widespread access to the terrorism risk insurance benefits of the Program, and spreading potential costs of the Program associated with any federal loss-sharing payments. For example, the cost spreading provisions in connection with recoupment as required by section 103(e)(7) and in connection with surcharges as required by section 103(e)(8) are to be applied to all commercial property and casualty policyholders.

As it relates to the overall administration of the Program, allowing for opt-in treatment would create the potential for adverse selection within the Program as those captive insurers that perceived themselves to have higher risk to terrorism would likely opt-in to the Program while others with lower perceived risks would likely opt-out of the Program. A major consequence of this type of action would be the potential policyholder recoupment base would be reduced, which in turn would increase the potential recoupment costs on the policyholders of other mandatory participants in the Program.

Treasury does not support the view set forth by some of the commenters that limited risk exposure to terrorism of the coverage provided by some captive insurers is a reason to provide for an opt-in option. This same type of argument could be made by any number of insurers and policyholders that feel they have limited risk exposure to terrorism. Because the recoupment base applies to all commercial property and casualty policyholders, potentially limited risk exposure to terrorism is not a valid reason to limit participation under the Program.

Treasury also finds little or no support for assertions that the potential recoupment provisions of the Act would have an adverse effect on U.S. domestic captive jurisdictions. It should be noted that any such recoupment would only be imposed in the case of a terrorist event that triggers Federal payments under the Program, and that any potential recoupment is limited to a maximum 3 percent of premium surcharge in any given year. Although it is possible that certain state-licensed or admitted captive insurers would find these potential costs unattractive and search out other jurisdications, other state-licensed or admitted captive insurers would recognize the benefits of Program participation. Therefore, the ultimate effect on any particular captive insurance jurisdiction is difficult to quantify.

In addition to the general comments on providing captive insurers opt-in treatment under the Program, two members of Congress offered the view that, in the case of captives, the Act must be read in the context of section 103(f). This section authorizes (but does not require) Treasury to apply the provisions of the Act to ''other'' classes or types of captive insurers. These commenters believe that the use of the word ''other'' in section 103(f) is a grammatical error in the Act and, for that reason, they contend that Treasury's interim final rule does not reflect the intent of Congress to create a process through which captive insurers could be integrated into the Program on an opt-in basis.

As previously noted, Section 102(6)(A)(i) of the Act mandates participation by insurers that are ''licensed or admitted'' by a State to engage in the business of providing property and casualty insurance. Following this state-licensed or admitted category in the definition of ''insurer'', is a category for ''any other entity described in Section 103(f), to the extent provided in the rules of the Secretary issued under section 103(f).'' (emphasis added). Section 103(f) of the Act gives discretionary authority to the Secretary to add to the Program, ''other classes or types of captive insurers * * *'' (emphasis added). A key principle of statutory construction is that words in a statute must be read to have meaning unless the reading of those words produces an absurd result. The bar for interpreting words in a statute to be a legislative error is extremely high. If the words in a statute can be construed as having a rational meaning, then the rules of statutory construction preclude an interpretation that they were enacted by Congress in error.

In this case, the word ''other'' in these two provisions can be easily construed as referring to captives other than those that are State-licensed or admitted. Adopting the interpretation of legislative error suggested by the two commenters would require the conclusion that Congress erred in two places in the Act. In addition, we found nothing in the Act's language or legislative history that would support treating state-licensed or admitted captives differently from other state-licensed or admitted insurers for purposes of the Program. For these reasons, the definition of ''insurer'' in the final rule, as in the interim final rule, includes those entities, including any captives, that are state-licensed or admitted. Therefore, if a captive is not state licensed or admitted, then it is not in the Program, unless subsequently brought in by any rules issued under section 103(f).

Pooling Arrangements and Joint Underwriting Associations

Treasury received comments requesting clarification on how insurance pooling arrangements, such as joint underwriting associations, are treated under the Act. These commenters found the interim final rule and previously issued interim guidance to be unclear with regard to (a) whether such entities are insurers under the Act, and (b) if they are insurers, the category of insurer under which they would belong (*e.g.*, State licensed or admitted, or federally approved). These commenters suggested that Treasury either clarify that State authorized joint underwriting associations are State licensed and admitted insurers under the Act, or directly inform a joint underwriting association of its status under the Act. Some commenters also

suggested that Treasury's treatment of federally approved insurers (see next section) should be broadened to include all types of coverage provided by this category of insurers.

The issue of Treasury's treatment of federally approved insurers is, for the most part, separable from the fundamental question of whether joint underwriting associations are State licensed or admitted insurers. With regard to joint underwriting associations operating in the United States, if such entities are considered to be State licensed or approved insurers, then they must participate in the Program as insurers in this category under the Act. The federally approved issue is not reached in this situation.

Treasury acknowledges that certain joint underwriting associations and other entities may not fit neatly within what is traditionally thought of as the ''State licensed or admitted'' market. To provide more clarity in the category of ''State licensed or admitted,'' the final rule provides that, with regard to joint underwriting associations and other pooling arrangements, such entities must meet all three of the following criteria to be an insurer under the Program:

- An entity must have gone through a process to be licensed or admitted to engage in the business of providing primary or excess insurance that is administered by the State's insurance regulator. If such a process differs from what a State's insurance regulator generally applies to insurance companies, such a process should be similar in scope and content;
- An entity must generally be subject to State insurance regulation (including financial reporting requirements) applicable to insurance companies within the State; and
- An entity must be managed independently from other insurers that are participating in the Program.

If a joint underwriting association, pooling arrangement or other entity is still uncertain of its status as State licensed or admitted insurers under the Program, such entities are encouraged to provide Treasury with an explanation of their particular circumstances and how the criteria listed above apply or do not apply. After reviewing this information, Treasury will directly contact such entities regarding their status under the Program. These Treasury decisions also will be made available to the public.

Federally Approved Insurers

Treasury received fifteen comments regarding Treasury's treatment of federally approved insurers in the interim final rule. Under the interim final rule, the scope of insurance coverage (''insured losses'') for federally approved insurers is only to the extent of federal approval of the commercial property and casualty insurance coverage approved by the Federal Agency in connection with maritime, energy or aviation activity. Most of these commenters contended that Treasury's interpretation regarding the scope of insurance coverage under the Program for federally approved insurers was too narrow and that such an interpretation was counter to the intent of Congress.

The maritime shipping industry and their mutually owned insurance companies (International Group of Protection and Indemnity Clubs) raised particular concerns that Treasury's interpretation regarding federally approved insurers would unduly limit access to the Program for the United States and world shipping fleets. As it relates to the maritime industry, the United States Maritime Administration (MARAD) has in place various mechanisms to approve underwriters providing insurance coverage for vessels built or operated with subsidy or covered by vessel obligation guarantees issued pursuant to Title XI of the Merchant Marine Act, 1936, as amended. (46 U.S.C. 1271–1279). Commenters noted that vessels built with Title XI subsidies or guarantees make up a small portion of the United States flag fleet. Therefore, to the extent that the portion of United States flag fleet not subject to MARAD insurance approval was relying solely on federally approved insurers for their insurance coverage, such vessels would currently have limited access to federal payments under the Program. Commenters also noted that a similar situation exists to the extent that foreign flag vessels are currently relying on federally approved insurers for their insurance coverage.

MARAD has set forth eligibility criteria for underwriters of marine hull insurance at 46 CFR 249.4 and 249.5. Broadly speaking, to be eligible under the MARAD program an insurer must be: licensed to do business in the United States; an underwriter at Lloyd's; a member company of the Institute of London Underwriters; or specifically approved by MARAD. There is a fair degree of overlap between MARAD's eligibility criteria for Marine Hull insurers and the definition of ''insurer'' under the Act. Under sections 102(6)(A)(i–iv), the Act includes entities that are State licensed or admitted and entities that are listed on the Quarterly Listing of Alien Insurers of the NAIC as ''insurers'' under the Act. These insurers participate in the Program for all coverages that fall within the definition of ''commercial property and casualty'' within the scope of the definition of ''insured loss'' under the Act. Thus, insurers that fall within the first three of MARAD's eligibility criteria are for the most part already eligible insurers under the Act (although there may be some uncertainty regarding the Institute of London Underwriters as it is our understanding that this group has merged with another organization to form the International Underwriting Association). For insurers that MARAD specifically approves as Marine Hull underwriters, based on the most recently available lists (NAIC's Quarterly Listing of Alien Insurers—April 1, 2003, and MARAD Approval List—May 16, 2003), 13 out of the 18 MARAD approved insurers were listed on the NAIC's Quarterly Listing of Alien Insurers, and 1 of the 5 insurers that were not currently on the NAIC's Quarterly Listing of Alien Insurers was on the list in recent years. Thus, as it relates to Marine Hull underwriters, Treasury's interpretation with regard to federally approved insurers does not appear to have caused major disruptions in insurance coverage. Treasury also notes that we did not receive any comments directly from Marine Hull underwriters objecting to the treatment of federally approved insurers.

MARAD, as part of its general insurance information and requirements, also accepts the International Group of Protection and Indemnity Clubs (International Group) as providers of liability coverage. The International Group is made up of 13 independent Protection and Indemnity Clubs. Each club is independently owned by its ship-owner members. The International Group allows for the individual clubs to share claims, purchase reinsurance as a group, and coordinate on maritime public policy issues. Unlike the case with MARAD-approved hull insurance underwriters, of the 13 members of the International Group only two qualify as eligible insurers under the Act in a category separate from the federally approved insurer category. Hence, the bulk of the comments Treasury received from the maritime community focused on the treatment of the International Group under the interim final rule.

Treasury also received similar comments from the offshore oil and gas drilling industry objecting to the interim final rule's interpretation regarding the participation of federally approved insurers under the Act. The Department of Interior's Minerals Management Service approves insurance coverage as one method covered offshore facilities can use for demonstrating oil spill

financial responsibility, and the Minerals Management Service has procedures in place (30 CFR 253.29) regarding eligibility criteria under their program. To further understand the oil and gas drilling industry's concerns, the Minerals Management Service provided Treasury with a list of insurers that had been approved to provide coverage under the oil spill financial responsibility program. Treasury, in consultation with the NAIC, identified 102 out of 105 insurers that were approved by the Minerals Management Service as being eligible participants under the Act because they either were State licensed or admitted or were on the NAIC's Quarterly Listing of Alien Insurers. Thus, as it relates to insurance coverage for offshore drilling interests, Treasury's interpretation with regard to federally approved insurers does not appear to have caused disruptions in insurance coverage. Treasury did not receive any comments from insurers providing coverage for offshore drilling interests objecting to the treatment of federally approved insurers.

Treasury also received comments regarding the treatment of federally approved insurers under the Department of Labor's authority to authorize workers' compensation coverage under the Longshore and Harbor Worker's Act (33 U.S.C. 901) and its extensions. The Department of Labor authorizes both insurance carriers (20 CFR 703.101) and self-insurers (20 CFR 703.301) for the purpose of meeting the requirements of the Longshore and Harbor Worker's Act. Insurers that are authorized under 20 CFR 703.101 clearly meet the criteria of section 50.5(f)(1)(C) of being ''approved or accepted for the purpose of offering property and casualty insurance by a Federal agency in connection with maritime, energy, or aviation activity.'' In this regard a key element is that such insurers are ''offering'' insurance coverage.

In contrast, the Department of Labor and other Federal agencies may approve self insurance as an acceptable means of meeting the financial requirements or responsibilities of their respective programs. In this regard, self insurance is just another means of establishing financial responsibility and is not a substitute for the requirement that insurance is being ''offered.'' Thus, self insurance arrangements approved by Federal agencies are not included under section 50.5(f)(1)(C). However, Treasury may consider self insurance arrangements for inclusion in the Program through Treasury's general authority to consider such arrangements under section 102(6)(A)(v) of the Act, which is also described in section 50.5(f)(1)(E) of the interim final rule. Treasury has not yet taken any action regarding the inclusion of self insurance arrangements under the Act.

In addition to the general concerns noted above regarding the treatment of federally approved insurers, airline insurance pools and other commenters (*e.g.*, those addressing issues related to nuclear insurers) noted that Federal approval may be for amounts of insurance coverage that is less than what is normally provided by the insurance industry. For example, commenters noted that standard airline liability limits are $1.5 billion, while the Federal Aviation Administration's required liability coverage is much lower. Likewise, commenters noted that policy limits on nuclear property coverage generally exceed the mandated requirements of $1.06 billion per licensee.

After consideration of these comments by the maritime industry and their mutually owned insurance companies and others, Treasury has decided not to make any changes to the interim final rule's treatment of federally approved insurers for the following reasons.

First, the interim final rule's treatment of federally approved insurers is in accord with the statutory language of the Act in section 102(6)(A)(iii) (''approved for the purpose of offering property and casualty insurance by a Federal agency in connection with maritime, energy or aviation activity''). While some commenters pointed to congressional intent supporting a broader interpretation, no express language in the Act's legislative history supports this view. Moreover, Treasury's treatment of federally approved insurers in the interim final rule is consistent with the underlying reason for the Federal government providing Federal agencies with the authority to approve insurers. In general, the Federal government provides agencies with approval authority to address important national interests or to protect the Federal government's interests. For example, the Federal government requires that airlines maintain a minimum amount of liability insurance coverage. In contrast, the Federal government has no similar overall liability requirements for ocean going vessels, but such vessels are required to demonstrate financial responsibility for oil spills. As an example of protecting the Federal government's interest, MARAD approves insurance coverage for vessels that were built with a government subsidy or guarantee. MARAD could have been granted broader insurance approval authority than just federally subsidized vessels if there were a clear national interest in ensuring that all ocean going vessels in U.S. waters had adequate overall liability insurance coverage.

Second, Treasury's treatment of federally approved insurers is consistent with Treasury's consideration of a pre-existing nexus (for example, the nexus of State-licensing or NAIC approval for listing on the Quarterly Listing of Alien Insurers) to be very important to the effective and efficient administration of the Program. Some commenters criticized Treasury for not more fully explaining the importance of this consideration.

The following three key factors highlight the importance of a pre-existing regulatory nexus or structure for the administration of the Program.

Ongoing Data Requirements. As Program administrator, Treasury has chosen not to impose new ongoing data reporting requirements on insurers. That does not mean that validating and collecting certain data is not important to the Program. The calculation of an insurer's DEP forms the basis for an insurer calculating its deductible under the Program, and in the event that insurers would submit a claim for payment under the Program, Treasury would expect to validate an insurer's calculation of its deductible. Treasury believes that the existing ongoing data reporting requirements of the State insurance regulators and the consolidated reporting requirements as implemented by the NAIC form a sound basis for the administration of the Program. Therefore, there was not a pressing need to implement new ongoing data reporting requirements through Treasury (and to create additional paperwork burdens for the insurance industry) for this temporary government Program.

However, such ongoing data is useful and important, especially as it relates to foreign insurers that are providing coverage on global risk policies. Global risk polices (*e.g.*, such as those provided to ocean going vessels) have historically not allocated premium income to reflect the scope of insured losses covered under the Act, which is a key measure in calculating an insurer's deductible. Treasury has determined to utilize data collected by the NAIC from insurers on the Quarterly Listing of Alien Insurers that captures the amount of premium income related to the scope of insured loss under the Act. Federal agencies approving insurers under section 102(6)(A)(iii), while generally having some type of financial criteria for

approving insurers, do not have in place any type of ongoing data reporting requirements similar to that of the NAIC.

Ability to Impose Surcharges or Take Enforcement Actions. Many of the insurers approved by Federal agencies may be outside the direct jurisdiction of the United States. Treasury has little leverage vis a vis these insurers and this could make it difficult for Treasury to impose surcharges in the case of any recoupment under the Act or to take enforcement actions if needed. In contrast, if an insurer on the NAIC's Quarterly Listing of Alien Insurers is not in compliance with provisions of the Act, the insurer could suffer the consequences of losing its NAIC listing for poor character, which in turn could adversely affect its U.S. business operations. It is possible that a Federal agency could also revoke approval for noncompliance with provisions of the Act. However, the limited nature of a Federal agency's approval authority could somewhat lessen the impact of any such action and Treasury has no authority to require such action by another federal agency.

Comparability Among Federally Approved Insurers. Treasury strongly believes that all federally approved insurers should be treated in a similar manner that is consistent with the statute. For example, such consistency implies that the mandatory participation requirements of the Act should be applied to all federally approved insurers in a similar fashion. In that regard, Treasury would find it difficult to justify one group of federally approved insurers having broader access to the Program than the current interim final rule provides, while other groups stayed with the current approach in the interim final rule.

Treasury has considered carefully the concerns raised by commenters regarding the interim final rule's treatment of federally approved insurers. At this time, Treasury has decided that no changes to the rule are warranted. It appears that many of the insurers that have been approved by a Federal agency also qualify to participate in the Program based on other criteria. Treasury also notes that obtaining a listing on the NAIC's Quarterly Listing of Alien Insurers is an option that insurers can employ if they are not satisfied with the treatment of federally approved insurers under the interim final rule. Obtaining such a listing would satisfy the concerns we noted above, while at the same time imposing limited burden on insurers. It is our understanding that perhaps the major obstacle to obtaining a listing is setting up the necessary trust fund.

Treasury will continue to evaluate this issue as the Program matures. While Treasury does not plan on making any changes to the treatment of federally approved insurers at this time, Treasury would be open to considering alternatives if the three key factors listed above '' ongoing data reporting requirements, ability to impose surcharges or take enforcement actions, and comparability among federally approved insurers—could be addressed.

Other Insurer Criteria

Under a separate notice of proposed rulemaking published at 68 FR 9814 Treasury solicited public comment on whether the Secretary should prescribe other criteria for certain insurers pursuant to the authority provided by section 102(6)(C) and, if so, what criteria Treasury should prescribe. Specifically, Treasury solicited comment on whether criteria should be developed to prevent newly formed insurance companies from participating in the Program if such companies were established for the purpose of evading the Act's deductible requirements.

A few commenters raised concerns that developing such criteria could limit the development of new structures to provide terrorism risk insurance coverage. One commenter acknowledged the concerns raised by Treasury and supported the interim final rule's treatment of the deductible requirements for newly formed insurance companies in section 50.5(g)(2) as an appropriate safeguard. Another commenter suggested a set of general criteria that Treasury could look to as it considers this issue. As Treasury noted in the preamble to interim final rule, we are seeking to balance the goals of encouraging new sources of capital in the market for terrorism risk insurance while also maintaining the integrity of the Program. Treasury is not proposing any additional criteria at this time, but we will continue to monitor developments in the market for terrorism risk insurance and the market's response to the Act.

Treasury also solicited comments on whether additional criteria should be proposed for federally approved insurers. Some commenters suggested that additional financial criteria could be applied if necessary, while one commenter suggested that the Act does not give Treasury the authority to regulate insurance. Given that the final rule retains the interim final rule's treatment of federally approved insurers, the scope of potential problems related to the financial integrity of such insurers is somewhat limited. Thus, Treasury is not proposing any additional criteria at this time, but we will continue to study and monitor this issue.

F. Insurer Deductible (Section 50.5.g)

The interim final rule incorporated the statutory definition of ''insurer deductible'' found in section 102(7) of the Act and set forth a procedure specifying how newly formed insurance companies would calculate their deductible under the Program. In particular, the interim final rule specified that for an insurer that came into existence after November 26, 2002, the insurer deductible will be based on data for direct earned premiums for the current Program Year. If the insurer has not had a full year of operations during the applicable Program Year, the direct earned premiums for the current Program Year will be annualized to determine the insurer deductible.

The two commenters who addressed this issue both indicated support for Treasury's determination that premiums for new insurers would be annualized in the calculation of their insurer deductible, and the language of the interim final rule is incorporated without change into the final rule.

III. Procedural Requirements

The Act established a Program to provide for loss sharing payments by the Federal Government for insured losses resulting from certified acts of terrorism. The Act became effective immediately upon the date of enactment (November 26, 2002). Preemptions of terrorism risk exclusions in policies, mandatory participation provisions, disclosure and other requirements and conditions for federal payment contained in the Act applied immediately to those entities that come within the Act's definition of ''insurer.'' Treasury has issued and will be issuing additional regulations to implement the Program. This final rule provides critical information concerning the definitions of Program terms that lays the groundwork for Treasury's implementation of the Program. No one can predict if, or when, an act of terrorism may occur. There is an urgent need for Treasury, as Program administrator, to lay the groundwork for Program implementation through regulations to provide clarity and certainty concerning which entities are required to participate in the Program; the scope and conditions of Program coverage; and other implementation issues that immediately affect insurers, their policyholders, State regulators and other interested parties. This includes the need to supplement, or modify as

necessary, the previously issued interim final rule.

Accordingly, pursuant to 5 U.S.C. 553(d)(3), Treasury has determined that there is good cause for the final rule to become effective immediately upon publication.

This final rule is a significant regulatory action and has been reviewed by the Office of Management and Budget under the terms of Executive Order 12866.

It is hereby certified that this final rule will not have a significant economic impact on a substantial number of small entities. The Act requires all licensed or admitted insurers to participate in the Program. This includes all insurers regardless of size or sophistication. The Act also defines property and casualty insurance to mean commercial lines without any reference to the size or scope of the commercial entity. Although the Act affects small insurers, the proposed rule also gives insurers flexibility in calculating their direct earned premium for policies that have both commercial and personal exposures, and it provides a safe harbor to exclude policies that have incidental coverage for commercial purposes. Accordingly, any economic impact associated with the proposed rule flows from the Act and not the proposed rule. However, the Act and the Program are intended to provide benefits to the U. S. economy and all businesses, including small businesses, by providing a federal reinsurance backstop to commercial property and casualty insurance policyholders and spreading the risk of insured loss resulting from an act of terrorism.

The collection of information contained in § 50.8 of this final rule has been reviewed and approved by the Office of Management and Budget (OMB) in accordance with the requirements of the Paperwork Reduction Act (44 U.S.C. 3507(j)) under control number 1505–0190. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid control number assigned by OMB.

This information is required in order for Treasury to determine whether an insurer has rebutted a presumption that the insurer exercises a controlling influence over the management or policies of another insurer. The collection of information is mandatory with respect to an insurer seeking to rebut a presumption. The estimated average burden associated with the collection of information in this final rule is 40 hours per respondent.

Comments concerning the accuracy of this burden estimate and suggestions for reducing this burden should be directed to the Office of Financial Institutions Policy, Room 3160 Annex, Department of the Treasury, 1500 Pennsylvania Ave., NW., Washington, DC 20220 and to OMB, Attention: Desk Officer for the Department of the Treasury, Office of Information and Regulatory Affairs, Washington, DC 20503.

List of Subjects in 31 CFR Part 50

Terrorism risk insurance.

Authority and Issuance

■ For the reasons set forth above, the interim final rule adding 31 CFR Part 50, which was published at 68 FR 9804 on February 28, 2003, is adopted as a final rule with the following changes:

PART 50—TERRORISM RISK INSURANCE PROGRAM

■ 1. The authority citation for 31 CFR Part 50 continues to read as follows:

Authority: 5 U.S.C. 301; 31 U.S.C. 321; Title I, Pub. L. 107–297, 116 Stat. 2322 (15 U.S.C. 6701 note).

■ 2. Section 50.2 is added to read as follows:

§ 50.2 Responsible office.

The office responsible for the administration of the Terrorism Risk Insurance Act in the Department of the Treasury is the Terrorism Risk Insurance Program Office. The Treasury Assistant Secretary for Financial Institutions prescribes the regulations under the Act.

■ 3. Section 50.5(c), (d)(1), (f)(1), and (l) are revised to read as follows:

§ 50.5 Definitions.

* * * * *

(c)(1) *Affiliate* means, with respect to an insurer, any entity that controls, is controlled by, or is under common control with the insurer. An affiliate must itself meet the definition of insurer to participate in the Program.

(2) For purposes of paragraph (c)(1) of this section, an insurer has control over another insurer for purposes of the Program if:

(i) The insurer directly or indirectly or acting through one or more other persons owns, controls, or has power to vote 25 percent or more of any class of voting securities of the other insurer;

(ii) The insurer controls in any manner the election of a majority of the directors or trustees of the other insurer; or

(iii) The Secretary determines, after notice and opportunity for hearing, that an insurer directly or indirectly exercises a controlling influence over the management or policies of the other insurer, even if there is no control as defined in paragraph (c)(2)(i) or (c)(2)(ii) of this section.

(3) An insurer described in paragraph (c)(2)(i) or (c)(2)(ii) of this section is conclusively deemed to have control.

(4) For purposes of a determination of controlling influence under paragraph (c)(2)(iii) of this section, if an insurer is not described in paragraph (c)(2)(i) or (c)(2)(ii) of this section, the following rebuttable presumptions will apply:

(i) If an insurer controls another insurer under any State law, and at least one of the factors listed in paragraph (c)(4)(iv) of this section applies, there is a rebuttable presumption that the insurer that has control under State law exercises a controlling influence over the management or policies of the other insurer for purposes of paragraph (c)(2)(iii) of this section.

(ii) If an insurer provides 25 percent or more of another insurer's capital (in the case of a stock insurer), policyholder surplus (in the case of a mutual insurer), or corporate capital (in the case of other entities that qualify as insurers), and at least one of the factors listed in paragraph (c)(4)(iv) of this section applies, there is a rebuttable presumption that the insurer providing such capital, policyholder surplus, or corporate capital exercises a controlling influence over the management or policies of the receiving insurer for purposes of paragraph (c)(2)(iii) of this section.

(iii) If an insurer, at any time during a Program Year, supplies 25 percent or more of the underwriting capacity for that year to an insurer that is a syndicate consisting of a group including incorporated and individual unincorporated underwriters, and at least one of the factors in paragraph (c)(4)(iv) of this section applies, there is a rebuttable presumption that the insurer exercises a controlling influence over the syndicate for purposes of paragraph (c)(2)(iii) of this section.

(iv) If paragraphs (c)(4)(i) through (c)(4)(iii) of this section are not applicable, but two or more of the following factors apply to an insurer, with respect to another insurer, there is a rebuttable presumption that the insurer exercises a controlling influence over the management or policies of the other insurer for purposes of paragraph (c)(2)(iii) of this section:

(A) The insurer is one of the two largest shareholders of any class of voting stock;

(B) The insurer holds more than 35 percent of the combined debt securities and equity of the other insurer;

(C) The insurer is party to an agreement pursuant to which the insurer possesses a material economic stake in the other insurer resulting from a profit-sharing arrangement, use of common names, facilities or personnel, or the provision of essential services to the other insurer;

(D) The insurer is party to an agreement that enables the insurer to influence a material aspect of the management or policies of the other insurer;

(E) The insurer would have the ability, other than through the holding of revocable proxies, to direct the votes of more than 25 percent of the other insurer's voting stock in the future upon the occurrence of an event;

(F) The insurer has the power to direct the disposition of more than 25 percent of a class of voting stock of the other insurer in a manner other than a widely dispersed or public offering;

(G) The insurer and/or the insurer's representative or nominee constitute more than one member of the other insurer's board of directors; or

(H) The insurer or its nominee or an officer of the insurer serves as the chairman of the board, chairman of the executive committee, chief executive officer, chief operating officer, chief financial officer or in any position with similar policymaking authority in the other insurer.

(5) An insurer that is not described in paragraph (c)(2)(i) or (c)(2)(ii) of this section may request a hearing in which the insurer may rebut a presumption of controlling influence under paragraph (c)(4)(i) through (c)(4)(iv) of this section or otherwise request a determination of controlling influence by presenting and supporting its position through written submissions to Treasury, and in Treasury's discretion, through informal oral presentations, in accordance with the procedure in § 50.8.

(d) * * *

(l) *State licensed or admitted insurers.* For a State licensed or admitted insurer that reports to the NAIC, direct earned premium is the premium information for commercial property and casualty insurance coverage reported by the insurer on column 2 of the NAIC Exhibit of Premiums and Losses of the Annual Statement (commonly known as Statutory Page 14). (See definition of property and casualty insurance).

(i) Premium information as reported to the NAIC should be included in the calculation of direct earned premiums for purposes of the Program only to the extent of commercial property and casualty coverage issued by the insurer against an insured loss under the Program.

(ii) Premiums for personal property and casualty insurance coverage (coverage primarily designed to cover personal, family or household risk exposures, with the exception of coverage written to insure 1 to 4 family rental dwellings owned for the business purpose of generating income for the property owner) or for insurance coverage for any loss that would not be an insured loss under the Program, should be excluded in the calculation of direct earned premiums for purposes of the Program.

(iii) Personal property and casualty insurance coverage that includes incidental coverage for commercial purposes is primarily personal coverage, and therefore premiums may be fully excluded by an insurer from the calculation of direct earned premium. For purposes of the Program, commercial coverage is incidental if less than 25 percent of the total direct earned premium is attributable to commercial coverage. Property and casualty insurance coverage for any loss that would not be an insured loss under the Program that includes incidental coverage for an insured loss under the Program is primarily non-Program coverage, and therefore premiums may be fully excluded by an insurer from the calculation of direct earned premium. For purposes of the Program, coverage for an insured loss is incidental if less than 25 percent of the total direct earned premium is attributable to such coverage.

(iv) If a property and casualty insurance policy covers both commercial and personal risk exposures, insurers may allocate the premiums in accordance with the proportion of risk between commercial and personal components in order to ascertain direct earned premium. If a property and casualty insurance policy covers risk exposures for both insured losses and losses that would not be insured losses under the Program, insurers may allocate the premiums in accordance with the proportion of risk between the insured loss and non-insured loss components in order to ascertain direct earned premium.

* * * * *

(f) *Insurer* means any entity, including any affiliate of the entity, that meets the following requirements:

(1)(i) The entity must fall within at least one of the following categories:

(A) It is licensed or admitted to engage in the business of providing primary or excess insurance in any State, (including, but not limited to, State licensed captive insurance companies, State licensed or admitted risk retention groups, and State licensed or admitted farm and county mutuals), and, if a joint underwriting association, pooling arrangement, or other similar entity, then the entity must:

(1) Have gone through a process of being licensed or admitted to engage in the business of providing primary or excess insurance that is administered by the State's insurance regulator, which process generally applies to insurance companies or is similar in scope and content to the process applicable to insurance companies;

(2) Be generally subject to State insurance regulation, including financial reporting requirements, applicable to insurance companies within the State; and

(3) Be managed independently from other insurers participating in the Program;

(B) It is not licensed or admitted to engage in the business of providing primary or excess insurance in any State, but is an eligible surplus line carrier listed on the Quarterly Listing of Alien Insurers of the NAIC, or any successor to the NAIC;

(C) It is approved or accepted for the purpose of offering property and casualty insurance by a Federal agency in connection with maritime, energy, or aviation activity, but only to the extent of such federal approval of commercial property and casualty insurance coverage offered by the insurer in connection with maritime, energy, or aviation activity;

(D) It is a State residual market insurance entity or State workers' compensation fund; or

(E) As determined by the Secretary, it falls within any other class or type of captive insurer or other self-insurance arrangement by a municipality or other entity, to the extent provided in Treasury regulations issued under section 103(f) of the Act.

(ii) If an entity falls within more than one category described in paragraph (f)(1)(i) of this section, the entity is considered to fall within the first category within which it falls for purposes of the Program.

* * * * *

(l) *Property and casualty insurance* means commercial lines of property and casualty insurance, including excess insurance, workers' compensation insurance, and surety insurance, and

(1) Means commercial lines within only the following lines of insurance from the NAIC's Exhibit of Premiums and Losses (commonly known as Statutory Page 14): Line 1—Fire; Line 2.1—Allied Lines; Line 3—Farmowners Multiple Peril; Line 5.1—Commercial

Multiple Peril (non-liability portion); Line 5.2—Commercial Multiple Peril (liability portion); Line 8—Ocean Marine; Line 9—Inland Marine; Line 16—Workers' Compensation; Line 17—Other Liability; Line 18—Products Liability; Line 19.3—Commercial Auto No-Fault (personal injury protection); Line 19.4—Other Commercial Auto Liability; Line 21.2—Commercial Auto Physical Damage; Line 22—Aircraft (all perils); Line 24—Surety; Line 26—Burglary and Theft; and Line 27—Boiler and Machinery; and

(2) Does not include:

(i) Federal crop insurance issued or reinsured under the Federal Crop Insurance Act (7 U.S.C. 1501 *et seq.*), or any other type of crop or livestock insurance that is privately issued or reinsured (including crop insurance reported under either Line 2.1—Allied Lines or Line 2.2—Multiple Peril (Crop) of the NAIC's Exhibit of Premiums and Losses (commonly known as Statutory Page 14);

(ii) Private mortgage insurance (as defined in section 2 of the Homeowners Protection Act of 1988 (12 U.S.C. 4901) or title insurance;

(iii) Financial guaranty insurance issued by monoline financial guaranty insurance corporations;

(iv) Insurance for medical malpractice;

(v) Health or life insurance, including group life insurance;

(vi) Flood insurance provided under the National Flood Insurance Act of 1968 (42 U.S.C. 4001 *et seq.*) or earthquake insurance reported under Line 12 of the NAIC's Exhibit of Premiums and Losses (commonly known as Statutory Page 14); or

(vii) Reinsurance or retrocessional reinsurance.

* * * * *

■ 4. Section 50.8 is added to Subpart A to read as follows:

§ 50.8 Procedure for requesting determinations of controlling influence.

(a) An insurer or insurers not having control over another insurer under § 50.5(c)(2)(i) or (c)(2)(ii) may make a written submission to Treasury to rebut a presumption of controlling influence under § 50.5(c)(4)(i) through (iv) or otherwise to request a determination of controlling influence. Such submissions shall be made to the Terrorism Risk Insurance Program Office, Department of the Treasury, Suite 2110, 1425 New York Ave NW, Washington, D.C. 20220. The submission should be entitled, ''Controlling Influence Submission,'' and should provide the full name and address of the submitting insurer(s) and the name, title, address and telephone number of the designated contact person(s) for such insurer(s).

(b) Treasury will review submissions and determine whether Treasury needs additional written or orally presented information. In its discretion, Treasury may schedule a date, time and place for an oral presentation by the insurer(s).

(c) An insurer or insurers must provide all relevant facts and circumstances concerning the relationship(s) between or among the affected insurers and the control factors in § 50.5(c)(4)(i) through (iv); and must explain in detail any basis for why the insurer believes that no controlling influence exists (if a presumption is being rebutted) in light of the particular facts and circumstances, as well as the Act's language, structure and purpose. Any confidential business or trade secret information submitted to Treasury should be clearly marked. Treasury will handle any subsequent request for information designated by an insurer as confidential business or trade secret information in accordance with Treasury's Freedom of Information Act regulations at 31 C.F.R. Part 1.

(d) Treasury will review and consider the insurer submission and other relevant facts and circumstances. Unless otherwise extended by Treasury, within 60 days after receipt of a complete submission, including any additional information requested by Treasury, and including any oral presentation, Treasury will issue a final determination of whether one insurer has a controlling influence over another insurer for purposes of the Program. The determination shall set forth Treasury's basis for its determination.

(e) This § 50.8 supersedes the Interim Guidance issued by Treasury in a notice published on March 27, 2003 (68 FR 15039).

(Approved by the Office of Management & Budget under control number 1505–0190)

■ 5. Section 50.9 is added to Subpart A to read as follows:

§ 50.9 Procedure for requesting general interpretations of statute.

Persons actually or potentially affected by the Act or regulations in this Part may request an interpretation of the Act or regulations by writing to the Terrorism Risk Insurance Program Office, Suite 2110, Department of the Treasury, 1425 New York Ave NW, Washington, DC 20220, giving a detailed explanation of the facts and circumstances and the reason why an interpretation is needed. A requester should segregate and mark any confidential business or trade secret information clearly. Treasury in its discretion will provide written responses to requests for interpretation. Treasury reserves the right to decline to provide a response in any case. Except in the case of any confidential business or trade secret information, Treasury will make written requests for interpretations and responses publicly available at the Treasury Department Library, on the Treasury Web site, or through other means as soon as practicable after the response has been provided. Treasury will handle any subsequent request for information that had been designated by a requester as confidential business or trade secret information in accordance with Treasury's Freedom of Information Act regulations at 31 CFR Part 1.

Dated: July 7, 2003.

Wayne A. Abernathy,

Assistant Secretary of the Treasury.

[FR Doc. 03–17585 Filed 7–10–03; 8:45 am]

BILLING CODE 4810–25–P

DEPARTMENT OF THE TREASURY

Fiscal Service

Bureau of the Public Debt

31 CFR Part 348

Regulations Governing Depositary Compensation Securities

AGENCY: Bureau of the Public Debt, Fiscal Service, Treasury.

ACTION: Final rule.

SUMMARY: The Bureau of the Public Debt (Public Debt) is issuing regulations governing Depositary Compensation Securities that will be used to compensate financial agents for work performed on behalf of the Department of the Treasury.

EFFECTIVE DATE: July 11, 2003.

ADDRESSES: You can download this final rule at the following World Wide Web address: *http://www.publicdebt.treas.gov*. You may also inspect and copy this rule at: Treasury Department Library, Room 1428, Main Treasury Building, 1500 Pennsylvania Ave., NW., Washington, DC 20220. Before visiting the library, you must call (202) 622–0990 for an appointment.

FOR FURTHER INFORMATION CONTACT: For information contact Ann Fowler in the Office of the Chief Counsel, Bureau of the Public Debt, at 304–480–8692, or at *CHCOUNSEL@bpd.treas.gov*.

SUPPLEMENTARY INFORMATION: The former 31 CFR part 348 is being reinstituted and revised to provide for

the issuance of Depositary Compensation Securities in book-entry form, and for their automatic reinvestment at maturity.

These special issue securities, formerly known as 2-Percent Depositary Bonds, were first offered in 1941 as a means to compensate depositaries and financial agents of the Government for essential banking services provided in support of the day-to-day operations of the Government, including the collection and deposit of all Treasury receipts. The securities were phased out when other methods of compensation were used. Hence, the offering was terminated in 1994.

The former 31 CFR part 348 is now being reinstituted and revised because we have determined that the use of Depositary Compensation Securities to compensate financial agents is in the public interest.

Financial agents will purchase Depositary Compensation Securities with funds placed by the United States Treasury in a non-interest bearing time balance account at the financial agent equal to the principal amount of the security. The interest earned from Depositary Compensation Securities will serve to compensate financial agents for services performed on behalf of the Treasury. Some financial agents have inquired regarding the proper accounting of this transaction and the potential impact on their balance sheet. The transaction, as more fully described in agreements between Treasury and its Financial Agents, is structured so that the principal amount of the security and the time balance will be set-off at maturity consistent with the criteria described in Financial Accounting Standards Board (FASB) Interpretation No. 39. Financial agents should consult with their auditors regarding the applicability of FASB Interpretation 39 to this transaction.

Procedural Requirements

This final rule does not meet the criteria for a ''significant regulatory action'' as defined in Executive Order 12866. Therefore, the regulatory review procedures contained therein do not apply.

This final rule relates to matters of public contract and procedures for United States securities. The notice and public procedures requirements and delayed effective date requirements of the Administrative Procedure Act are inapplicable, pursuant to 5 U.S.C. 553(a)(2).

As no notice of proposed rulemaking is required, the Regulatory Flexibility Act (5 U.S.C. 601, *et seq.*) does not apply. We ask for no new collections of information in this final rule. Therefore, the Paperwork Reduction Act (44 U.S.C. 3507) does not apply.

List of Subjects in 31 CFR Part 348

Banks, Banking, Electronic funds transfer, Government securities.

■ Accordingly, for the reasons set out in the preamble, 31 CFR Chapter II, Subchapter B, is amended by adding Part 348 to read as follows:

PART 348—REGULATIONS GOVERNING DEPOSITARY COMPENSATION SECURITIES

Sec.

348.0 Offering of securities.
348.1 Description of securities.
348.2 Redemption/call/reinvestment.
348.3 Reservations.

Authority: 31 U.S.C. 3121; 5 U.S.C. 301.

§ 348.0 Offering of securities.

The Secretary of the Treasury (the Secretary) under authority of Title 31, Chapter 31, offers, at par, Depositary Compensation Securities (securities) to financial agents of the Department of the Treasury. The securities are offered to financial agents of the Department of the Treasury designated under federal law (including, but not limited to: 12 U.S.C. 90, 265–266, 1464(k), and 1789a; 31 U.S.C. 3303) which have executed a Depositary, Financial Agency, and Collateral Agreement satisfactory to the Secretary, and are authorized to provide essential banking services to the Department of the Treasury. The securities will be issued in an amount not to exceed, in any case, the amount for which the financial agents are authorized. The securities are non-marketable Treasury securities that will be utilized to compensate financial agents, in whole or in part, for services performed on behalf of the Department of the Treasury. The financial agents will be compensated from the interest earned on the securities. This offering will continue until terminated by the Secretary. The Fiscal Assistant Secretary is authorized to act on behalf of the Secretary upon all matters contained in these regulations.

§ 348.1 Description of securities.

(a) *General.* The securities will be issued in book-entry form on the books of the Department of the Treasury, Bureau of the Public Debt, Parkersburg, WV.

(b) *Terms and rate of interest.* The securities will be issued as notes or bonds, depending on their maturity, under such terms and at such rates as determined and announced by the Secretary. The Secretary will set a given rate of interest that will apply to all securities issued while the rate is in effect. The interest will be payable on a monthly basis. The securities will be issued in a minimum of $1,000 each.

(c) *Nontransferability.* The securities are not transferable, but they will be acceptable to secure compensating balances with financial agents (as described in § 348.0) and may not be used for any other purpose.

§ 348.2 Redemption/call/reinvestment.

(a) *Redemption by financial agents.* The securities may be redeemed prior to maturity by financial agents only under such terms and conditions as set forth in agreements between the financial agents and the Department of the Treasury, Financial Management Service, Washington, DC.

(b) *Call by the Treasury.* The securities are subject to call before maturity. The Secretary will announce such call by any means the Secretary deems appropriate.

(c) *Reinvestment at maturity.* The securities shall be automatically redeemed at maturity and the principal amount reinvested in new securities having the same description in all material respects as the ones redeemed, except that the Secretary shall have the authority to modify the rate of interest for the re-issued securities. The securities shall be automatically redeemed and re-invested unless the agent certifies in writing, to the Treasury, Financial Management Service, Washington, DC, that it declines automatic reinvestment within seven calendar days prior to maturity date.

§ 348.3 Reservations.

The Secretary reserves the right to reject any application for the purchase of securities hereunder, in whole or in part, and to refuse to issue or permit to be issued any such securities in any case if the Secretary deems such action to be in the public interest, and the Secretary's action in any such respect shall be final. The Secretary may also at any time, supplement or amend the terms of these regulations, or of any amendments or supplements thereto.

Dated: July 7, 2003.

Donald V. Hammond,

Fiscal Assistant Secretary.

[FR Doc. 03–17531 Filed 7–10–03; 8:45 am]

BILLING CODE 4810–39–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[CGD09–03–206]

RIN 1625–AA00
RIN 1625–AA11

Regulated Navigation Area and Safety Zone; Huntington Cleveland Harborfest and Parade of Sail, Cleveland, OH, July 9–14, 2003

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary Regulated Navigation Area (RNA) during the Huntington Cleveland Harborfest and a moving safety zone during the Parade of Sail in the Port of Cleveland, Ohio. These regulations are necessary to manage vessel traffic and ensure the safety of both spectators and participant vessels. These regulations are intended to restrict vessel traffic from a portion of Lake Erie in the vicinity of Cleveland Harbor.

DATES: This rule is effective from 12 p.m. on Wednesday, July 9, 2003 through 1 p.m. on Monday, July 14, 2003.

ADDRESSES: Documents indicated in this preamble as being available in the docket are part of docket (CGD09–03–206) and are available for inspection or copying at U.S. Coast Guard Marine Safety Office (MSO) Cleveland between 8 a.m. and 3:30 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Lieutenant Allen Turner, Chief Port Operations Department, Coast Guard MSO Cleveland (216) 937–0128.

SUPPLEMENTARY INFORMATION:

Regulatory Information

On Wednesday, April 16, 2003, the Coast Guard published a notice of proposed rulemaking (NPRM) entitled Regulated Navigation Area and Safety Zone; Huntington Cleveland Harborfest and Parade of Sail, Cleveland Harbor, Cleveland, OH in the **Federal Register** (68 FR 18579). We received no letters commenting on the proposed rule. No public hearing was requested, and none was held.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. Delaying the effective date of this rule would be contrary to the public interest of ensuring the safety of spectators and vessels during this event and immediate action is necessary to prevent possible loss of life or property. The Coast Guard has not received any complaints or negative comments with regard to this event.

Background and Purpose

During Huntington Cleveland Harborfest, tall ships will moor in Cleveland Harbor at the Cleveland Port Authority and along Cleveland's Inner Harbor. A Regulated Navigation Area (RNA) will be established inside Cleveland's break wall to protect tall ships and spectators from other vessels passing at excessive speed and creating large wakes. The RNA will also aid in preventing obstructed waterways.

A moving Safety Zone will be established around the Parade of Sail during the transit through Cleveland Harbor and Lake Erie. Vessel congestion is expected, and the Safety Zone will ensure that spectator craft do not impede the path of the parade vessels.

Discussion of Rule

The RNA will be established from 12 p.m. (noon) on Wednesday, July 9, 2003 until 1 p.m. on Monday, July 14, 2003. The RNA will encompass Cleveland Harbor, between Dock 28 of Cleveland Port Authority and the western edge of Burke Lake Front Airport, and include the Inner Harbor. No vessel shall exceed 5 mph nor produce a wake within the RNA. Any vessel within the RNA shall not pass within 20 feet of a moored tall ship. Any vessel within the RNA must adhere to the direction of the Patrol Commander or other official patrol craft.

On July 9, 2003, from 2 p.m. until the conclusion of the Parade of Sail, the moving Safety Zone will be established around and between all tall ships participating in the parade. The Safety Zone will extend 100 yards ahead of the first vessel in the parade, 50 yards abeam each vessel and the line formed by the parade, and 50 yards astern of the last vessel in the parade. The parade will begin approximately 2 miles northwest of Cleveland Harbor inlet and pass through Cleveland Harbor via the main entrance channel. The parade will travel east through the harbor inside the eastern end of the break wall and exit through the eastern inlet. The parade will turn around in Lake Erie east of the harbor, and then reenter the harbor through the eastern inlet of the break wall south of the original track. The parade will terminate once the vessels are moored. The Safety Zone will be in effect until the last vessel moors at approximately 6 p.m.

Regulatory Evaluation

This rule is not ''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 the Order. The Office of Management and Budget has not reviewed it under that Order. It is not significant under the regulatory policies and procedures of the Department of Homeland Security.

We expect the economic impact of this temporary final rule to be so minimal that a full Regulatory Evaluation under the regulatory policies and procedures of DHS is unnecessary.

This determination is based on the short amount of time that vessels will be restricted from the zones, and the actual location of the safety zones within the waterways.

Small Entities

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

The Coast Guard certifies under 5 U.S.C. 605(b) that this rule would not have a significant economic impact on a substantial number of small entities. If you think that your business, organization, or governmental jurisdiction qualifies as a small entity and that this rule would have a significant economic impact on it, please submit a comment (see **ADDRESSES**) explaining why you think it qualifies and how and to what degree this rule would economically affect it.

Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this rule so that they can better evaluate its effects and participate in the rulemaking process. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact Marine Safety Office Cleveland (see **ADDRESSES.**)

Collection of Information

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

Federalism

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

Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000 or more in any one year. Though this rule would not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

Taking of Private Property

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

Civil Justice Reform

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

Protection of Children

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

Indian Tribal Governments

This rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it would not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

Energy Effects

The Coast Guard has analyzed this rule under Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use. We have determined that it is not a ''significant energy action'' under that Order because it is not a ''significant regulatory action'' under Executive Order 12866 and is not likely to have a significant adverse effect on the supply, distribution, or use of energy. It has not been designated by the Administrator of the Office of Information and Regulatory Affairs as a significant energy action. Therefore, it does not require a Statement of Energy Effects under Executive Order 13211.

Environment

We have considered the environmental impact of this rule and concluded that, under figure 2–1, paragraph 32(g) of Commandant Instruction M16475.1C, this rule is categorically excluded from further environmental documentation. A written categorical exclusion determination is available in the docket for inspection or copying where indicated under **ADDRESSES.**

List of Subjects in 33 CFR Part 165

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

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

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

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

Authority: 33 U.S.C. 1226, 1231; 46 U.S.C. chapter 701; 50 U.S.C. 191, 195; 33 CFR 1.05–1(g), 6.04–1, 6.04–6, and 160.5; Pub. L. 107–295, 116 Stat. 2064; Department of Homeland Security Delegation No. 0170.1.

■ 2. From 12 p.m. on July 9, 2003 through 1 p.m. on July 14, 2003 add temporary § 165.T09–206 to read as follows:

§ 165.T09–206 Regulated Navigation Area: Huntington Cleveland Harborfest, Cleveland, Ohio.

(a) *Regulated navigation area.*—(1) *Location.* All waters of Cleveland Harbor, including the Inner Harbor, encompassed by a line starting at 41°30′49.38″ N, 081°41′37.2″ W (northwest corner of Burke Lakefront Airport); then northwest to 41°31′1.2″ N, 081°41′49.2″ W; then southwesterly following the breakwall to 41°30′41.4″ N, 081°42′25.2″ W; then southeasterly to 41°30′27″ N, 081°42′13.3″ W (extending directly across the harbor from the northwestern corner of Dock 28 of the Cleveland Port Authority to the breakwall); then following the contours of the waterfront back to the point of origin including all portions of the Rock and Roll Museum inner harbor. These coordinates are based upon North American Datum 1983 (NAD 83).

(2) *Enforcement period.* This section is effective from 12 p.m. (noon) on Wednesday, July 9, 2003 through 1 p.m. on Monday, July 14, 2003. Paragraph (a) of this section will be enforced during this same period.

(3) *Special regulations.* Vessels within the Regulated Navigation Area (RNA) shall not exceed 5 miles per hour or shall proceed at no-wake speed, which ever is slower. Vessels within the RNA shall not pass within 20 feet of a moored tall ship. Vessels within the RNA must adhere to the direction of the Patrol Commander or other official patrol craft.

(b) *Safety zone*—(1) *Location.* The following is a moving safety zone: All navigable waters and adjacent shoreline 100 yards ahead of the first official parade vessel, 50 yards abeam of each parade vessel, and 50 yards astern of the last vessel in the parade between the muster point at 41°31′30″ N, 081°45′00″ W until each official parade vessel is moored. All coordinates are NAD 83.

(2) *Enforcement period.* This rule is effective from 12 p.m. on Wednesday, July 9, 2003 through 1 p.m. on Monday, July 14, 2003. Paragraph (b) of this section enforced from 2 p.m. through 8 p.m., or until the conclusion of the parade when the last tall ship has moored, whichever is later, on Wednesday, July 9, 2003.

(3) *Regulations.* All vessel operators shall comply with the instructions of the U.S. Coast Guard Captain of the Port Cleveland, Ohio, or his on scene representative, the Patrol Commander. Permission to deviate from the above rules must be obtained from the Captain of the Port or the Patrol Commander via VHF/FM radio, Channel 6 or by telephone at (216) 937–0111.

Dated: July 1, 2003.

Ronald F. Silva,

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

[FR Doc. 03–17598 Filed 7–10–03; 8:45 am]

BILLING CODE 4910–15–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[CGD09–03–222]

RIN 1625–AA00

Safety Zone; Lake Michigan, Chicago, IL

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety encompassing a portion of Lake Michigan, Chicago, IL. This safety zone is necessary to protect vessels and spectators from potential airborne hazards during a planned fireworks display over a portion of Lake Michigan. The safety zone is intended to restrict vessel traffic from a portion of Lake Michigan, Chicago, Illinois.

DATES: This temporary final rule is effective from 11 p.m. (local), July 14, 2003 until 1 a.m. on July 15, 2003.

ADDRESSES: Documents indicated in this preamble as being available in the docket are part of docket CDG09–03–222 and are available for inspection or copying at U.S. Coast Guard Marine Safety Office Chicago, 215 W. 83rd Street, Suite D, Burr Ridge, IL 60527, between 7:30 a.m. and 4 p.m. Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: MST2 Kenneth Brockhouse, U. S. Coast Guard Marine Safety Office Chicago, at (630) 986–2125.

SUPPLEMENTARY INFORMATION:

Regulatory Information

We did not publish a notice of proposed rulemaking (NPRM) for this regulation. Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing an NPRM. The permit application was not received in time to publish an NPRM followed by a final rule before the effective date. Delaying this rule would be contrary to the public interest of ensuring the safety of spectators and vessels during this event and immediate action is necessary to prevent possible loss of life or property. The Coast Guard has not received any complaints or negative comments previously with regard to this event.

For the same reasons, under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. The Coast Guard will issue a broadcast notice to mariners and may place Coast Guard vessels in the vicinity of this zone to advise mariners of the restriction.

Background and Purpose

A temporary safety zone is necessary to ensure the safety of vessels and spectators from the hazards associated with fireworks display. Based on recent accidents that have occurred in other Captain of the Port zones, and the explosive hazard of fireworks, the Captain of the Port Chicago has determined fireworks launches in close proximity to watercraft pose significant risks to public safety and property. The likely combination of large numbers of recreational vessels, congested waterways, darkness punctuated by bright flashes of light, alcohol use, and debris falling into the water could easily result in serious injuries or fatalities. Establishing a safety zone to control vessel movement around the location of the launch platform will help ensure the safety of persons and property at these events and help minimize the associated risks.

Discussion of Rule

The safety zone will encompass all waters of Lake Michigan bounded by the arc of a circle with a 700 foot radius with its center in approximate position 41°52′15″ N; 087°36′44″ W. These coordinates are based upon North American Datum 1983 (NAD 83). All vessels except those officially participating in this event are prohibited from entering the safety zone without the permission of the Captain of the Port Chicago or his on-scene representative. The on-scene representative will be the Patrol Commander, and may be contacted via VHF Channel 16.

Regulatory Evaluation

This rule is not a ''significant regulatory action'' under section 3(f) of Executive Order 12866 and does not require an assessment of potential costs and benefits under section 6(a)(3) of that Order. The Office of Management and Budget has not reviewed this rule under that Order. It is not significant under the regulatory policies and procedures of the Department of Homeland Security (DHS).

We expect the economic impact of this proposed rule to be so minimal that a full Regulatory Evaluation under paragraph 10(e) of the regulatory policies and procedures of DOT is unnecessary.

This determination is based on the minimal time that vessels will be restricted from the zone and the zone is in an area where the Coast Guard expects insignificant adverse impact to mariners from the zones' activation.

Small Entities

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

The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities.

This rule will affect the following entities, some of which might be small entities: The owners or operators of commercial vessels intending to transit a portion of an activated safety zone.

This safety zone will not have a significant economic impact on a substantial number of small entities for the following reasons: The zone is only in effect for two hours on the day of the event. The designated area is being established to allow for maximum use of the waterway for commercial vessels to enjoy the fireworks display in a safe manner. In addition, commercial vessels transiting the area can transit around the area. The Coast Guard will give notice to the public via a Broadcast to Mariners that the regulation is in effect.

Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this rule so that they can better evaluate its effects and participate in the rulemaking process. If the rule will affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact Marine Safety Office Chicago (*see* **ADDRESSES**.)

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247).

Collection of Information

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

Federalism

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

Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) governs

the issuance of Federal regulations that requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000 or more in any one year. Though this rule would not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

Taking of Private Property

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

Civil Justice Reform

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

Protection of Children

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

Environment

We have considered the environmental impact of this rule and concluded that, under figure 2–1, paragraph 32(g) of Commandant Instruction Manual M16475.1D, this rule is categorically excluded from further environmental documentation. A ''Categorical Exclusion Determination'' is available in the docket for inspection or copying where indicated under **ADDRESSES**.

Energy Effects

We have analyzed this rule under Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use. We have determined that it is not a ''significant energy action'' under that Order because it is not a ''significant regulatory action'' under Executive Order 12866 and is not likely to have a significant adverse effect on the supply, distribution, or use of energy. It has not been designated by the Administrator of the Office of Information and Regulatory Affairs as a significant energy action. Therefore, it does not require a Statement of Energy Effects under Executive Order 13211.

Indian Tribal Governments

This rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

List of Subjects in 33 CFR Part 165

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

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

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

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

Authority: 33 U.S.C. 1226, 1231; 46 U.S.C. Chapter 701; 50 U.S.C. 191, 195; 33 CFR 1.05–1(g), 6.04–1, 6.04–6 and 160.5; Pub. L. 107–295, 116 Stat. 2064; Department of Homeland Security Delegation No. 0170.1.

■ 2. A new temporary § 165.T09–222 is added to read as follows:

§ 165.T09–222 Safety Zone; Lake Michigan, Chicago, Illinois.

(a) *Location.* The following is a safety zone: All waters of Lake Michigan bounded by the arc of a circle with a 700-foot radius with its center in approximate position 41°52′15″ N; 087°36′44″ W (NAD 83).

(b) *Regulations.* In accordance with the general regulations in § 165.23 of this part, entry into the zone is prohibited unless authorized by the Coast Guard Captain of the Port, Chicago, or the designated Patrol Commander.

(c) *Effective date.* This section is effective from 11 p.m. July 14, 2003 until 1 a.m. on July 15, 2003.

Dated: June 25, 2003.

Raymond E. Seebald,

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

[FR Doc. 03–17599 Filed 7–10–03; 8:45 am]

BILLING CODE 4910–15–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2003–0103; FRL–7317–1]

Imidacloprid; Pesticide Tolerances Technical Correction

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule; technical correction.

SUMMARY: EPA issued a final rule in the **Federal Register** of June 13, 2003, concerning the establishment of tolerances for combined residues of imidacloprid. This document is being issued to properly display the table in the regulatory text.

DATES: This document is effective on July 11, 2003.

FOR FURTHER INFORMATION CONTACT: Shaja R. Brothers, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW.,Washington, DC 20460–0001; telephone number: (703) 308–3194; e-mail address: *brothers.shaja@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

The Agency included in the final rule a list of those who may be potentially affected by this action. If you have questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Get Copies of this Document and Other Related Information?

1. *Docket.* EPA has established an official public docket for this action under docket identification (ID) number OPP–2003–0103. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

2. *Electronic access.* You may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at http://www.epa.gov/fedrgstr/. A frequently updated electronic version of 40 CFR part 180 is available at *http://www.access.gpo.gov/nara/cfr/cfrhtml_00/Title_ 40/40cfr180_00.html*, a beta site currently under development.

An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at *http://www.epa.gov/edocket/* to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Once in the system, select ''search,'' then key in the appropriate docket ID number.

II. What Does this Correction Do?

In a final rule published in the **Federal Register** of June 13, 2003 (68 FR 35303) (FRL–7310–8) an amendment to § 180.472 inadvertently omitted the third column of the table (Expiration/Revocation date) in paragraph (a). This correction is being published to show the table as it should have appeared with the newly added commodities.

III. Why is this Correction Issued as a Final Rule?

Section 553 of the Administrative Procedure Act (APA), 5 U.S.C. 553(b)(B), provides that, when an Agency for good cause finds that notice and public procedure are impracticable, unnecessary or contrary to the public interest, the agency may issue a final rule without providing notice and an opportunity for public comment. EPA has determined that there is good cause for making today's technical correction final without prior proposal and opportunity for comment, because EPA is merely inserting language that was inadvertently omitted from the previously published final rule. EPA finds that this constitutes good cause under 5 U.S.C. 553(b)(B).

IV. Do Any of the Statutory and Executive Order Reviews Apply to this Action?

This final rule implements a technical correction to the CFR, and it does not otherwise impose or amend any requirements. As such, the Office of Management and Budget (OMB) has determined that a technical correction is not a ''significant regulatory action'' subject to review by OMB under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Nor does this final rule contain any information collection requirements that require review and approval by OMB pursuant to the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501 *et seq.*). Since the Agency has made a ''good cause'' finding that this action is not subject to notice-and-comment requirements under the APA or any other statute (see Unit III.), this action is not subject to provisions of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), or to sections 202 and 205 of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4). In addition, this action does not significantly or uniquely affect small governments or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4). This final rule will not have substantial direct effects on the States or on one or more Indian tribes, on the relationship between the national government and the States or one or more Indian tribes, or on the distribution of power and responsibilities among the various levels of government or between the Federal government and Indian tribes. As such, this action does not have any ''federalism implications'' as described in Executive Order 13132, entitled Federalism (64 FR 43255, August 10, 1999), or any ''tribal implications'' as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Since this direct final rule is not a ''significant regulatory action'' as defined by Executive Order 12866, it does not require OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997), and is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001). This action does not involve any technical standards that require the Agency's consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note). This action will not result in environmental justice related issues and does not, therefore, require special consideration under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994) or Executive Order 12630, entitled *Governmental Actions and Interference with Constitutionally Protected Property Rights* (53 FR 8859, March 15, 1988). In issuing this final rule, EPA has taken the necessary steps to eliminate drafting errors and ambiguity, minimize potential litigation, and provide a clear legal standard for affected conduct, as required by section 3 of Executive Order 12988, entitled *Civil Justice Reform* (61 FR 4729, February 7, 1996).

V. Congressional Review Act

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

List of Subjects in 40 CFR Part 180

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

Dated: July 8, 2003.

Peter Caulkins,

Acting Director, Registration Division, Office of Pesticide Programs.

■ Therefore, 40 CFR part 180 is corrected as follows:

PART 180—[AMENDED]

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

Authority: 21 U.S.C. 321(q), 346(a) and 371.

■ 2. On page 35314, in FR Doc. 03–14880, in the third column, the table to § 180.472(a), as amended, is corrected by adding the third column (Revocation/Expiration date) and in the footnote, ''registration'' should read ''registrations'' to read as follows:

§ 180.472 Imidacloprid; tolerances for residues.

(a) * * *

Commodity	Parts per million	Revocation/ Expiration date
Acerola	1.0	None
* * * *	*	* *
Artichoke, globe	2.5	None
Avocado	1.0	None
Banana[1]	0.02	None
* * * *	*	* *
Canistel	1.0	None
* * * *	*	* *
Corn, pop, grain	0.05	None
Corn, pop, stover	0.20	None
* * * *	*	* *
Cranberry	0.05	None
Currant	3.5	None
* * * *	*	* *
Elderberry	3.5	None
* * * *	*	* *
Feijoa	1.0	None
* * * *	*	* *
Fruit, stone, group 12	3.0	None
Gooseberry	3.5	None
* * * *	*	* *
Guava	1.0	None
* * * *	*	* *
Huckleberry	3.5	None
Jaboticaba	1.0	None
Juneberry	3.5	None
* * * *	*	* *
Lingonberry	3.5	None
Longan	3.0	None
Lychee	3.0	None
Mango	1.0	None
* * * *	*	* *
Mustard, seed	0.05	None
Okra	1.0	None
Passionfruit	1.0	None
Papaya	1.0	None
* * * *	*	* *
Persimmon	3.0	None
* * * *	*	* *
Pulasan	3.0	None
Rambutan	3.0	None
Salal	3.5	None
Sapodilla	1.0	None
Sapote, black	1.0	None
Sapote, mamey	1.0	None
* * * *	*	* *
Spanish lime	3.0	None
Star apple	1.0	None
Starfruit	1.0	None
Strawberry	0.50	None
* * * *	*	* *
Vegetable, leaves of root and tuber, group 2	4.0	None
Vegetable, legume, except soybean, group 6	4.0	None
Vegetable, root and tuber, group 1, except sugar beet	0.40	None
* * * *	*	* *
Watercress	3.5	None
Wax jambu	1.0	None
* * * *	*	* *

[1] There are no U.S. registrations as of June 13, 2003 for use on banana.

* * * * *

[FR Doc. 03–17674 Filed 7–10–03; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 300

[FRL–7526–2]

National Oil and Hazardous Substances Pollution Contingency Plan; National Priorities List Update

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of deletion of the Pepe Field Superfund Site (Site) from the National Priorities List.

SUMMARY: The EPA Region II Office announces the deletion of the Pepe Field Superfund Site, located in Boonton, New Jersey from the National Priorities List (NPL). The NPL is appendix B of 40 CFR part 300 which is the National Oil and Hazardous Substances Pollution Contingency Plan (NCP), which EPA promulgated pursuant to section 105 of the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA), as amended. EPA and the State of New Jersey have determined that the Site poses no significant threat to public health or the environment and, therefore, no further remedial measures pursuant to CERCLA are appropriate.

EFFECTIVE DATE: July 11, 2003.

FOR FURTHER INFORMATION CONTACT: Romona Pezzella, Remedial Project Manager; U.S. Environmental Protection Agency; Region II, 290 Broadway, 19th Floor; New York, New York 10007–1866; (212) 637–4385; *pezzella.romona@epa.gov.*

SUPPLEMENTARY INFORMATION: The site to be deleted from the NPL is: Pepe Field Superfund Site, Boonton, New Jersey.

A Notice of Intent To Delete for this Site was published in the **Federal Register** on May 6, 2003 (68 FR 23939). The closing date for comments on the Notice of Intent To Delete was June 7, 2003. No comments were received, therefore, EPA has not prepared a Responsiveness Summary.

EPA identifies sites that appear to present a significant risk to public health, welfare, or the environment and it maintains the NPL as the list of those sites. Any site deleted from the NPL remains eligible for Fund-financed remedial actions in the unlikely event that conditions at the site warrant such action. Section 300.425(e)(3) of the NCP states that Fund-financed actions may be taken at sites deleted from the NPL. Deletion of a site from the NPL does not affect responsible party liability or impede agency efforts to recover costs associated with response efforts.

List of Subjects in 40 CFR Part 300

Environmental protection, Air pollution control, Chemicals, Hazardous substances, Hazardous waste, Intergovernmental relations, Penalties, Reporting and recordkeeping requirements, Superfund, Water pollution control, Water supply.

Dated: June 30, 2003.

William J. Muszynski,

Acting Regional Administrator, Region II.

■ For the reasons set out in the preamble, 40 CFR part 300 is amended as follows:

PART 300—[AMENDED]

■ 1. The authority citation for part 300 continues to read as follows:

Authority: 42 U.S.C. 9601–9657; 33 U.S.C. 1321(c)(2); E.O. 12777, 56 FR 54757, 3 CFR, 1991 Comp., p. 351; E.O. 12580, 52 FR 2923, 3 CFR, 1987 Comp., p. 193.

[Amended]

Appendix B—[Amended]

■ 2. Table 1 of Appendix B to part 300 is amended by removing the entry for the Pepe Field, Boonton, NJ Superfund Site.

[FR Doc. 03–17611 Filed 7–10–03; 8:45 am]

BILLING CODE 6560–50–P

GENERAL SERVICES ADMINISTRATION

41 CFR Part 105–55

[GSPMR Case 2003–105–1]

RIN 3090–AH84

General Services Administration Property Management Regulations; Collection of Claims Owed the United States

AGENCY: Office of Finance, General Services Administration (GSA).

ACTION: Proposed rule.

SUMMARY: The General Services Administration (GSA) is proposing to amend and reissue its regulations concerning the procedures used to collect debts owed to GSA by incorporating applicable provisions as required by the Debt Collection Improvement Act of 1996 (DCIA) and the Federal Claims Collection Standards.

DATES: Interested parties should submit comments in writing on or before September 9, 2003 to be considered in the formulation of a final rule.

ADDRESSES: Submit written comments to: General Services Administration, Office of Finance (BCD), Office of the Chief Financial Officer, 1800 F Street, NW, Room 3121, ATTN: Michael J. Kosar, Washington, DC 20405. Submit electronic comments via the Internet to: *Michael.Kosar@gsa.gov.* Please submit comments only and cite GSPMR case 2003–105–1 in all correspondence related to this case.

FOR FURTHER INFORMATION CONTACT: The Regulatory Secretariat, Room 4035, GS Building, Washington, DC, 20405, at (202) 501–4755 for information pertaining to status or publication schedules. For clarification of content, contact Michael J. Kosar, Office of the Chief Financial Officer (202) 501–2029. Please cite GSPMR case 2003–105–1.

SUPPLEMENTARY INFORMATION:

A. Background

The GSA proposes to amend and reissue its debt collection procedures to incorporate changes presented in the amended Federal Claims Collection Standards (FCCS) issued jointly on November 22, 2000, by the Department of the Treasury (Treasury) and the Department of Justice (DoJ), under the Debt Collection Improvement Act of 1996 (DCIA). GSA currently has rules for collecting unpaid debts through three offset methods: administrative, salary, and tax refund. These rules were adopted with then existing provisions of the Debt Collection Act of 1982, the FCCS of 1966, and other authorities governing the collection of Federal debts.

B. Executive Order 12866

GSA has determined this regulation is not a significant regulatory action as defined in Executive Order 12866 and, accordingly, this regulation has not been reviewed by the Office of Management and Budget.

C. Regulatory Flexibility Act

It is hereby certified this regulation will not have a significant economic impact on a substantial number of small entities because the regulation either: (1) Results in greater flexibility for GSA to streamline debt collection regulations, or (2) reflects the statutory language contained in the DCIA. Accordingly, a Regulatory Flexibility Analysis is not required.

D. Executive Order 13132

This regulation will not have a substantial direct effect on the states, on the relationship between the national government and the states, or on distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 13132, it is determined this regulation does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

E. Unfunded Mandates Reform Act of 1995

This regulation will not result in the expenditure by state, local and tribal governments, in the aggregate, or by the private sector, of $100 million or more in any one (1) year, and it will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

F. Small Business Regulatory Enforcement Fairness Act of 1996

This rule is not a major rule as defined by section 251 of the Small Business Regulatory Enforcement Act, 5 U.S.C. 804. This 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 on the ability of United States-based companies to compete with foreign-based companies in domestic or export markets.

G. Paperwork Reduction Act

This rule does not contain information collection requirements that require approval by the Office of Management and Budget under the Paperwork Reduction Act, 44 U.S.C. 3507, *et seq.*

List of Subjects in 41 CFR Part 105–55

Claims owed the United States, antitrust, fraud, taxes, interagency claims, offset, payments, administrative practice and procedure, credit bureaus, compromise, suspension, termination and discharge of debts, hearing and appeals procedures, debts.

Dated: June 30, 2003.

Kathleen M. Turco,

Chief Financial Officer, Office of the Chief Financial Officer.

■ For the reasons set forth in the preamble, GSA proposes to revise 41 CFR part 105–55 as follows:

CHAPTER 105—GENERAL SERVICES ADMINISTRATION

PART 105–55—COLLECTION OF CLAIMS OWED THE UNITED STATES

Sec.

105–55.001 Prescription of standards.
105–55.002 Definitions.
105–55.003 Antitrust, fraud, tax, interagency claims, and claims over $100,000 excluded.
105–55.004 Compromise, waiver, or disposition under other statutes not precluded.
105–55.005 Form of payment.
105–55.006 Subdivision of claims not authorized.
105–55.007 Required administrative proceedings.
105–55.008 No private rights created.
105–55.009 Aggressive agency collection activity.
105–55.010 Demand for payment.
105–55.011 Collection by administrative offset.
105–55.012 Contracting with private collection contractors and with entities that locate and recover unclaimed assets.
105–55.013 Suspension or revocation of eligibility for loans and loan guaranties, licenses, permits, or privileges.
105–55.014 Liquidation of collateral.
105–55.015 Collection in installments.
105–55.016 Interest, penalties, and administrative costs.
105–55.017 Use and disclosure of mailing addresses.
105–55.018 Exemptions.
105–55.019 Compromise of claims.
105–55.020 Bases for compromise.
105–55.021 Enforcement policy.
105–55.022 Joint and several liability.
105–55.023 Further review of compromise offers.
105–55.024 Consideration of tax consequences to the Government.
105–55.025 Mutual releases of the debtor and the Government.

105–55.026 Suspending or terminating collection activity.
105–55.027 Suspension of collection activity.
105–55.028 Termination of collection activity.
105–55.029 Exception to termination.
105–55.030 Discharge of indebtedness; reporting requirements.
105–55.031 Prompt referral to the Department of Justice.
105–55.032 Claims Collection Litigation Report.
105–55.033 Preservation of evidence.
105–55.034 Minimum amount of referrals to the Department of Justice.

Authority: 5 U.S.C. 552–553, 31 U.S.C. 321, 3701, 3711, 3716, 3717, 3718, 3719, 3720B, 3720D; 31 CFR Parts 900–904.

§ 105–55.001 Prescription of standards.

(a) The Secretary of the Treasury and the Attorney General of the United States issued regulations for collecting debts owed the United States under the authority contained in 31 U.S.C. 3711(d)(2). The regulations in this part prescribe standards for GSA use in the administrative collection, offset, compromise, and the suspension or termination of collection activity for civil claims for money, funds, or property, as defined by 31 U.S.C. 3701(b), unless specific GSA statutes or regulations apply to such activities or, as provided for by Title 11 of the United States Code, when the claims involve bankruptcy. The regulations in this part also prescribe standards for referring debts to the Department of Justice for litigation. Additional guidance is contained in the Office of Management and Budget's Circular A–129 (Revised), ''Policies for Federal Credit Programs and Non-Tax Receivables'' (available at *http://www.whitehouse.gov/omb*), the Department of the Treasury's ''Managing Federal Receivables,'' and other publications concerning debt collection and debt management (available at *http://www/fms.treas.gov/debt/regulations.html*).

(b) GSA is not limited to the remedies contained in this part and will use all authorized remedies, including alternative dispute resolution and arbitration, to collect civil claims, to the extent such remedies are not inconsistent with the Federal Claims Collection Act, as amended, Chapter 37 of Title 31, U.S. Code; the Debt Collection Act of 1982, 5 U.S.C. 5514; the Debt Collection Improvement Act of 1996, 31 U.S.C. 3701, *et seq.*, or other relevant statutes. The regulations in this part are not intended to impair GSA's common law rights to collect debts.

(c) Standards and policies regarding the classification of debt for accounting purposes (for example, write off of uncollectible debt) are contained in the Office of Management and Budget's Circular A–129 (Revised), ''Policies for Federal Credit Programs and Non-Tax Receivables.''

§ 105–55.002 Definitions.

(a) *Administrative offset*, as defined in 31 U.S.C. 3701(a)(1), means withholding funds payable by the United States (including funds payable by the United States on behalf of a State government) to, or held by the United States for, a person to satisfy a claim.

(b) *Compromise* means the reduction of a debt as provided in §§ 101–55.019 and 101–55.020 of this part.

(c) *Debt collection center* means the Department of the Treasury or other Government agency or division designated by the Secretary of the Treasury with authority to collect debts on behalf of creditor agencies in accordance with 31 U.S.C. 3711(g).

(d) *Debtor* means an individual, organization, association, corporation, partnership, or a State or local government indebted to the United States or a person or entity with legal responsibility for assuming the debtor's obligation.

(e) *Delinquent* or *past-due non-tax debt* means any non-tax debt that has not been paid by the date specified in GSA's initial written demand for payment or applicable agreement or instrument (including a post-delinquency payment agreement), unless other satisfactory payment arrangements have been made.

(f) For the purposes of the standards in this part, unless otherwise stated, the term *Administrator* refers to the Administrator of General Services or the Administrator's delegate.

(g) For the purposes of the standards in this part, the terms *claim* and *debt* are synonymous and interchangeable. They refer to an amount of money, funds, or property that has been determined by GSA to be due the United States from any person, organization, or entity, except another Federal agency, from sources which include loans insured or guaranteed by the United States and all other amounts due the United States from fees, leases, rents, royalties, services, sales of real or personal property, overpayments, penalties, damages, interest, fines and forfeitures and all other similar sources, including debt administered by a third party as an agent for the Federal Government. For the purposes of administrative offset under 31 U.S.C. 3716, the terms *claim* and *debt* include an amount of money, funds, or property owed by a person to a State (including past-due support being enforced by a State), the District of Columbia, American Samoa, Guam, the United States Virgin Islands, the Commonwealth of the Northern Mariana Islands, or the Commonwealth of Puerto Rico.

(h) For the purposes of the standards in this part, unless otherwise stated, the terms *GSA* and *Agency* are synonymous and interchangeable.

(i) For the purposes of the standards in this part, unless otherwise stated, *Secretary* means the Secretary of the Treasury or the Secretary's delegate.

(j) For the standards in this part, Federal agencies include agencies of the executive, legislative, and judicial branches of the Government, including Government corporations.

(k) *Hearing* means a review of the documentary evidence concerning the existence and/or amount of a debt, and/or the terms of a repayment schedule, provided such repayment schedule is established other than by a written agreement entered into pursuant to this part. If the hearing official determines the issues in dispute cannot be resolved solely by review of the written record, such as when the validity of the debt turns on the issue of credibility or veracity, an oral hearing may be provided.

(1) *Hearing official* means a Board Judge of the GSA Board of Contract Appeals.

(m) In this part, words in the plural form shall include the singular and vice versa, and words signifying the masculine gender shall include the feminine and vice versa. The terms *includes* and *including* do not exclude matters not listed but do include matters that are in the same general class.

(n) *Reconsideration* means a request by the employee to have a secondary review by GSA of the existence and/or amount of the debt, and/or the proposed offset schedule.

(o) *Recoupment* is a special method for adjusting debts arising under the same transaction or occurrence. For example, obligations arising under the same contract generally are subject to recoupment.

(p) *Taxpayer identifying number* means the identifying number described under section 6109 of the Internal Revenue Code of 1986 (26 U.S.C. 6109). For an individual, the taxpayer identifying number is the individual's social security number.

(q) *Waiver* means the cancellation, remission, forgiveness, or non-recovery of a debt or debt-related charge as permitted or required by law.

§ 105–55.003 Antitrust, fraud, tax, interagency claims, and claims over $100,000 excluded.

(a) The standards in this part relating to compromise, suspension, and termination of collection activity do not apply to any debt based in whole or in part on conduct in violation of the antitrust laws or to any debt involving fraud, the presentation of a false claim, or misrepresentation on the part of the debtor or any party having an interest in the claim. The standards of this part relating to the administrative collection of claims do apply, but only to the extent authorized by the Department of Justice in a particular case. Upon identification of a claim based in whole or in part on conduct in violation of the antitrust laws or any claim involving fraud, the presentation of a false claim, or misrepresentation on the part of the debtor or any party having an interest in the claim, GSA will promptly refer the case to the GSA Office of Inspector General (OIG). The OIG has the responsibility for investigating or referring the matter, where appropriate, to the Department of Justice (DoJ) for action. At its discretion, DoJ may return the claim to GSA for further handling in accordance with the standards of this part.

(b) This part does not apply to tax debts.

(c) This part does not apply to claims between GSA and other Federal agencies.

(d) This part does not apply to claims over $100,000.

§ 105–55.004 Compromise, waiver, or disposition under other statutes not precluded.

Nothing in this part precludes GSA disposition of any claim under statutes and implementing regulations other than subchapter II of chapter 37 of Title 31 of the United States Code (Claims of the United States Government) and the standards in this part. *See, e.g.*, the Federal Medical CareRecovery Act, 42 U.S.C. 2651–2653, and applicable regulations, 28 CFR part 43. In such cases, the laws and regulations specifically applicable to claims collection activities of GSA generally take precedence.

§ 105–55.005 Form of payment.

Claims may be paid in the form of money or, when a contractual basis exists, GSA may demand the return of specific property or the performance of specific services.

§ 105–55.006 Subdivision of claims not authorized.

Debts will not be subdivided to avoid the monetary ceiling established by 31 U.S.C. 3711(a)(2). A debtor's liability arising from a particular transaction or contract shall be considered a single debt in determining whether the debt is one of less than $100,000 (excluding interest, penalties, and administrative costs) or such higher amount as the Attorney General shall from time to time prescribe for purposes of compromise, suspension, or termination of collection activity.

§ 105–55.007 Required administrative proceedings.

GSA is not required to omit, foreclose, or duplicate administrative proceedings required by contract or other laws or regulations.

§ 105–55.008 No private rights created.

The standards in this part do not create any right or benefit, substantive or procedural, enforceable at law or in equity by a party against the United States, its agencies, its officers, or any other person, nor shall the failure of GSA to comply with any of the provisions of this part be available to any debtor as a defense.

§ 105–55.009 Aggressive agency collection activity.

(a) GSA will aggressively collect all debts arising out of activities of, or referred or transferred for collection services to, GSA. Collection activities will be undertaken promptly, including letters, telephone calls, electronic mail (e-mail), and internet inquiries, with follow-up action taken as necessary.

(b) Debts referred or transferred to Treasury, or Treasury-designated debt collection centers under the authority of 31 U.S.C. 3711(g), will be serviced, collected, or compromised, or the collection action will be suspended or terminated, in accordance with the statutory requirements and authorities applicable to the collection of such debts.

(c) GSA will cooperate with other agencies in their debt collection activities.

(d) GSA will consider referring debts that are less than 180 days delinquent to Treasury or to Treasury-designated ''debt collection centers'' to accomplish efficient, cost effective debt collection. Treasury is a debt collection center, is authorized to designate otherFederal agencies as debt collection centers based on their performance in collecting delinquent debts, and may withdraw such designations. Referrals to debt collection centers shall be at the discretion of, and for a time period acceptable to, the Secretary. Referrals may be for servicing, collection, compromise, suspension, or termination of collection action.

(e) GSA will transfer to the Secretary any debt that has been delinquent for a period of 180 days or more so the Secretary may take appropriate action to collect the debt or terminate collection action. See 31 CFR 285.12(Transfer of Debts to Treasury for Collection). This requirement does not apply to any debt that—

(1) Is in litigation or foreclosure;

(2) Will be disposed of under an approved asset sale program;

(3) Has been referred to a private collection contractor for a period of time acceptable to the Secretary;

(4) Is at a debt collection center for a period of time acceptable to the Secretary (see paragraph (d) of this section);

(5) Will be collected under internal offset procedures within three years after the debt first became delinquent;

(6) Is exempt from this requirement based on a determination by the Secretary that exemption for a certain class of debt is in the best interest of the United States. GSA may request the Secretary to exempt specific classes of debts;

(7) Is in bankruptcy (see § 105–55.010(h) of this part);

(8) Involves a deceased debtor;

(9) Is owed to GSA by a foreign government; or

(10) Is in an administrative appeals process, until the process is complete and the amount due is set.

(f) Agencies operating Treasury-designated debt collection centers are authorized to charge a fee for services rendered regarding referred or transferred debts. The fee may be paid out of amounts collected and will be added to the debt as an administrative cost (see § 105-55.016 of this part).

§ 105–55.010 Demand for payment.

(a) Written demand, as described in paragraph (b) of this section, will be made promptly upon a debtor of the United States in terms informing the debtor of the consequences of failing to cooperate with GSA to resolve the debt. The specific content, timing, and number of demand letters (usually no more than three, thirty days apart) will depend upon the type and amount of the debt and the debtor's response, if any, to GSA's letters, telephone calls, electronic mail (e-mail) or internet inquiries. In determining the timing of the demand letter(s), GSA will give due regard to the need to refer debts promptly to the Department of Justice for litigation, in accordance with § 105–55.031 of this part. When necessary to protect the Government's interest (for example, to prevent the running of a statute of limitations), written demand

may be preceded by other appropriate actions under this part, including immediate referral for litigation.

(b) Demand letters will inform the debtor of—

(1) The basis and the amount of the indebtedness and the rights, if any, the debtor may have to seek review withinGSA (see § 105–55.011(e) of this part);

(2) The applicable standards for imposing any interest, penalties, or administrative costs (see § 105–55.016 of this part);

(3) The date by which payment should be made to avoid late charges (*i.e.*, interest, penalties, and administrative costs) and enforced collection, which generally will not be more than 30 days from the date the demand letter is mailed or hand-delivered; and

(4) The name, address, and phone number of a contact person or office within GSA.

(c) GSA will exercise care to ensure that demand letters are mailed or hand-delivered on the same day they are dated. For the purposes of written demand, notification by electronic mail (e-mail) and/or internet delivery is considered a form of written demand notice. There is no prescribed format for demand letters. GSA will utilize demand letters and procedures that will lead to the earliest practicable determination of whether the debt can be resolved administratively or must be referred for litigation.

(d) GSA may include in demand letters such items as the willingness to discuss alternative methods of payment; agency policies with respect to the use of credit bureaus, debt collection centers, and collection agencies; agency remedies to enforce payment of the debt (including assessment of interest, administrative costs and penalties, administrative garnishment, the use of collection agencies, Federal salary offset, tax refund offset, administrative offset, and litigation); the requirement that any debt delinquent for more than 180 days will be transferred to the Department of the Treasury for collection; and, depending on applicable statutory authority, the debtor's entitlement to consideration of a waiver.

(e) GSA will respond promptly to communications from debtors, within 30 days whenever feasible, and will advise debtors who dispute debts to furnish available evidence to support their contentions.

(f) Prior to the initiation of the demand process or at any time during or after completion of the demand process, if GSA determines to pursue, or is required to pursue offset, the procedures applicable to offset will be followed (see § 105–55.011 of this part). The availability of funds or money for debt satisfaction by offset and GSA's determination to pursue collection by offset will release the agency from the necessity of further compliance with paragraphs (a), (b), (c), and (d) of this section.

(g) Prior to referring a debt for litigation, GSA will advise each person determined to be liable for the debt that, unless the debt can be collected administratively, litigation may be initiated. This notification will comply with Executive Order 12988 (3 CFR, 1996 Comp. pp. 157–163) and may be given as part of a demand letter under paragraph (b) of this section or in a separate document.

(h) When GSA learns a bankruptcy petition has been filed with respect to a debtor, before proceeding with further collection action, the agency will ascertain the impact of the Bankruptcy Code on any pending or contemplated collection activities. Unless the agency determines the automatic stay imposed at the time of filing pursuant to 11U.S.C. § 362 has been lifted or is no longer in effect, in most cases collection activity against the debtor will stop immediately.

(1) A proof of claim will be filed in most cases with the bankruptcy court or the Trustee. GSA will refer to the provisions of 11 U.S.C. 106 relating to the consequences on sovereign immunity of filing a proof of claim.

(2) If GSA is a secured creditor, it may seek relief from the automatic stay regarding its security, subject to the provisions and requirements of 11 U.S.C. 362.

(3) Offset is stayed in most cases by the automatic stay. However, GSA will determine whether its payments to the debtor and payments of other agencies available for offset may be frozen by the agency until relief from the automatic stay can be obtained from the bankruptcy court. GSA also will determine whether recoupment is available.

§ 105–55.011 Collection by administrative offset.

(a) *Scope.* (1) The term ''administrative offset'' has the meaning provided in 31 U.S.C. 3701(a)(1).

(2) This section does not apply to—

(i) Debts arising under the Social Security Act, except as provided in 42 U.S.C. 404;

(ii) Payments made under the Social Security Act, except as provided for in 31 U.S.C. 3716(c) (see 31 CFR 285.4, Federal Benefit Offset);

(iii) Debts arising under, or payments made under, the Internal Revenue Code (see 31 CFR 285.2, Tax Refund Offset) or the tariff laws of the United States;

(iv) Offsets against Federal salaries to the extent these standards are inconsistent with regulations published to implement such offsets under 5 U.S.C. 5514 and 31 U.S.C. 3716 (see 5 CFR part 550, subpart K, and 31 CFR 285.7, Federal Salary Offset);

(v) Offsets under 31 U.S.C. 3728 against a judgment obtained by a debtor against the United States;

(vi) Offsets or recoupments under common law, State law, or Federal statutes specifically prohibiting offsets or recoupments of particular types of debts; or

(vii) Offsets in the course of judicial proceedings, including bankruptcy.

(3) Unless otherwise provided for by contract or law, debts or payments that are not subject to administrative offset under 31 U.S.C. 3716 may be collected by administrative offset under the common law or other applicable statutory authority.

(4) Unless otherwise provided by law, administrative offset of payments under the authority of 31 U.S.C. 3716 to collect a debt may not be conducted more than 10 years after GSA's right to collect the debt first accrued, unless facts material to GSA's right to collect the debt were not known and could not reasonably have been known by the official or officials of GSA who were charged with the responsibility to discover and collect such debts. This limitation does not apply to debts reduced to a judgment.

(5) In bankruptcy cases, GSA will ascertain the impact of the Bankruptcy Code, particularly 11 U.S.C. 106, 362, and 553, on pending or contemplated collections by offset.

(b) *Mandatory centralized administrative offset.* (1) GSA is required to refer past due, legally enforceable non-tax debts that are over 180 days delinquent to the Secretary for collection by centralized administrative offset. Debts that are less than 180 days delinquent also may be referred to the Secretary for this purpose. See paragraph (b)(5) of this section for debt certification requirements.

(2) The names and taxpayer identifying numbers (TINs) of debtors who owe debts referred to the Secretary as described in paragraph (b)(1) of this section will be compared to the names and TINs on payments to be made by Federal disbursing officials. Federal disbursing officials include disbursing officials of the Department of the Treasury, the Department of Defense, the United States Postal Service, other

Government corporations, and disbursing officials of the United States designated by the Secretary. When the name and TIN of a debtor match the name and TIN of a payee and all other requirements for offset have been met, the payment will be offset to satisfy the debt.

(3) Federal disbursing officials will notify the debtor/payee in writing that an offset has occurred to satisfy, in part or in full, a past due, legally enforceable delinquent debt. The notice will include a description of the type and amount of the payment from which the offset was taken, the amount of offset that was taken, the identity of GSA as the creditor agency requesting the offset, and a contact point within GSA who will respond to questions regarding the offset.

(4)(i) Offsets may be initiated only after the debtor—

(A) Has been sent written notice of the type and amount of the debt, the intention of GSA to use administrative offset to collect the debt, and an explanation of the debtor's rights under 31 U.S.C. 3716 (c)(7); and

(B) The debtor has been given—

(*1*) The opportunity to inspect and copy agency records related to the debt;

(*2*) The opportunity for a review within GSA of the determination of indebtedness (see paragraph (e) of this section); and

(*3*) The opportunity to make a written agreement to repay the debt.

(ii) The procedures set forth in paragraph (b)(4)(i) of this section may be omitted when—

(A) The offset is in the nature of a recoupment;

(B) The debt arises under a contract as set forth in *Cecile Industries, Inc.* v. *Cheney,* 995 F.2d 1052 (Fed. Cir. 1993) (notice and other procedural protections set forth in 31 U.S.C. 3716(a) do not supplant or restrict established procedures for contractual offsets accommodated by the Contracts Disputes Act); or

(C) In the case of non-centralized administrative offsets conducted under paragraph (c) of this section, GSA first learns of the existence of the amount owed by the debtor when there is insufficient time before payment would be made to the debtor/payee to allow for prior notice and an opportunity for review. When prior notice and an opportunity for review are omitted, GSA will give the debtor such notice and an opportunity for review as soon as practicable and will promptly refund any money ultimately found not to have been owed to the Government.

(iii) When GSA previously has given a debtor any of the required notice and review opportunities with respect to a particular debt (see, *e.g.,* § 105–55.010 of this part), the agency need not duplicate such notice and review opportunities before administrative offset may be initiated.

(5) When referring delinquent debts to the Secretary, GSA will certify, in a form acceptable to the Secretary, that—

(i) The debt(s) is (are) past due and legally enforceable; and

(ii) GSA has complied with all due process requirements under 31 U.S.C. 3716(a) and agency regulations.

(6) Payments that are prohibited by law from being offset are exempt from centralized administrative offset. The Secretary shall exempt payments under means-tested programs from centralized administrative offset when requested in writing by the Administrator. Also, the Secretary may exempt other classes of payments from centralized offset upon the written request of the Administrator.

(7) Benefit payments made under the Social Security Act (42 U.S.C. 301 *et seq.*), part B of the Black Lung Benefits Act (30 U.S.C. 921 *et seq.*), and any law administered by the Railroad Retirement Board (other than tier 2 benefits), may be offset only in accordance with Treasury regulations, issued in consultation with the Social Security Administration, the Railroad Retirement Board, and the Office of Management and Budget. See 31 CFR 285.4.

(8) In accordance with 31 U.S.C. 3716(f), the Secretary may waive the provisions of the Computer Matching and Privacy Protection Act of 1988 concerning matching agreements and post-match notification and verification (5 U.S.C. 552a(o) and (p)) for centralized administrative offset upon receipt of a certification from GSA that the due process requirements enumerated in 31 U.S.C. 3716(a) have been met. The certification of a debt in accordance with paragraph (b)(5) of this section will satisfy this requirement. If such a waiver is granted, only the Data Integrity Board of the Department of the Treasury is required to oversee any matching activities, in accordance with 31 U.S.C. § 3716(g). This waiver authority does not apply to offsets conducted under paragraphs (c) and (d) of this section.

(c) *Non-centralized administrative offset.* (1) Generally, non-centralized administrative offsets are ad hoc case-by-case offsets that GSA conducts, at the agency's discretion, internally or in cooperation with another agency certifying or authorizing payments to the debtor. Unless otherwise prohibited by law, when centralized administrative offset is not available or appropriate, past due, legally enforceable non-tax delinquent debts may be collected through non-centralized administrative offset. In these cases, GSA may make a request directly to a payment authorizing agency to offset a payment due a debtor to collect a delinquent debt. For example, it may be appropriate for GSA to request the Office of Personnel Management (OPM) offset a Federal employee's lump-sum payment upon leaving Government service to satisfy an unpaid advance.

(2) Such offsets will occur only after—

(i) The debtor has been provided due process as set forth in paragraph (b)(4) of this section; and

(ii) The payment authorizing agency has received written certification from GSA that the debtor owes the past due, legally enforceable delinquent debt in the amount stated, and that GSA has fully complied with its regulations concerning administrative offset.

(3) Payment authorizing agencies will comply with offset requests by GSA to collect debts owed to the United States, unless the offset would not be in the best interests of the United States with respect to the program of the payment authorizing agency, or would otherwise be contrary to law.

(4) When collecting multiple debts by non-centralized administrative offset, GSA will apply the recovered amounts to those debts in accordance with the best interests of the United States, as determined by the facts and circumstances of the particular case, particularly the applicable statute of limitations.

(d) *Requests to OPM to offset a debtor's anticipated or future benefit payments under the Civil Service Retirement and Disability Fund.* Upon providing OPM written certification that a debtor has been afforded the procedures provided in paragraph (b)(4) of this section, GSA may request OPM to offset a debtor's anticipated or future benefit payments under the Civil Service Retirement and Disability Fund (Fund) in accordance with regulations codified at 5 CFR 831.1801 to 831.1808. Upon receipt of such a request, OPM will identify and ''flag'' a debtor's account in anticipation of the time when the debtor requests, or becomes eligible to receive, payments from the Fund. This will satisfy any requirement that offset be initiated prior to the expiration of the time limitations referenced in paragraph (a)(4) of this section.

(e) *Review requirements.* (1) A debtor may seek review of a debt by sending a signed and dated petition for review to the official named in the demand letter. A copy of the petition must also be sent to the GSA Board of Contract Appeals

(GSBCA) at the address indicated in paragraph (e)(6) of this section.

(2) For purposes of this section, whenever GSA is required to afford a debtor a review within the agency, the hearing official will provide the debtor with a reasonable opportunity for an oral hearing when the debtor requests reconsideration of the debt and the hearing official determines that the question of the indebtedness cannot be resolved by review of the documentary evidence; for example, when the validity of the debt turns on an issue of credibility or veracity.

(3) Witnesses will be asked to testify under oath or affirmation, and a written transcript of the hearing will be kept and made available to either party in the event of an appeal under the Administrative Procedure Act, 5 U.S.C. 701–706. Arrangements for the taking of the transcript will be made by the hearing official, and all charges associated with the taking of the transcript will be the responsibility of GSA.

(4) In those cases when an oral hearing is not required by this section, the hearing official will accord the debtor a ''paper hearing,'' that is, a determination of the request for reconsideration based upon a review of the written record.

(5) Hearings will be conducted by a Board Judge of the GSBCA. GSA must provide proof that a valid non-tax debt exists, and the debtor must provide evidence that no debt exists or that the amount of the debt is incorrect.

(6) If an oral hearing is provided, the debtor may choose to have it conducted in the hearing official's office located at GSA Central Office, 1800 F St., NW., Washington, DC 20405, at another location designated by the hearing official, or may choose a hearing by telephone. All personal and travel expenses incurred by the debtor in connection with an in-person hearing will be borne by the debtor. All telephonic charges incurred during a hearing will be the responsibility of GSA.

(7) If the debtor is an employee of GSA, the employee may represent himself or herself or may be represented by another person of his or her choice at the hearing. GSA will not compensate the employee for representation expenses, including hourly fees for attorneys, travel expenses, and costs for reproducing documents.

(8) A written decision will be issued by the hearing official no later than 60 days from the date the petition for review is received by GSA. The decision will state the—

(i) Facts supporting the nature and origin of the debt;

(ii) Hearing official's analysis, findings, and conclusions as to the debtor's and/or GSA's grounds;

(iii) Amount and validity of the debt; and

(iv) Repayment schedule, if applicable.

(9) The hearing official's decision will be the final agency action for the purposes of judicial review under the Administrative Procedure Act (5 U.S.C. 701 *et seq.*).

(f) *Waiver requirements.* (1) Under certain circumstances, a waiver of a claim against an employee of GSA arising out of an erroneous payment of pay, allowances, travel, transportation, or relocation expenses and allowances may be granted in whole or in part.

(2) GSA procedures for waiving a claim of erroneous payment of pay and allowances can be found in GSA Order CFO 4200.1, ''Waiver of Claims for Overpayment of Pay and Allowances''.

(3) GSA will follow the procedures of 5 U.S.C. 5584 when considering a request for waiver of erroneous payment of travel, transportation, or relocation expenses and allowances.

§ 105–55.012 Contracting with private collection contractors and with entities that locate and recover unclaimed assets.

(a) Subject to the provisions of paragraph (b) of this section, GSA may contract with private collection contractors, as defined in 31 U.S.C. 3701(f), to recover delinquent debts provided that—

(1) GSA retain the authority to resolve disputes, compromise debts, suspend or terminate collection activity, and refer debts for litigation;

(2) The private collection contractor is not allowed to offer the debtor, as an incentive for payment, the opportunity to pay the debt less the private collection contractor's fee unless GSA has granted such authority prior to the offer;

(3) The contract provides that the private collection contractor is subject to the Privacy Act of 1974 to the extent specified in 5 U.S.C. 552a(m), and to applicable Federal and state laws and regulations pertaining to debt collection practices, including but not limited to the Fair Debt Collection Practices Act, 15 U.S.C. 1692; and

(4) The private collection contractor is required to account for all amounts collected.

(b) GSA will use Governmentwide debt collection contracts to obtain debt collection services provided by private collection contractors. However, GSA may refer debts to private collection contractors pursuant to a contract between the agency and the private collection contractor only if such debts are not subject to the requirement to transfer debts to Treasury for debt collection. See 31 U.S.C. 3711(g); 31 CFR 285.12(e).

(c) GSA may fund private collection contractor contracts in accordance with 31 U.S.C. 3718(b), or as otherwise permitted by law.

(d) GSA may enter into contracts for locating and recovering assets of the United States, such as unclaimed assets.

(e) GSA may enter into contracts for debtor asset and income search reports. In accordance with 31 U.S.C. 3718(b), such contracts may provide that the fee a contractor charges the agency for such services may be payable from the amounts recovered, unless otherwise prohibited by statute.

§ 105–55.013 Suspension or revocation of eligibility for loans and loan guaranties, licenses, permits, or privileges.

(a) Unless waived by the Administrator, GSA will not extend financial assistance in the form of a loan, loan guarantee, or loan insurance to any person delinquent on a non-tax debt owed to a Federal agency. This prohibition does not apply to disaster loans. The authority to waive the application of this section may be delegated to the Chief Financial Officer and re-delegated only to the Deputy Chief Financial Officer of GSA. GSA may extend credit after the delinquency has been resolved. The Secretary may exempt classes of debts from this prohibition and has prescribed standards defining when a ''delinquency'' is ''resolved'' for purposes of this prohibition. See 31 CFR 285.13.

(b) In non-bankruptcy cases, GSA, when seeking the collection of statutory penalties, forfeitures, or other types of claims, will consider the suspension or revocation of licenses, permits, or other privileges for any inexcusable or willful failure of a debtor to pay such a debt in accordance with GSA regulations or governing procedures. The debtor will be advised in GSA's written demand for payment of the agency's ability to suspend or revoke licenses, permits, or privileges. If GSA makes, guarantees, insures, acquires, or participates in loans, the agency will consider suspending or disqualifying any lender, contractor, or broker from doing further business with the agency or engaging in programs sponsored by the agency if such lender, contractor, or broker fails to pay its debts to the Government within a reasonable time or if such lender, contractor, or broker has been

suspended, debarred, or disqualified from participation in a program or activity by another Federal agency. The failure of any surety to honor its obligations in accordance with 31 U.S.C. § 9305 will be reported to the Treasury. The Treasury will forward notification to all interested agencies that a surety's certificate of authority to do business with the Government has been revoked by the Treasury.

(c) The suspension or revocation of licenses, permits, or privileges also may extend to GSA programs or activities administered by the states on behalf of GSA, to the extent they affect GSA's ability to collect money or funds owed by debtors.

(d) In bankruptcy cases, before advising the debtor of GSA's intention to suspend or revoke licenses, permits, or privileges, the agency will ascertain the impact of the Bankruptcy Code, particularly 11 U.S.C. 362 and 525, which may restrict such action.

§ 105–55.014 Liquidation of collateral.

(a) GSA will liquidate security or collateral through the exercise of a power of sale in the security instrument or a non-judicial foreclosure, and apply the proceeds to the applicable debt(s), if the debtor fails to pay the debt(s) within a reasonable time after demand and if such action is in the best interest of the United States. Collection from other sources, including liquidation of security or collateral, is not a prerequisite to requiring payment by a surety, insurer, or guarantor unless such action is expressly required by statute or contract.

(b) When GSA learns a bankruptcy petition has been filed with respect to a debtor, the agency will ascertain the impact of the Bankruptcy Code, including, but not limited to, 11 U.S.C. 362, to determine the applicability of the automatic stay and the procedures for obtaining relief from such stay prior to proceeding under paragraph (a) of this section.

§ 105–55.015 Collection in installments.

(a) Whenever feasible, GSA will collect the total amount of a debt in one lump sum. If a debtor is financially unable to pay a debt in one lump sum, GSA may accept payment in regular installments. GSA may obtain financial statements from debtors who represent they are unable to pay in one lump sum and independently verify such representations whenever possible (see §105–55.020(g) of this part). When GSA agrees to accept payments in regular installments, a legally enforceable written agreement from the debtor will be obtained specifying all of the terms of the arrangement and containing a provision accelerating the debt in the event of default. If the debtor's financial statement discloses the ownership of assets which are free and clear of liens or security interests, or assets in which the debtor owns an equity, the debtor may be asked to secure the payment of an installment note by executing a Security Agreement and Financing Statement transferring to the United States a security interest in the asset until the debt is paid.

(b) The size and frequency of installment payments will bear a reasonable relation to the size of the debt and the debtor's ability to pay. The installment payments will be sufficient in size and frequency to liquidate the debt in three years or less, unless circumstances warrant a longer period.

(c) Security for deferred payments may be obtained in appropriate cases. GSA may accept installment payments notwithstanding the refusal of the debtor to execute a written agreement or to give security, at the agency's option.

§ 105–55.016 Interest, penalties, and administrative costs.

(a) Except as provided in paragraphs (g), (h), and (i) of this section, GSA will charge interest, penalties, and administrative costs on debts owed to the United States pursuant to 31 U.S.C. 3717. GSA will send by U.S. mail, overnight delivery service, or hand-delivery a written notice to the debtor, at the debtor's most recent address available to the agency, explaining the agency's requirements concerning these charges, except where these requirements are included in a contractual or repayment agreement. These charges will continue to accrue until the debt is paid in full or otherwise resolved through compromise, termination, or waiver of the charges.

(b) GSA will charge interest on debts owed the United States as follows:

(1) Interest will accrue from the date of delinquency, or as otherwise provided by law.

(2) Unless otherwise established in a contract, repayment agreement, or by statute, the rate of interest charged will be the rate established annually by the Secretary in accordance with 31 U.S.C. 3717(a)(1). Pursuant to 31 U.S.C. 3717, GSA may charge a higher rate of interest if it is reasonably determined that a higher rate is necessary to protect the rights of the United States. GSA will document the reason(s) for a determination that the higher rate is necessary.

(3) The rate of interest, as initially charged, will remain fixed for the duration of the indebtedness. When a debtor defaults on a repayment agreement and seeks to enter into a new agreement, GSA may require payment of interest at a new rate that reflects the Current Value of Funds Rate (CVFR) at the time the new agreement is executed. Interest will not be compounded; that is, interest will not be charged on interest, penalties, or administrative costs required by this section. If a debtor defaults on a previous repayment agreement, charges that accrued but were not collected under the defaulted agreement will be added to the principal under the new repayment agreement.

(c) GSA will assess administrative costs incurred for processing and handling delinquent debts. The calculation of administrative costs will be based on actual costs incurred or upon estimated costs as determined by the agency.

(d) Unless otherwise established in a contract, repayment agreement, or by statute, GSA will charge a penalty, pursuant to 31 U.S.C. 3717(e)(2), not to exceed six percent a year on the amount due on a debt that is delinquent for more than 90 days. This charge will accrue from the date of delinquency.

(e) GSA may increase an ''administrative debt'' by the cost of living adjustment in lieu of charging interest and penalties under this section. ''Administrative debt'' includes, but is not limited to, a debt based on fines, penalties, and overpayments, but does not include a debt based on the extension of Government credit, such as those arising from loans and loan guaranties. The cost of living adjustment is the percentage by which the Consumer Price Index for the month of June of the calendar year preceding the adjustment exceeds the Consumer Price Index for the month of June of the calendar year in which the debt was determined or last adjusted. Increases to administrative debts will be computed annually. GSA will use this alternative only when there is a legitimate reason to do so, such as when calculating interest and penalties on a debt would be extremely difficult because of the age of the debt.

(f) When a debt is paid in partial or installment payments, amounts received by GSA will be applied first to outstanding penalties, second to administrative charges, third to interest, and last to principal.

(g) GSA will waive the collection of interest, penalty and administrative charges imposed pursuant to this section on the portion of the debt that is paid within 30 days after the date on which interest began to accrue. GSA may extend this 30-day period on a

case-by-case basis. In addition, GSA may waive interest, penalties, and administrative costs charged under this section, in whole or in part, without regard to the amount of the debt, either under the criteria set forth in these standards for the compromise of debts, or if the agency determines that collection of these charges resulted from agency error, is against equity and good conscience, or is not in the best interest of the United States.

(h) Unless a statute or regulation specifically prohibits collection, interest, penalties and administrative costs will continue to accrue for periods during which collection activity has been suspended pending agency review or waiver consideration.

(i) GSA is authorized to impose interest and related charges on debts not subject to 31 U.S.C. 3717, in accordance with the common law.

§ 105–55.017 Use and disclosure of mailing addresses.

(a) When attempting to locate a debtor in order to collect or compromise a debt under this part or other authority, GSA may send a request to the Secretary (or designee) to obtain a debtor's mailing address from the records of the Internal Revenue Service.

(b) GSA is authorized to use mailing addresses obtained under paragraph (a) of this section to enforce collection of a delinquent debt and may disclose such mailing addresses to other agencies and to collection agencies for collection purposes.

§ 105–55.018 Exemptions.

(a) The preceding sections of this part, to the extent they reflect remedies or procedures prescribed by the Debt Collection Act of 1982 and the Debt Collection Improvement Act of 1996, such as administrative offset, use of credit bureaus, contracting for collection agencies, and interest and related charges, do not apply to debts arising under, or payments made under, the Internal Revenue Code of 1986, as amended (26 U.S.C. 1 *et seq.*); the Social Security Act (42 U.S.C. 301 *et seq.*), except to the extent provided under 42 U.S.C. 404 and 31 U.S.C. 3716(c); or the tariff laws of the United States. These remedies and procedures, however, may be authorized with respect to debts that are exempt from the Debt Collection Act of 1982 and the Debt Collection Improvement Act of 1996, to the extent they are authorized under some other statute or the common law.

(b) Claims arising from the audit of transportation accounts pursuant to 31 U.S.C. 3726 will be determined, collected, compromised, terminated or settled in accordance with regulation published under the authority of 31 U.S.C. 3726 (see 41 CFR part 101–41, administered by the Director, Office of Transportation Audits) and are otherwise exempted from this part.

§ 105–55.019 Compromise of claims.

(a) The standards set forth in this section apply to the compromise of debts pursuant to 31 U.S.C. 3711. GSA may exercise such compromise authority for debts arising out of activities of, or referred or transferred for collection services to, the agency when the amount of the debt then due, exclusive of interest, penalties, and administrative costs, does not exceed $100,000 or any higher amount authorized by the Attorney General. The Administrator may designate other GSA officials to exercise the authorities in this section.

(b) Unless otherwise provided by law, when the principal balance of a debt, exclusive of interest, penalties, and administrative costs, exceeds $100,000 or any higher amount authorized by the Attorney General, the authority to accept the compromise rests with the Department of Justice. GSA will evaluate the compromise offer, using the factors set forth in § 105–55.020 of this part. If an offer to compromise any debt in excess of $100,000 is acceptable to the agency, GSA will refer the debt to the Civil Division or other appropriate litigating division in the Department of Justice using a Claims Collection Litigation Report (CCLR). The referral will include appropriate financial information and a recommendation for the acceptance of the compromise offer. Justice Department approval is not required if GSA rejects a compromise offer.

§ 105–55.020 Bases for compromise.

(a) GSA may compromise a debt if the full amount cannot be collected because—

(1) The debtor is unable to pay the full amount in a reasonable time, as verified through credit reports or other financial information;

(2) GSA is unable to collect the debt in full within a reasonable time by enforced collection proceedings;

(3) The cost of collecting the debt does not justify the enforced collection of the full amount; or

(4) There is significant doubt concerning the Government's ability to prove its case in court.

(b) In determining the debtor's inability to pay, GSA will consider relevant factors such as the following:

(1) Age and health of the debtor.

(2) Present and potential income.

(3) Inheritance prospects.

(4) The possibility that assets have been concealed or improperly transferred by the debtor.

(5) The availability of assets or income that may be realized by enforced collection proceedings.

(c) GSA will verify the debtor's claim of inability to pay by using a credit report and other financial information as provided in paragraph (g) of this section. GSA will consider the applicable exemptions available to the debtor under state and Federal law in determining the Government's ability to enforce collection. GSA also may consider uncertainty as to the price that collateral or other property will bring at a forced sale in determining the Government's ability to enforce collection. A compromise effected under this section will be for an amount that bears a reasonable relation to the amount that can be recovered by enforced collection procedures, with regard to the exemptions available to the debtor and the time that collection will take.

(d) If there is significant doubt concerning the Government's ability to prove its case in court for the full amount claimed, either because of the legal issues involved or because of a bona fide dispute as to the facts, then the amount accepted in compromise of such cases will fairly reflect the probabilities of successful prosecution to judgment, with due regard given to the availability of witnesses and other evidentiary support for the Government's claim. In determining the litigative risks involved, GSA will consider the probable amount of court costs and attorney fees pursuant to the Equal Access to Justice Act, 28 U.S.C. 2412 that may be imposed against the Government if it is unsuccessful in litigation.

(e) GSA may compromise a debt if the cost of collecting the debt does not justify the enforced collection of the full amount. The amount accepted in compromise in such cases may reflect an appropriate discount for the administrative and litigative costs of collection, with consideration given to the time it will take to effect collection. Collection costs may be a substantial factor in the settlement of small debts. In determining whether the cost of collection justifies enforced collection of the full amount, GSA will consider whether continued collection of the debt, regardless of cost, is necessary to further an enforcement principle, such as the Government's willingness to pursue aggressively defaulting and uncooperative debtors.

(f) GSA generally will not accept compromises payable in installments. This is not an advantageous form of compromise in terms of time and administrative expense. If, however, payment of a compromise in installments is necessary, GSA will obtain a legally enforceable written agreement providing that, in the event of default, the full original principal balance of the debt prior to compromise, less sums paid thereon, is reinstated. Whenever possible, GSA will obtain security for repayment in the manner set forth in § 105–55.015 of this part.

(g) To assess the merits of a compromise offer based in whole or in part on the debtor's inability to pay the full amount of a debt within a reasonable time, GSA may obtain a current financial statement from the debtor, executed under penalty of perjury, showing the debtor's assets, liabilities, income and expenses. GSA also may obtain credit reports or other financial information to assess compromise offers. GSA may use their own financial information form or may request suitable forms from the Department of Justice or the local United States Attorney's Office.

§ 105–55.021 Enforcement policy.

Pursuant to this section, GSA may compromise statutory penalties, forfeitures, or claims established as an aid to enforcement and to compel compliance, if the agency's enforcement policy in terms of deterrence and securing compliance, present and future, will be adequately served by the agency's acceptance of the sum to be agreed upon.

§ 105–55.022 Joint and several liability.

(a) When two or more debtors are jointly and severally liable, GSA may pursue collection activity against all debtors, as appropriate. GSA will not attempt to allocate the burden of payment between the debtors but will proceed to liquidate the indebtedness as quickly as possible.

(b) GSA will ensure that a compromise agreement with one debtor does not release the agency's claim against the remaining debtors. The amount of a compromise with one debtor will not be considered a precedent or binding in determining the amount that will be required from other debtors jointly and severally liable on the claim.

§ 105–55.023 Further review of compromise offers.

If GSA is uncertain whether to accept a firm, written, substantive compromise offer on a debt that is within the agency's delegated compromise authority, it may refer the offer to the Civil Division or other appropriate litigating division in the Department of Justice, using a CCLR accompanied by supporting data and particulars concerning the debt. The Department of Justice may act upon such an offer or return it to GSA with instructions or advice.

§ 105–55.024 Consideration of tax consequences to the Government.

In negotiating a compromise, GSA may consider the tax consequences to the Government. In particular, GSA may consider requiring a waiver of tax-loss-carry-forward and tax-loss-carry-back rights of the debtor. For information on discharge of indebtedness reporting requirements see § 105–55.030 of this part.

§ 105–55.025 Mutual releases of the debtor and the Government.

In all appropriate instances, a compromise that is accepted by GSA may be implemented by means of a mutual release, in which the debtor is released from further non-tax liability on the compromised debt in consideration of payment in full of the compromise amount and the Government and its officials, past and present, are released and discharged from any and all claims and causes of action arising from the same transaction that the debtor may have. In the event a mutual release is not executed when a debt is compromised, unless prohibited by law, the debtor is still deemed to have waived any and all claims and causes of action against the Government and its officials related to the transaction giving rise to the compromised debt.

§ 105–55.026 Suspending or terminating collection activity.

(a) The standards set forth in §§ 105–55.027 and 105–55.028 of this part apply to the suspension or termination of collection activity pursuant to 31 U.S.C. 3711 on debts that do not exceed $100,000, or such other amount as the Attorney General may direct, exclusive of interest, penalties, and administrative costs, after deducting the amount of partial payments or collections, if any. Prior to referring a debt to the Department of Justice for litigation, GSA may suspend or terminate collection under this part with respect to debts arising out of activities of, or referred or transferred for collection services to, the agency.

(b) If, after deducting the amount of any partial payments or collections, the principal amount of a debt exceeds $100,000, or such other amount as the Attorney General may direct, exclusive of interest, penalties, and administrative costs, the authority to suspend or terminate rests solely with the Department of Justice. If GSA believes suspension or termination of any debt in excess of $100,000 may be appropriate, the agency will refer the debt to the Civil Division or other appropriate litigating division in the Department of Justice, using the CCLR. The referral will specify the reasons for the agency's recommendation. If, prior to referral to the Department of Justice, GSA determines a debt is plainly erroneous or clearly without legal merit, the agency may terminate collection activity regardless of the amount involved without obtaining Department of Justice concurrence.

§ 105–55.027 Suspension of collection activity.

(a) GSA may suspend collection activity on a debt when—

(1) The agency cannot locate the debtor;

(2) The debtor's financial condition is expected to improve; or

(3) The debtor has requested a waiver or review of the debt.

(b) Based on the current financial condition of the debtor, GSA may suspend collection activity on a debt when the debtor's future prospects justify retention of the debt for periodic review and collection activity and—

(1) The applicable statute of limitations has not expired; or

(2) Future collection can be effected by administrative offset, notwithstanding the expiration of the applicable statute of limitations for litigation of claims, with due regard to the 10-year limitation for administrative offset prescribed by 31 U.S.C. 3716(e)(1); or

(3) The debtor agrees to pay interest on the amount of the debt on which collection will be suspended, and such suspension is likely to enhance the debtor's ability to pay the full amount of the principal of the debt with interest at a later date.

(c)(1) GSA will suspend collection activity during the time required for consideration of the debtor's request for waiver or administrative review of the debt if the statute under which the request is sought prohibits the agency from collecting the debt during that time.

(2) If the statute under which the request is sought does not prohibit collection activity pending consideration of the request, GSA will use discretion, on a case-by-case basis, to suspend collection. Further, GSA ordinarily will suspend collection

action upon a request for waiver or review if the agency is prohibited by statute or regulation from issuing a refund of amounts collected prior to agency consideration of the debtor's request. However, GSA will not suspend collection when the agency determines the request for waiver or review is frivolous or was made primarily to delay collection.

(d) When GSA learns a bankruptcy petition has been filed with respect to a debtor, in most cases the collection activity on a debt will be suspended, pursuant to the provisions of 11 U.S.C. 362, 1201, and 1301, unless the agency can clearly establish the automatic stay has been lifted or is no longer in effect. GSA will, if legally permitted, take the necessary legal steps to ensure no funds or money are paid by the agency to the debtor until relief from the automatic stay is obtained.

§ 105–55.028 Termination of collection activity.

(a) GSA may terminate collection activity when—

(1) The agency is unable to collect any substantial amount through its own efforts or through the efforts of others;

(2) The agency is unable to locate the debtor;

(3) Costs of collection are anticipated to exceed the amount recoverable;

(4) The debt is legally without merit or enforcement of the debt is barred by any applicable statute of limitations;

(5) The debt cannot be substantiated; or

(6) The debt against the debtor has been discharged in bankruptcy.

(b) Before terminating collection activity, GSA will pursue all appropriate means of collection and determine, based upon the results of the collection activity, that the debt is uncollectible. Termination of collection activity ceases active collection of the debt. The termination of collection activity does not preclude GSA from retaining a record of the account for purposes of—

(1) Selling the debt, if the Secretary determines that such sale is in the best interests of the United States;

(2) Pursuing collection at a subsequent date in the event there is a change in the debtor's status or a new collection tool becomes available;

(3) Offsetting against future income or assets not available at the time of termination of collection activity; or

(4) Screening future applicants of loans and loan guaranties, licenses, permits, or privileges for prior indebtedness.

(c) Generally, GSA will terminate collection activity on a debt that has been discharged in bankruptcy, regardless of the amount. GSA may continue collection activity, however, subject to the provisions of the Bankruptcy Code, for any payments provided under a plan of reorganization. Offset and recoupment rights may survive the discharge of the debtor in bankruptcy and, under some circumstances, claims also may survive the discharge. For example, the claims of GSA that it is a known creditor of a debtor may survive a discharge if the agency did not receive formal notice of the proceedings.

§ 105–55.029 Exception to termination.

When a significant enforcement policy is involved, or recovery of a judgment is a prerequisite to the imposition of administrative sanctions, GSA may refer debts for litigation even though termination of collection activity may otherwise be appropriate.

§ 105–55.030 Discharge of indebtedness; reporting requirements.

(a) Before discharging a delinquent debt (also referred to as a close out of the debt), GSA will take all appropriate steps to collect the debt in accordance with 31 U.S.C. 3711(g), including, as applicable, administrative offset, tax refund offset, Federal salary offset, referral to Treasury, Treasury-designated debt collection centers or private collection contractors, credit bureau reporting, wage garnishment, litigation, and foreclosure. Discharge of indebtedness is distinct from termination or suspension of collection activity and is governed by the Internal Revenue Code. When collection action on a debt is suspended or terminated, the debt remains delinquent and further collection action may be pursued at a later date in accordance with the standards set forth in this part. When GSA discharges a debt in full or in part, further collection action is prohibited. Therefore, GSA will make the determination that collection action is no longer warranted before discharging a debt. Before discharging a debt, GSA will terminate debt collection action.

(b) Section 3711(i), Title 31, United States Code, requires GSA to sell a delinquent non-tax debt upon termination of collection action if the Secretary determines such a sale is in the best interests of the United States. Since the discharge of a debt precludes any further collection action (including the sale of a delinquent debt), GSA may not discharge a debt until the requirements of 31 U.S.C. 3711(i) have been met.

(c) Upon discharge of a debt of more than $600, GSA must report the discharge to the IRS in accordance with the requirements of 26 U.S.C. 6050P and 26 CFR 1.6050P–1. GSA may request Treasury or Treasury-designated debt collection centers to file such a discharge report to the IRS on the agency's behalf.

(d) When discharging a debt, GSA will request the GSA Office of General Counsel to release any liens of record securing the debt.

§ 105–55.031 Prompt referral to the Department of Justice.

(a) GSA will promptly refer to the Department of Justice (DoJ) for litigation debts on which aggressive collection activity has been taken in accordance with § 105-55.009 of this part and that cannot be compromised, or on which collection activity cannot be suspended or terminated, in accordance with §§ 105–55.027 and 105–55.028 of this part. GSA may refer those debts arising out of activities of, or referred or transferred for collection services to, the agency. Debts for which the principal amount is over $1,000,000, or such other amount as the Attorney General may direct, exclusive of interest and penalties, will be referred to the Civil Division or other division responsible for litigating such debts at DoJ, Washington, DC. Debts for which the principal amount is $1,000,000, or less, or such other amount as the Attorney General may direct, exclusive of interest or penalties, will be referred to DoJ's Nationwide Central Intake Facility as required by the CCLR instructions. Debts will be referred as early as possible, consistent with aggressive GSA collection activity and the observance of the standards contained in this part, and, in any event, well within the period for initiating timely lawsuits against the debtors. GSA will make every effort to refer delinquent debts to DoJ for litigation within one year of the date such debts last became delinquent. In the case of guaranteed or insured loans, GSA will make every effort to refer these delinquent debts to DoJ for litigation within one year from the date the loan was presented to the agency for payment or re-insurance.

(b) DoJ has exclusive jurisdiction over the debts referred to it pursuant to this section. GSA, as the referring agency, will immediately terminate the use of any administrative collection activities to collect a debt at the time of the referral of that debt to DoJ. GSA will advise DoJ of the collection activities which have been utilized to date, and their result. GSA will refrain from having any contact with the debtor and will direct all debtor inquiries concerning the debt to DoJ, except as

otherwise agreed between GSA and DoJ. GSA will immediately notify DoJ of any payments credited by the agency to the debtor's account after referral of a debt under this section. DoJ will notify GSA of any payments it receives from the debtor.

§ 105–55.032 Claims Collection Litigation Report.

(a) Unless excepted by the Department of Justice (DoJ), GSA will complete the Claims Collection Litigation Report (CCLR) (see § 105–55.019(b) of this part), accompanied by a signed Certificate of Indebtedness, to refer all administratively uncollectible claims to DoJ for litigation. GSA will complete all sections of the CCLR appropriate to each claim as required by the CCLR instructions and furnish such other information as may be required in specific cases.

(b) GSA will indicate clearly on the CCLR the actions DoJ should take with respect to the referred claim. The CCLR permits the agency to indicate specifically any of a number of litigative activities which DoJ may pursue, including enforced collection, judgment lien only, renew judgment lien only, renew judgment lien and enforce collection, program enforcement, foreclosure only, and foreclosure and deficiency judgment.

(c) GSA also will use the CCLR to refer claims to DoJ to obtain approval of any proposals to compromise the claims or to suspend or terminate agency collection activity.

§ 105–55.033 Preservation of evidence.

GSA will take care to preserve all files and records that may be needed by DoJ to prove their claims in court. GSA ordinarily will include certified copies of the documents that form the basis for the claim in the packages referring their claims to DoJ for litigation. GSA will provide originals of such documents immediately upon request by DoJ.

§ 105–55.034 Minimum amount of referrals to the Department of Justice.

(a) GSA will not refer for litigation claims of less than $2,500, exclusive of interest, penalties, and administrative costs, or such other amount as the Attorney General shall from time to time prescribe. The Department of Justice (DoJ) will notify GSA if the Attorney General changes this minimum amount.

(b) GSA will not refer claims of less than the minimum amount unless—

(1) Litigation to collect such smaller claims is important to ensure compliance with the agency's policies or programs;

(2) The claim is being referred solely for the purpose of securing a judgment against the debtor, which will be filed as a lien against the debtor's property pursuant to 28 U.S.C. 3201 and returned to GSA for enforcement; or

(3) The debtor has the clear ability to pay the claim and the Government effectively can enforce payment, with due regard for the exemptions available to the debtor under state and Federal law and the judicial remedies available to the Government.

(c) GSA will consult with the Financial Litigation Staff of the Executive Office for United States Attorneys in DoJ prior to referring claims valued at less than the minimum amount.

[FR Doc. 03–17286 Filed 7–10–03; 8:45 am]

BILLING CODE 6820–34–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[DA 03–2187, MB Docket No. 02–45, RM–10373]

Digital Television Broadcast Service; Cadillac and Manistee, MI

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: The Commission, at the request of Central Michigan University, substitutes DTV channel *17 for DTV channel *58 at Cadillac, and substitutes DTV channel *58 for DTV channel *17 at Manistee. *See* 67 FR 10871, March 11, 2002. DTV channel *17 can be allotted to Cadillac in compliance with the principle community coverage requirements of Section 73.625(a) at reference coordinates 44–44–53 N. and 85–04–08 W. with a power of 500, HAAT of 399 meters and with a DTV service population of 327 thousand. DTV channel *58 can be allotted to Manistee in compliance with the principle community coverage requirements of Section 73.625(a) at reference coordinates 44–03–57 N. and 86–19–58 W. with a power of 200, HAAT of 104 meters and with a DTV service population of 78 thousand. Since the communities of Cadillac and Manistee are located within 400 kilometers of the U.S.-Canadian border, concurrence from the Canadian government has been obtained for these allotments. With this action, this proceeding is terminated.

DATES: Effective August 21, 2003.

FOR FURTHER INFORMATION CONTACT: Pam Blumenthal, Media Bureau, (202) 418–1600.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's Report and Order, MB Docket No. 02–45, adopted July 2, 2003, and released July 7, 2003. The full text of this document is available for public inspection and copying during regular business hours in the FCC Reference Information Center, Portals II, 445 12th Street, SW., Room CY-A257, Washington, DC. This document may also be purchased from the Commission's duplicating contractor, Qualex International, Portals II, 445 12th Street, SW, CY-B402, Washington, DC, 20554, telephone 202–863–2893, facsimile 202–863–2898, or via e-mail *qualexint@aol.com.*

List of Subjects in 47 CFR Part 73

Digital television broadcasting, Television.

■ Part 73 of Title 47 of the Code of Federal Regulations is amended as follows:

PART 73—[AMENDED]

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

Authority: 47 U.S.C. 154, 303, 334 and 336.

§ 73.622 [Amended]

■ 2. Section 73.622(b), the Table of Digital Television Allotments under Michigan, is amended by removing DTV channel *58 and adding DTV channel *17 at Cadillac.

■ 3. Section 73.622(b), the Table of Digital Television Allotments under Michigan, is amended by removing DTV channel *17 and adding DTV channel *58 at Manistee.

Barbara A. Kreisman,

Chief, Video Division, Media Bureau.

[FR Doc. 03–17575 Filed 7–10–03; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 74

[ET Docket No. 01–75; RM–9418; RM–9856; DA 03–1141]

Revision of Broadcast Auxiliary Service

AGENCY: Federal Communications Commission.

ACTION: Final rule; suspension.

SUMMARY: This document suspends the effectiveness of §§ 74.502(d) and 74.638(b), of the rules published March 17, 2003, (68 FR 12743) from April 16, 2003 to October 16, 2003. Society of Broadcast Engineers requested a

Temporary Stay to allow Broadcast Auxiliary Service (BAS) licensees time to provide and to correct BAS receive site information in our licensing database, the Universal Licensing System (ULS), to ensure that the new procedures effectively avert interference to existing systems. The Commission adopted and released an Order granting the requested relief for six months, on April 16, 2003, suspending the effectiveness of the rules until October 16, 2003.

DATES: Effective April 16, 2003, §§ 74.502(d) and 74.638(b), of 47 CFR Chapter I are suspended until October 16, 2003.

FOR FURTHER INFORMATION CONTACT: Ted Ryder, Office of Engineering and Technology, (202) 418–2803.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's Order, ET Docket No. 01–75, DA 03–1141, adopted April 15, 2003, and released April 15, 2003. The full text of this document is available for inspection and copying during regular business hours in the FCC Reference Center (Room CY–A257), 445 12th Street, SW., Washington, DC 20554. The complete text of this document also may be purchased from the Commission's copy contractor, Qualex International, 445 12th Street, SW., Room, CY–B402, Washington, DC 20554. The full text may also be downloaded at: *http://www.fcc.gov.* Alternative formats are available to persons with disabilities by contacting Brian Millin at (202) 418–7426 or TTY (202) 418–7365.

Summary of the Order

1. In the *Order,* we granted a Request for Temporary Stay (Request) filed by the Society of Broadcast Engineers (SBE) to stay the effective date of prior coordination procedures adopted by *Report and Order,* for most fixed point-to-point Aural and TV Broadcast Auxiliary Service (BAS) stations. *See, Revisions to Broadcast Auxiliary Service Rules in Part 74 and Conforming Technical Rules for Broadcast Auxiliary Service, Cable Television Relay Service and Fixed Services in Parts 74, 78 and 101 of the Commission's rules,* ET Docket No. 01–75, FCC 02–298, 17 FCC Rcd 22979, 2002, 68 FR 12743, March 17, 2003. SBE requests the stay to allow BAS licensees time to provide and to correct BAS receive site information in our licensing database, the Universal Licensing System (ULS), to ensure that the new procedures effectively avert interference to existing systems. We grant the requested relief for six months, staying the effectiveness of §§ 74.502(d) and 74.638(b), of the rules until October 16, 2003.

2. In the *Report and Order,* we adopted prior coordination procedures for fixed Aural BAS stations above 944 MHz and fixed Television BAS (TV BAS) stations above 2110 MHz under part 74. We adopted these procedures to conform procedures for fixed BAS, and Cable Auxiliary Relay Service (CARS) under part 78, with those already in effect for Fixed Microwave Services (FS) under part 101, § 101.103(d). We found that the FS procedures were appropriate for fixed BAS and CARS, stating that uniform procedures for bands shared among these services are necessary to promote spectrum efficiency and to minimize the possibility of harmful interference. We note that because these procedures were already in effect for Aural and TV BAS stations in the bands 6425–6525 MHz and 17700–19700 MHz, the new rules only affect fixed BAS in the bands 944–952 MHz (950 MHz), 2450–2583.5 MHz (2.5 GHz), 6875–7125 MHz (7 GHz), and 12700–13250 MHz (13 GHz).

3. SBE requests a one-year stay to allow BAS licensees time to correct inaccurate receive site information, such as geographic coordinates, antenna height, make, and model. It notes that these errors are a legacy of licensing schemes previous to the ULS and occur in 29% of all fixed point-to-point BAS license records. SBE further notes that receive site information was not even required prior to 1974 and that it remains missing on many old licenses. SBE explains that, compared to the information coordination procedures currently in effect, prior coordination procedures require a more accurate database. SBE acknowledges previous Commission public notices asking broadcasters to examine and correct inaccuracies in the ULS, via informal correction procedures, but asserts that with the adoption of the prior coordination procedures, BAS licensees will now have a greater incentive to ensure that their license records are up to date. We also note that SBE asserts that interference standards for the mix of analog, hybrid analog-digital, and digital links encountered in BAS need to be developed and formalized before prior coordination procedures can take effect. Life Talk Radio and CPBE support SBE's Request.

4. We agree with SBE that legacy database inaccuracies in the ULS could seriously affect the efficacy of prior coordination procedures, which was not anticipated when the *Order* setting these procedures was adopted. We will therefore stay for six months the effective date of the prior coordination procedures for fixed BAS. We find that this six month time period is the proper balance to allow sufficient time for BAS licensees to correct legacy database inaccuracies without unnecessarily delaying the efficiency and protection benefits offered by prior coordination procedures.

5. The Commission generally employs a four-part test under the standard set forth in *Virginia Petroleum Jobbers Association* v. *Federal Power Commission* in determining whether to grant motions for stay. Under this standard, the petitioner must demonstrate (1) That it is likely to prevail on the merits; (2) that it will suffer irreparable harm if a stay is not granted; (3) that other interested parties will not be harmed if the stay is granted; (4) that the public interest favors grant of the stay. We find that a stay is warranted.

6. First, we believe the database issues raised by SBE are valid and have merit. The period of the stay will provide time for Commission staff to address completion and correction of receive site information in the ULS database, so that prior coordination procedures can begin. Second, we find that SBE has demonstrated that, absent a stay, BAS licensees will suffer irreparable harm because there is an increased likelihood of interference to their receive facilities. Third, we find that granting a stay for six months will not harm any interested parties. As with our finding in the *Report and Order* that use of existing local coordination procedures would be sufficient to avert harmful interference until the effective date of the prior coordination procedures, we find that continuance of these procedures during a six-month period will be sufficient to avert harmful interference. Finally, we find that the public interest favors a grant of a temporary stay, given the short time before the new rules would be effective and the benefits of reducing the risk for harmful interference to existing BAS receive facilities.

7. With regard to SBE's assertion that adequate time must be provided for interference standards to be developed, we note that five months has already passed since the release of the *Report and Order* on November 13, 2002. Moreover, as we pointed out in the *Report and Order,* the existing baseline interference criteria for 13 GHz BAS in current § 74.638 are identical to those for FS in § 101.105. Also, the FS criteria in § 101.105(c) already provide the flexibility to follow generally acceptable good engineering practices, such as the existing interference criteria already in use by broadcasters and cited by SBE, and we would therefore be hesitant to

further delay prior coordination for the mix of signals needed to effect transition to DTV pending the development of more detailed criteria.

Ordering Clauses

8. Pursuant to sections 4(i) of the Communications Act, as amended, 47 U.S.C. 154(i), and 1.429 (k) of the Commission's rules, 47 CFR 1.429 (k), that the Society of Broadcast Engineers' Request for Temporary Stay of the rules *is granted,* suspending effect of these rules until October 16, 2003.

Federal Communications Commission.

Geraldine Matise,

Deputy Chief, Policy and Rules Division, Office of Engineering and Technology.

[FR Doc. 03–17569 Filed 7–10–03; 8:45 am]

BILLING CODE 6712–01–P

GENERAL SERVICES ADMINISTRATION

48 CFR Parts 501, 538, and 552

[GSAR Amendment 2003–02; GSAR Case No. 2002–G507]

RIN 3090–AH79

General Services Administration Acquisition Regulation; Consolidation of Industrial Funding Fee and Sales Reporting Clauses; Reduction in Amount of Industrial Funding Fee

AGENCIES: General Services Administration (GSA), Office of Acquisition Policy.

ACTION: Final rule.

SUMMARY: The General Services Administration (GSA) is amending the General Services Administration Acquisition Regulation (GSAR) to give GSA's Federal Supply Service (FSS) the unilateral right to change the percentage rate of the Industrial Funding Fee (IFF) in Multiple Award Schedule (MAS) contracts. The final rule also modifies and consolidates provisions of two existing GSA clauses that implement collection of the IFF by FSS on sales from all Federal Supply Schedule contracts. These clauses are Industrial Funding Fee and Contractor's Report of Sales. They have been consolidated into a single clause, Industrial Funding Fee and Sales Reporting. This new clause eliminates duplicative information from the preceding clauses, clarifies sales reporting procedures, and describes the procedures FSS will utilize to unilaterally effect future IFF rate changes.

Additionally, while the GSAR does not specify the percentage rate of the IFF, GSA's Federal Supply Service intends to lower the current IFF rate from 1.0 percent to 0.75 percent of reported sales, effective January 1, 2004. The final rule gives GSA's Federal Supply Service the authority to change the IFF after consulting with OMB prior to effecting any future changes.

The January 1, 2004, change will be implemented by means of a bilateral contract modification to be executed electronically. As consideration to Federal Supply Schedule contractors for any potential costs incurred as the direct result of this change, FSS will allow these vendors to continue to include the 1 percent IFF in their contract prices until December 31, 2003, but to forward to FSS an IFF of 0.75 percent for reported sales for the period of October 1, 2003, through December 31, 2003. Examples of the type of costs GSA anticipates contractors could incur include updating published prices and modifying accounting systems.

DATES: *Effective Date:* July 11, 2003.

Applicability Date: Solicitations issued and contracts awarded after July 1, 2003, shall comply with this change. Existing FSS contracts shall be modified by December 31, 2003.

FOR FURTHER INFORMATION CONTACT: Ms. Laurie Duarte, Regulatory Secretariat, Room 4035, GS Building, Washington, DC, 20405, (202) 501–4225, for information pertaining to status or publication schedules. For clarification of content, contact Vonda J. Sines, Procurement Analyst, at (703) 305–7542, or Linda Nelson, Procurement Analyst, at (202) 501–1900. Please cite GSAR Amendment 2003–02, GSAR case 2002–G507. The TTY Federal Relay Number for further information is 1–800–877–8973.

SUPPLEMENTARY INFORMATION:

A. Background

The General Services Administration published a proposed rule in the **Federal Register** at 68 FR 13212, March 18, 2003, with request for comments. Comments were received from 11 respondents, representing individual vendors as well as associations. GSA considered all comments and concluded that the proposed rule should be converted to a final rule with certain changes. Accordingly, the final rule:

1. Revises the clause at 552.238–74(a)(3) to make clear that reportable sales do not include those made under FAR Part 14 or non-FAR contracts, but do include sales to states and localities under Cooperative Purchasing authority.

2. Makes minor restructuring and editorial changes to the clause at 552.238–74 to provide a clearer intent of the clause language.

3. Adds the words ''and Sales Reporting'' to the clause at 552.215–71, Examination of Records by GSA (Multiple Award Schedules).

B. Summary and Discussion of Significant Public Comments

1. *IFF not currently included.* Five Schedule contractors indicated that they did not realize the IFF was intended to be passed on to their customers.

Response: GSA intends that the IFF cost be borne by the customer and merely collected and remitted by Schedule contractors. All current Multiple Award Schedule (MAS) contracts contain the clause at 552.238–76, Industrial Funding Fee. This clause requires that the IFF be included in the award price(s) and reflected in the total amount charged to ordering activities. GSA is consolidating and streamlining the current Industrial Funding Fee and Contractor's Report of Sales clauses to make doing business with the agency easier for Schedule contractors.

2. *Covered sales.* Three respondents stated that a sale should be subject to the IFF only if the order references the vendor's GSA Schedule or both the vendor and the purchasing agency agree that the purchase is being made under the vendor's MAS contract. They further commented that GSA should not require a vendor to provide the burden of proof that a sale was made outside the Schedule.

Response: Under current policy, GSA will consider the totality of the circumstances in determining if a sale is subject to the IFF. The final rule does not alter this policy, but recognizes various circumstances under which a sale would not be subject to the IFF (*e.g.*, contracts awarded under FAR parts 12, 13, 14, or 15, or a non-FAR contract). This clarification is designed to help ensure that sales conducted outside the authority of the Schedules program are not made subject to the IFF, even if the product or service being purchased is also available on a Schedule contract.

Since vendors always have the ability to make sales outside the Schedule, they need to establish with their customers at the time of order placement whether a sale is being conducted under or outside the Schedule. This distinction is important, since FSS, as a fee-for-service operation, must rely on the fees generated from Schedule sales to cover expenses associated with the MAS program.

3. *Consideration.* Five comments suggested that the costs of reprinting price lists/catalogs or of maintaining separate price lists are substantially greater than the consideration offered,

or that some unrecoverable vendor costs might not have been identified by GSA. Two respondents made suggestions regarding consideration to contractors for future IFF changes.

Response: The consideration GSA offered takes into account the types of costs that GSA believes vendors, especially small businesses, would reasonably be expected to encounter. In an effort to minimize contractor costs associated with this action, the final rule requires only that vendors update catalogs or price lists; vendors need not reprint them. Contractors may utilize stickers to announce price changes until their supply of catalogs is exhausted. With respect to future consideration, GSA will make this determination based on the totality of circumstances of any future IFF change.

4. *Implementation schedule.* Two comments suggested that GSA consider delaying the rule to permit further evaluation of a more reasonable implementation schedule or revise the proposed implementation schedule.

Response: GSA believes the final implementation schedule is reasonable given the underlying policy objectives of the program and based on informal dialogue with industry during the development of the rule. Industry will have been on notice of the coming change nearly 9 months before the changes take effect. To reduce disruption, the selected implementation schedule coincides with the beginning of a sales quarter.

5. *Advance notice.* Four respondents requested that Schedule contractors be notified a specified number of months (*e.g.*, 9 months) in advance of a change to the IFF.

Response: GSA believes that the imposition of a mandatory minimum wait period would place an inappropriate constraint on its ability to effectively manage the schedules program. However, GSA appreciates vendors' need for sufficient notice of IFF rate changes and intends to provide notice as far in advance as is practicable under the circumstances surrounding any future changes to the IFF.

6. *Affected sales.* Four respondents stated that the rule should (1) clarify that the change would be effective only on new sales after January 1, 2004, and (2) explain how delivery and task orders with extended delivery periods will be treated.

Response: As stated in this *Federal Register* notice, the IFF rate change applies to sales made on or after January 1, 2004. With respect to purchase orders with extended delivery and task orders with extended delivery/performance periods, contractors will be expected to remit 0.75 percent (rather than 1.0 percent) upon the effective date of the IFF rate change. However, prices in that order will stay the same through the remainder of performance. Orders may be renegotiated at the option of the applicable buying agency and the contractor. For example, a firm-fixed-price order placed on August 1, 2003, with a period of performance through July 31, 2004, would not need to be renegotiated during the order period, but the contractor would report and remit IFF at the reduced 0.75 percent rate beginning on January 1, 2004. Under certain circumstances, vendors will be expected to renegotiate Blanket Purchase Agreements (BPAs) with their customers in order to pass along a price reduction to the customer when the IFF is reduced. For example, if BPA pricing at award had been set at $100 per unit, it will have to be renegotiated. On the other hand, if the pricing had been discounted to be 10 percent below prices in the applicable MAS contract, there would be no need to renegotiate the BPA.

7. *Special pricing arrangements.* Two comments stated that the draft rule is not explicit enough on the subject of existing leases, leasebacks, and other contractual pricing conditions and could lead to future questions and possible misinterpretations involving the proper IFF collection and remittance on October 1.

Response: All leases established on or before December 31, 2003, will not have to be renegotiated. Renegotiation may occur at the option of the applicable buying agency and the contractor. Contractors will start remitting 0.75 percent vs. 1 percent IFF as of January 1, 2004. All new leases awarded on or after January 1, 2004, must contain the 0.75 percent IFF rate.

8. *Voluntary pass-through reduction.* One contractor suggested that GSA permit vendors, at their option, to continue charging the 1 percent IFF until the next negotiation for a price increase (or decrease), even though contractors would be remitting IFF to GSA at the reduced 0.75 percent rate.

Response: Reducing the IFF collected from vendors without requiring a corresponding reduction in the price charged to customers does not meet GSA's objective of helping customers meet mission needs at less expense to the taxpayer.

9. *Requiring IFF in contract prices.* One respondent stated that while GSA has the unilateral right to revise the IFF, it does not have the unilateral right to require contractors to modify their contracts to reflect any IFF that GSA might choose to establish.

Response: By executing the bilateral modification resulting from the rule, a contractor will agree to GSA's Federal Supply Service having the unilateral right to require that the contract contain prices that include the current IFF. To successfully manage the Schedules program, FSS needs to have the ability to manage its revenue and needs to retain this unilateral right. Upon implementation of any rate change, contractor prices will not move upward or downward; the published contract prices will change only according to the portion that is IFF.

10. *Web site content.* One comment suggested that in addition to utilizing an agency website to publish the current IFF, GSA should use all other available means to publish the rate and should maintain additional, historic IFF data on the website.

Response: The agency website will continuously post the current IFF rate, and the site's content will be periodically reviewed. FSS values its partnership with industry and related associations and will continue to work with them to take every practicable step to widely publicize any future changes.

11. *Transitioning electronic vendor registration.* One respondent recommended that FSS develop a transition plan to phase out the registration requirements under its Vendor Support system and develop a mechanism linked to Central Contractor Registration (CCR).

Response: While this comment does not pertain to the rule-making process, FSS appreciates the suggestion and will consider it in the future.

12. *Designated official.* One comment cited the inconsistency in wording within the clause and in the explanatory material in the draft rule regarding the official designated the authority to change the IFF rate. The respondent recommended more uniform language.

Response: Wherever possible in the clause and in other parts of the final rule, wording has been changed to use ''GSA's Federal Supply Service'' or ''FSS,'' as appropriate, as the authority for purposes of consistency.

13. *Clarifying clause wording.* One comment suggested deleting ''statutorily-based'' from paragraph (b)(2) of the clause at 552.238–74, stating that the wording is confusing, unnecessary, and creates the impression that the IFF amount is set by statute.

Response: This language has been deleted from the clause.

C. Executive Order 12866

This is not a significant regulatory action and, therefore, was not subject to 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.

D. Regulatory Flexibility Act

The General Services Administration certifies that this final rule will not have a significant economic impact on a substantial number of small entities within the meaning of the Regulatory Flexibility Act, 5 U.S.C. 601, *et seq.*, because the purpose of the rule is to assign to GSA the sole discretion to set the rate of the IFF and to clarify for contractors how to handle changes in the IFF. The rule also modifies and consolidates the provisions of two existing GSAR clauses in terms of sales reporting and procedures changes when the IFF rate changes. While some 78 percent of the Federal Supply Schedule contracts represent small business concerns, all contractors holding Federal Supply Schedules are already required to report quarterly sales and to periodically submit the Industrial Funding Fee to FSS. The final rule does not change these two requirements. It does require both small and large businesses to execute appropriate bilateral contract modifications and to make changes to published prices and accounting systems. GSA will mitigate the anticipated cost to contractors for these changes by offering consideration based on reported sales for the period of October 1, 2003, through December 31, 2003.

E. Paperwork Reduction Act

Prior clause 552.238–74, Contractor's Report of Sales, contained an information requirement subject to the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*) that was previously approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act and assigned control number 3090–0121. Prior clause 552.238–76, Industrial Funding Fee, also contains an information collection requirement that is subject to the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*). However, the estimated burden for this clause has been determined to be zero, and GSA has a blanket approval under control number 3090–0250 from OMB for information collections with a zero burden estimate.

The consolidation of information from these two clauses into a single clause results in no additional burden and, therefore, no additional approval from OMB is required.

List of Subjects in 48 CFR Parts 501, 538, and 552

Government procurement.

Dated: July 7, 2003.

David A. Drabkin,

Deputy Associate Administrator, Office of Acquisition Policy.

■ Therefore, GSA amends 48 CFR parts 501, 538, and 552 as set forth below:

■ 1. The authority citation for 48 CFR parts 501, 538, and 552 continues to read as follows:

Authority: 40 U.S.C. 486(c).

PART 501—GENERAL SERVICES ADMINISTRATION ACQUISITION REGULATION SYSTEM

501–106 [Amended]

■ 2. Amend section 501.106 at GSAR reference 552.238–74 by removing the OMB Control Number ''3090–0121'' and adding ''3090–0121 & 3090–0250'' in its place.

■ 3. Amend section 538.273 by revising paragraph (b)(1); and by removing paragraph (b)(3). The revised text reads as follows:

538.273 Contract clauses.

* * * * *

(b) * * *

(1) 552.238–74, Industrial Funding Fee and Sales Reporting.

* * * * *

PART 552—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

■ 4. Amend section 552.212–71 by revising the date of the clause; and in paragraph (b) by revising entry 552.238–74 to read as follows:

552.212–71 Contract Terms and Conditions Applicable to GSA Acquisition of Commercial Items.

* * * * *

Contract Terms and Conditions Applicable to GSA Acquisition of Commercial Items (July 2003)

* * * * *

(b) *Clauses.*

* * * * *

_____552.238–74 Industrial Funding Fee and Sales Reporting

* * * * *

552.212–72 [Amended]

■ 5. Amend section 552.212–72 by revising the date of the clause to read ''(July 2003)''; and by removing from the end of paragraph (b) ''_____552.238–76 Industrial Funding Fee''.

552.215–71 [Amended]

■ 6. Amend section 552.215–71 by revising the date of the clause to read ''(JULY 2003)''; and in the first sentence of the clause by adding ''and Sales Reporting'' after the word ''Fee''.

■ 7. Revise section 552.238–74 to read as follows:

552.238–74 Industrial Funding Fee and Sales Reporting.

As prescribed in 538.273(b)(1), insert the following clause:

Industrial Funding Fee and Sales Reporting (July 2003)

(a) *Reporting of Federal Supply Schedule Sales.* The Contractor shall report all contract sales under this contract as follows:

(1) The Contractor shall accurately report the dollar value, in U.S. dollars and rounded to the nearest whole dollar, of all sales under this contract by calendar quarter (January 1–March 31, April 1–June 30, July 1–September 30, and October 1–December 31). The dollar value of a sale is the price paid by the Schedule user for products and services on a Schedule task or delivery order. The reported contract sales value shall include the Industrial Funding Fee (IFF). The Contractor shall maintain a consistent accounting method of sales reporting, based on the Contractor's established commercial accounting practice. The acceptable points at which sales may be reported include—

(i) Receipt of order;

(ii) Shipment or delivery, as applicable;

(iii) Issuance of an invoice; or

(iv) Payment.

(2) Contract sales shall be reported to FSS within 30 calendar days following the completion of each reporting quarter. The Contractor shall continue to furnish quarterly reports, including ''zero'' sales, through physical completion of the last outstanding task order or delivery order of the contract.

(3) Reportable sales under the contract are those resulting from sales of contract items to authorized users unless the purchase was conducted pursuant to a separate contracting authority such as a Governmentwide Acquisition Contract (GWAC); a separately awarded FAR Part 12, FAR Part 13, FAR Part 14, or FAR Part 15 procurement; or a non-FAR contract. Sales made to state and local governments under Cooperative Purchasing authority shall be counted as reportable sales for IFF purposes.

(4) The Contractor shall electronically report the quarterly dollar value of sales, including ''zero'' sales, by utilizing the automated reporting system at an Internet website designated by the General Services Administration (GSA)'s Federal Supply Service (FSS). Prior to using this automated system, the Contractor shall complete contract registration with the FSS Vendor Support Center (VSC). The website address, as well as registration instructions and reporting procedures, will be provided at the time of award. The Contractor shall report sales separately for each National Stock Number (NSN), Special Item Number (SIN), or sub-item.

(5) The Contractor shall convert the total value of sales made in foreign currency to U.S. dollars using the ''Treasury Reporting Rates of Exchange'' issued by the U.S. Department of Treasury, Financial

Management Service. The Contractor shall use the issue of the Treasury report in effect on the last day of the calendar quarter. The report is available from Financial Management Service, International Funds Branch, Telephone: (202) 874–7994, Internet: *http://www.fms.treas.gov/intn.html.*

(b) The Contractor shall remit the IFF at the rate set by GSA's FSS.

(1) The Contractor shall remit the IFF to FSS in U.S. dollars within 30 calendar days after the end of the reporting quarter; final payment shall be remitted within 30 days after physical completion of the last outstanding task order or delivery order of the contract.

(2) The IFF represents a percentage of the total quarterly sales reported. This percentage is set at the discretion of GSA's FSS. GSA's FSS has the unilateral right to change the percentage at any time, but not more than once per year. FSS will provide reasonable notice prior to the effective date of the change. The IFF reimburses FSS for the costs of operating the Federal Supply Schedules Program and recoups its operating costs from ordering activities. Offerors must include the IFF in their prices. The fee is included in the award price(s) and reflected in the total amount charged to ordering activities. FSS will post notice of the current IFF at *http://72a.fss.gsa.gov/* or successor website as appropriate.

(c) Within 60 days of award, an FSS representative will provide the Contractor with specific written procedural instructions on remitting the IFF. FSS reserves the unilateral right to change such instructions from time to time, following notification to the Contractor.

(d) Failure to remit the full amount of the IFF within 30 calendar days after the end of the applicable reporting period constitutes a contract debt to the United States Government under the terms of FAR Subpart 32.6. The Government may exercise all rights under the Debt Collection Improvement Act of 1996, including withholding or setting off payments and interest on the debt (see FAR clause 52.232–17, Interest). Should the Contractor fail to submit the required sales reports, falsify them, or fail to timely pay the IFF, this is sufficient cause for the Government to terminate the contract for cause.

(End of clause)

552.238–76 [Reserved]

■ 8. Remove and reserve section 552.238–76.

552.238–79 [Amended]

■ 9. Amend section 552.238–79 by revising the date of the clause to read ''(July 2003)''; and in the first sentence of paragraph (c) of the clause by removing ''Contractor's Report of Sales'' and adding ''Industrial Funding Fee and Sales Reporting'' in its place.

[FR Doc. 03–17552 Filed 7–8–03; 3:24 pm]

BILLING CODE 6820–BR–P

Proposed Rules

Federal Register
Vol. 68, No. 133
Friday, July 11, 2003

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.

GENERAL SERVICES ADMINISTRATION

41 CFR Part 105–57

[GSPMR Case 2003–105–2]

RIN 3090–AH85

Administrative Wage Garnishment

AGENCY: Office of Finance, General Services Administration (GSA).

ACTION: Proposed rule.

SUMMARY: The General Services Administration (GSA) is proposing to amend its regulations to implement the administrative wage garnishment provisions contained in the Debt Collection Improvement Act of 1996 (DCIA). Wage garnishment is a process whereby an employer withholds amounts from an employee's wages and pays those amounts to the employee's creditor in satisfaction of a withholding order. The DCIA authorizes Federal agencies to administratively garnish the disposable pay of an individual to collect delinquent non-tax debts owed to the United States in accordance with regulations issued by the Secretary of the Treasury.

This part was previously titled Collection of Debts by Tax Refund Offset. Effective January 1, 1999, the Department of Treasury started to conduct the tax refund offset program as part of the centralized offset program, known as the Treasury Offset Program (TOP), operated by the Financial Management Service (FMS), a bureau of the Department of Treasury. Since GSA has a cross-servicing agreement with FMS, which includes the TOP, the collection of debts by tax refund offset is no longer valid and is rescinded and replaced with the new part regarding administrative wage garnishment.

DATES: Interested parties should submit comments in writing on or before September 9, 2003 to be considered in the formulation of a final rule.

ADDRESSES: Submit written comments to: General Services Administration, Office of the Chief Financial Officer (BCD), 1800 F Street, NW., Room 3121, ATTN: Michael J. Kosar, Washington, DC 20405. Submit electronic comments via the Internet to: *mike.kosar@gsa.gov* Please submit comments only and cite GSPMR Case 2003–105–2 in all correspondence related to this case.

FOR FURTHER INFORMATION CONTACT: The Regulatory Secretariat, Room 4035, GS Building, Washington, DC 20405, at (202) 501–4755 for information pertaining to status or publication schedules. For clarification of content, contact Mr. Michael J. Kosar, (202) 501–2029. Please cite GSPMR case 2003–105–2.

SUPPLEMENTARY INFORMATION:

A. Background

This rule is proposed to implement the wage garnishment provision in section 31001(o) of the Debt Collection Improvement Act of 1996 (DCIA), Pub. L. 104–134, 110 Stat. 1321–358 (Apr. 26, 1996), codified at 31 U.S.C. 3720D. Wage garnishment is a process whereby an employer withholds amounts from an employee's wages and pays those amounts to the employee's creditor in satisfaction of a withholding order. The DCIA authorizes Federal agencies to administratively garnish up to 15% of the disposable pay of a debtor to satisfy delinquent non-tax debt owed to the United States. Prior to the enactment of the DCIA, agencies were required to obtain a court judgment before garnishing the wages of non-Federal employees. Section 31001(o) of the DCIA pre-empts State laws that prohibit wage garnishment or otherwise govern wage garnishment procedures.

As authorized by the DCIA, a Federal agency collecting delinquent non-tax debt may administratively garnish a delinquent debtor's wages in accordance with regulations promulgated by the Secretary of the Treasury. The Financial Management Service (FMS), a bureau of the Department of the Treasury, is responsible for promulgating the regulations implementing this and other debt collection tools established by the DCIA.

In accordance with the requirements of the DCIA, this proposed rule establishes the following rules and procedures:

1. Notice

At least 30 days before GSA initiates garnishment proceedings, the Agency will give the debtor written notice informing him or her of the nature and amount of the debt, the intention of GSA to collect the debt through deductions from pay, and an explanation of the debtor's rights regarding the proposed action.

2. Rights of the Debtor

GSA will provide the debtor with an opportunity to inspect and copy records related to the debt, to establish a repayment agreement, and to receive a hearing concerning the existence and/or amount of the debt and/or the terms of a repayment schedule. A hearing will be held prior to the issuance of a withholding order if the debtor's request is received timely. For hearing requests that are not received in the specified time frame, GSA will not delay issuance of the withholding order prior to conducting a hearing. GSA will not garnish the wages of a debtor who has been involuntarily separated from employment until that individual has been reemployed continuously for at least 12 months. The debtor bears the burden of informing GSA of the circumstances surrounding an involuntary separation from employment.

3. Employer's Responsibilities

GSA will send to the employer of a delinquent debtor a wage garnishment order directing that the employer pay a portion of the debtor's wages to GSA. This proposed rule requires the debtor's employer to certify certain payment information about the debtor. Employers will not be required to vary their normal pay cycles in order to comply with the garnishment order.

The DCIA prohibits employers from taking disciplinary actions against the debtor based on the fact that the debtor's wages are subject to administrative garnishment. In addition, the DCIA authorizes GSA to sue an employer for amounts not properly withheld from the wages payable to the debtor.

B. Executive Order 12866

This rule is not a significant regulatory action as defined in Executive Order 12866. It is hereby certified this regulation, including the certification referenced in this proposed rule (see § 105–57.007 of this part), will not have a significant economic impact on a substantial number of small entities. Although a substantial number

of small entities will be subject to this regulation and to the certification requirement in this rule, the requirements will not have a significant economic impact on these entities. Employers of delinquent debtors must certify certain information about the debtor such as the debtor's employment status and earnings. This information is contained in the employer's payroll records. Therefore, it will not take a significant amount of time or result in a significant cost for an employer to complete the certification form. Even if an employer is served withholding orders on several employees over the course of a year, the cost imposed on the employer to complete the certifications would not have a significant economic impact on that entity. Employers are not required to vary their normal pay cycles in order to comply with a withholding order issued pursuant to this rule.

C. Regulatory Flexibility Act

It is hereby certified this regulation will not have a significant economic impact on a substantial number of small entities because the regulation either (1) results in greater flexibility for GSA to streamline debt collection regulations, or (2) reflects the statutory language contained in the DCIA. Accordingly, a Regulatory Flexibility Analysis is not required.

D. Executive Order 13132

This regulation will not have a substantial direct effect on the states, on the relationship between the national government and the states, or on distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 13132, it is determined this regulation does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

E. Unfunded Mandates Reform Act of 1995

This regulation will not result in the expenditure by state, local and tribal governments, in the aggregate, or by the private sector, of $100 million or more in any one (1) year, and it will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

F. Small Business Regulatory Enforcement Fairness Act of 1996

This rule is not a major rule as defined by section 251 of the Small Business Regulatory Enforcement Act, 5 U.S.C. 804. This 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 on the ability of United States-based companies to compete with foreign-based companies in domestic or export markets.

G. Paperwork Reduction Act

This rule does not contain information collection requirements that require approval by the Office of Management and Budget under the Paperwork Reduction Act, 44 U.S.C. 3507 *et seq.*

List of Subjects 41 CFR Part 105–57

Claims, Government public contracts and property management, income taxes.

Dated: July 2, 2003.

Kathleen M Turco,

Chief Financial Officer, Office of the Chief Financial Officer.

For the reasons set out in the preamble, GSA proposes to amend 41 CFR part 105–57 as follows:

CHAPTER 105 [Amended]

1. Revise part 105–57 to read as follows:

PART 105–57—ADMINISTRATIVE WAGE GARNISHMENT

Sec.

105–57.001 Purpose, authority and scope.
105–57.002 Definitions.
105–57.003 General rule.
105–57.004 Notice requirements.
105–57.005 Hearing.
105–57.006 Wage garnishment order.
105–57.007 Certification by employer.
105–57.008 Amounts withheld.
105–57.009 Exclusions from garnishment.
105–57.010 Financial hardship.
105–57.011 Ending garnishment.
105–57.012 Actions prohibited by the employer.
105–57.013 Refunds.
105–57.014 Right of action.

Authority: 5 U.S.C. §§ 552–553, 31 U.S.C. 3720D, 31 CFR part 285.11.

§ 105–57.001 Purpose, authority and scope.

(a) This part provides standards and procedures for GSA to collect money from a debtor's disposable pay by means of administrative wage garnishment to satisfy delinquent non-tax debt owed to the United States.

(b) These standards and procedures are authorized under the wage garnishment provisions of the Debt Collection Improvement Act of 1996, codified at 31 U.S.C. 3720D, and Department of Treasury Wage Garnishment Regulations at 31 CFR 285.11.

(c) *Scope.* (1) This part applies to any GSA program that gives rise to a delinquent non-tax debt owed to the United States and that pursues recovery of such debt.

(2) This part will apply notwithstanding any provision of State law.

(3) Nothing in this part precludes the compromise of a debt or the suspension or termination of collection action in accordance with applicable law. See, for example, the Federal Claims Collection Standards (FCCS), 31 CFR parts 900 through 904.

(4) The receipt of payments pursuant to this part does not preclude GSA from pursuing other debt collection remedies, including the offset of Federal payments to satisfy delinquent non-tax debt owed to the United States. GSA may pursue such debt collection remedies separately or in conjunction with administrative wage garnishment.

(5) This part does not apply to the collection of delinquent non-tax debt owed to the United States from the wages of Federal employees from their Federal employment. Federal pay is subject to the Federal salary offset procedures set forth in 5 U.S.C. 5514 and other applicable laws. GSA standards and procedures for offsetting Federal wage payments are stated in 41 CFR part 105–56.

(6) Nothing in this part requires GSA to duplicate notices or administrative proceedings required by contract or other laws or regulations.

§ 105–57.002 Definitions.

(a) *Administrative offset,* as defined in 31 U.S.C. 3701(a)(1), means withholding funds payable by the United States (including funds payable by the United States on behalf of a State government) to, or held by the United States for, a person to satisfy a claim.

(b) *Business day* means Monday through Friday, excluding Federal legal holidays. For purposes of computation, the last day of the period will be included unless it is a Federal legal holiday.

(c) *Day* means calendar day. For purposes of computation, the last day of the period will be included unless it is a Saturday, a Sunday, or a Federal legal holiday.

(d) *Debtor* means an individual who owes a delinquent non-tax debt to the United States.

(e) *''Delinquent'' or ''past-due '' non-tax debt* means any non-tax debt that has not been paid by the date specified in GSA's initial written demand for payment or applicable agreement or

instrument (including a post-delinquency payment agreement), unless other satisfactory payment arrangements have been made.

(f) *Disposable pay* means that part of the debtor's compensation (including, but not limited to, salary, bonuses, commissions, and vacation pay) from an employer remaining after the deduction of health insurance premiums and any amounts required by law to be withheld. For purposes of this part, ''amounts required by law to be withheld'' include amounts for deductions such as social security taxes and withholding taxes, but do not include any amount withheld pursuant to a court order.

(g) *Employer* means a person or entity that employs the services of others and that pays their wages or salaries. The term employer includes, but is not limited to, State and local Governments, but does not include an agency of the Federal Government as defined by 31 CFR Part 285.11(c).

(h) *Evidence of service* means information retained by GSA indicating the nature of the document to which it pertains, the date of submission of the document, and to whom the document is being submitted. Evidence of service may be retained electronically or otherwise, so long as the manner of retention is sufficient for evidentiary purposes.

(i) *Financial hardship* means an inability to meet basic living expenses for goods and services necessary for the survival of the debtor and his or her spouse and dependents. See § 105–57.010 of this part.

(j) For the purposes of the standards in this part, unless otherwise stated, the term ''Administrator'' refers to the Administrator of General Services or the Administrator's delegate.

(k) For the purposes of the standards in this part, the terms ''claim'' and ''debt'' are synonymous and interchangeable. They refer to an amount of money, funds, or property that has been determined by GSA to be due the United States from any person, organization, or entity, except another Federal agency, from sources which include loans insured or guaranteed by the United States and all other amounts due the United States from fees, leases, rents, royalties, services, sales of real or personal property, overpayments, penalties, damages, interest, fines and forfeitures and all other similar sources, including debt administered by a third party as an agent for the Federal Government. For the purposes of administrative offset under 31 U.S.C. 3716, the terms ''claim'' and ''debt'' include an amount of money, funds, or property owed by a person to a State (including past-due support being enforced by a State), the District of Columbia, American Samoa, Guam, the United States Virgin Islands, the Commonwealth of the Northern Mariana Islands, or the Commonwealth of Puerto Rico.

(l) For the purposes of the standards in this part, unless otherwise stated, the terms ''GSA'' and ''Agency'' are synonymous and interchangeable.

(m) For the purposes of the standards in this part, unless otherwise stated, ''Secretary'' means the Secretary of the Treasury or the Secretary's delegate.

(n) *Garnishment* means the process of withholding amounts from an employee's disposable pay and the paying of those amounts to GSA in satisfaction of a withholding order.

(o) *Hearing* means a review of the documentary evidence concerning the existence and/or amount of a debt, and/or the terms of a repayment schedule, provided such repayment schedule is established other than by a written agreement entered into pursuant to this part. If the hearing official determines that the issues in dispute cannot be resolved solely by review of the written record, such as when the validity of the debt turns on the issue of credibility or veracity, an oral hearing may be provided.

(p) *Hearing official* means a Board Judge of the GSA Board of Contract Appeals.

(q) *Withholding order* means ''Wage Garnishment Order (SF 329B)'', issued by GSA. For purposes of this part, the terms '''wage garnishment order''' and ''garnishment order''' have the same meaning as ''withholding order.''

(r) In this part, words in the plural form shall include the singular and vice versa, and words signifying the masculine gender shall include the feminine and vice versa. The terms ''includes'' and ''including'' do not exclude matters not listed but do include matters that are in the same general class.

§ 105–57.003 General rule.

Whenever GSA determines a delinquent debt is owed by an individual, the Agency may initiate administrative proceedings to garnish the wages of the delinquent debtor.

§ 105–57.004 Notice requirements.

(a) At least 30 days before the initiation of garnishment proceedings, GSA will send, by first class mail, overnight delivery service, or hand delivery to the debtor's last known address a written notice informing the debtor of—

(1) The nature and amount of the debt;

(2) The intention of GSA to initiate proceedings to collect the debt through deductions from pay until the debt and all accumulated interest, penalties and administrative costs are paid in full; and

(3) The debtor's rights, including those set forth in paragraph (b) of this section, and the time frame within which the debtor may exercise his or her rights.

(b) The debtor will be afforded the opportunity:

(1) To inspect and copy Agency records related to the debt;

(2) To enter into a written repayment agreement with GSA under terms agreeable to the Agency; and

(3) To request a hearing in accordance with § 105–57.005 of this part concerning the existence and/or amount of the debt, and/or the terms of the proposed repayment schedule under the garnishment order. However, the debtor is not entitled to a hearing concerning the terms of the proposed repayment schedule if these terms have been established by written agreement under paragraph (b)(2) of this section.

(c) The notice required by this section may be included with GSA's demand letter required by 41 CFR 105–55.010.

(d) GSA will keep a copy of the evidence of service indicating the date of submission of the notice. The evidence of service may be retained electronically so long as the manner of retention is sufficient for evidentiary purposes.

§ 105–57.005 Hearing.

(a) GSA will provide a hearing, which at the hearing official's option may be oral or written, if within fifteen (15) business days of submission of the notice by GSA, the debtor submits a signed and dated written request for a hearing, to the official named in the notice, concerning the existence and/or amount of the debt, and/or the terms of the repayment schedule (for repayment schedules established other than by written agreement under § 105–57.004(b)(2) of this part). A copy of the request for a hearing must also be sent to the GSA Board of Contract Appeals at the address indicated in paragraph (b)(2) of this section.

(b) Types of hearing or review.

(1) For purposes of this section, whenever GSA is required to afford a debtor a hearing, the hearing official will provide the debtor with a reasonable opportunity for an oral hearing when he/she determines that the issues in dispute cannot be resolved by review of the documentary evidence, for example, when the validity of the

claim turns on the issue of credibility or veracity.

(2) If the hearing official determines that an oral hearing is appropriate, he/she will establish the time and location of the hearing. An oral hearing may, at the debtor's option, be conducted either in-person or by telephone conference. In-person hearings will be conducted in the hearing officials office located at GSA Central Office, 1800 F St., NW., Washington, DC 20405, or at another location designated by the hearing official. All personal and travel expenses incurred by the debtor in connection with an in-person hearing will be borne by the debtor. All telephonic charges incurred during a hearing will be the responsibility of GSA.

(3) The debtor may represent himself or herself or may be represented by another person of his or her choice at the hearing. GSA will not compensate the debtor for representation expenses, including hourly fees for attorneys, travel expenses, or costs for reproducing documents.

(4) In those cases when an oral hearing is not required by this section, the hearing official will nevertheless conduct a ''paper hearing'', that is, the hearing official will decide the issues in dispute based upon a review of the written record. The hearing official will establish a reasonable deadline for the submission of evidence.

(c) Subject to paragraph (k) of this section, if the debtor's written request is received by GSA on or before the 15th business day after the submission of the notice described in § 105–57.004(a) of this part, the Agency will not issue a withholding order under § 105–57.006 of this part until the debtor has been provided the requested hearing and a decision in accordance with paragraphs (h) and (i) of this section has been rendered.

(d) If the debtor's written request for a hearing is received by GSA after the 15th business day following the mailing of the notice described in § 105–57.004(a) of this part, GSA may consider the request timely filed and provide a hearing if the debtor can show that the delay was because of circumstances beyond his or her control. However, GSA will not delay issuance of a withholding order unless the Agency determines that the delay in filing the request was caused by factors over which the debtor had no control, or GSA receives information that the Agency believes justifies a delay or cancellation of the withholding order.

(e) After the debtor requests a hearing, the hearing official will notify the debtor of:

(1) The date and time of a telephonic hearing;

(2) The date, time, and location of an in-person oral hearing; or

(3) The deadline for the submission of evidence for a written hearing.

(f) Burden of proof. (1) GSA will have the burden of establishing the existence and/or amount of the debt.

(2) Thereafter, if the debtor disputes the existence and/or amount of the debt, the debtor must prove by a preponderance of the evidence that no debt exists or that the amount of the debt is incorrect. In addition, the debtor may present evidence that the terms of the repayment schedule are unlawful, would cause a financial hardship to the debtor, or that collection of the debt may not be pursued due to operation of law.

(g) The hearing official will maintain a written transcript of any hearing provided under this section. The transcript will be made available to either party in the event of an appeal under the Administrative Procedure Act, 5 U.S.C. 701–706. A hearing is not required to be a formal evidentiary-type hearing, however, witnesses who testify in oral hearings will do so under oath or affirmation.

(h) The hearing official will issue a written opinion stating his or her decision, as soon as practicable, but not later than sixty (60) days after the date on which the request for such hearing was received by GSA. If the hearing official is unable to provide the debtor with a hearing and render a decision within 60 days after the receipt of the request for such hearing—

(1) GSA will not issue a withholding order until the hearing is held and a decision rendered; or

(2) If GSA had previously issued a withholding order to the debtor's employer, the Agency will suspend the withholding order beginning on the 61st day after the receipt of the hearing request and continuing until a hearing is held and a decision is rendered.

(i) The written decision will include—

(1) A summary of the facts presented;

(2) The hearing official's findings, analysis and conclusions; and

(3) The terms of any repayment schedules, if applicable.

(j) The hearing official's decision will be the final Agency action for the purposes of judicial review under the Administrative Procedure Act (5 U.S.C. 701 *et seq.*).

(k) In the absence of good cause shown, a debtor who fails to appear at a hearing scheduled pursuant to paragraph (e) of this section, or to provide written submissions within the time set by the hearing official, will be deemed to have waived his or her right to appear and present evidence.

§ 105–57.006 Wage garnishment order.

(a) Unless GSA receives information it believes justifies a delay or cancellation of the withholding order, the Agency will send, by first class mail, overnight delivery service or hand delivery, a SF 329A (Letter to Employer & Important Notice to Employer), a SF 329B (Wage Garnishment Order), a SF 329C (Wage Garnishment Worksheet), and a SF 329D (Employer Certification), to the debtor's employer—

(1) Within 30 days after the debtor fails to make a timely request for a hearing (*i.e.,* within 15 business days after the mailing of the notice described in § 105–57.004(a) of this part), or

(2) If a timely request for a hearing is made by the debtor, within 30 days after a final decision is made by the hearing official to proceed with garnishment.

(b) The withholding order sent to the employer under paragraph (a) of this section will contain the signature of, or the image of the signature of, the Administrator or his or her delegate. The order will contain only the information necessary for the employer to comply with the withholding order. Such information includes the debtor's name, address, and social security number, as well as instructions for withholding and information as to where payments are to be sent.

(c) GSA will retain a copy of the evidence of service indicating the date of submission of the order. The evidence of service may be retained electronically so long as the manner of retention is sufficient for evidentiary purposes.

§ 105–57.007 Certification by employer.

The employer must complete and return the SF 329D (Employer Certification) to GSA within the time-frame prescribed in the instructions to the form. The certification will address matters such as information about the debtor's employment status and disposable pay available for withholding.

§ 105–57.008 Amounts withheld.

(a) After receipt of the garnishment order issued under this part, the employer shall deduct from all disposable pay paid to the applicable debtor during each pay period the amount of garnishment described in paragraph (b) of this section. The employer may use the SF 329C (Wage Garnishment Worksheet) to calculate the amount to be deducted from the debtor's disposable pay.

(b) Subject to the provisions of paragraphs (c) and (d) of this section, the amount of garnishment will be the lesser of—

(1) The amount indicated on the garnishment order up to 15% of the debtor's disposable pay; or

(2) The amount set forth in 15 U.S.C. 1673(a)(2) (Restriction on Garnishment), which is the amount by which a debtor's disposable pay exceeds an amount equivalent to thirty times the minimum wage. *See* 29 CFR 870.10.

(c) When a debtor's pay is subject to withholding orders with priority, the following will apply:

(1) Unless otherwise provided by Federal law, withholding orders issued under this part will be paid in the amounts set forth under paragraph (b) of this section and will have priority over other withholding orders which are served later in time. Notwithstanding the foregoing, withholding orders for family support will have priority over withholding orders issued under this part.

(2) If amounts are being withheld from a debtor's pay pursuant to a withholding order served on an employer before a withholding order issued pursuant to this part, or if a withholding order for family support is served on an employer at any time, the amounts withheld pursuant to the withholding order issued under this part will be the lesser of—

(i) The amount calculated under paragraph (b) of this section, or

(ii) An amount equal to 25% of the debtor's disposable pay less the amount(s) withheld under the withholding order(s) with priority.

(3) If a debtor owes more than one debt to GSA, the Agency may issue multiple withholding orders provided the total amount garnished from the debtor's pay for such orders does not exceed the amount set forth in paragraph (b) of this section.

(d) An amount greater than that set forth in paragraphs (b) and (c) of this section may be withheld upon the written consent of the debtor.

(e) The employer shall promptly pay to GSA all amounts withheld in accordance with the withholding order issued pursuant to this part.

(f) An employer will not be required to vary its normal pay and disbursement cycles in order to comply with the withholding order.

(g) Any assignment or allotment by an employee of his or her earnings will be void to the extent it interferes with or prohibits execution of the withholding order issued under this part, except for any assignment or allotment made pursuant to a family support judgment or order.

(h) The employer will withhold the appropriate amount from the debtor's wages for each pay period until the employer receives notification from GSA to discontinue wage withholding. The garnishment order will indicate a reasonable period of time within which the employer is required to commence wage withholding, usually the first payday after the employer receives the order. However, if the first payday is within ten (10) days after the receipt of the garnishment order, the employer may begin deductions on the second payday.

(i) Payments received through a wage garnishment order will be applied in the following order:

(1) To outstanding penalties.

(2) To administrative costs incurred by GSA to collect the debt.

(3) To interest accrued on the debt at the rate established by the terms of the obligation under which it arose or by applicable law.

(4) To outstanding principal.

§ 105–57.009 Exclusions from garnishment.

GSA will not garnish the wages of a debtor who it knows has been involuntarily separated from employment until the debtor has been reemployed continuously for at least 12 months. The debtor has the burden of informing GSA of the circumstances surrounding an involuntary separation from employment.

§ 105–57.010 Financial hardship.

(a) A debtor whose wages are subject to a wage withholding order under this part, may, at any time, request a review by GSA of the amount garnished, based on materially changed circumstances such as disability, divorce, or catastrophic illness which result in financial hardship.

(b) A debtor requesting a review under paragraph (a) of this section shall submit the basis for claiming the current amount of garnishment results in a financial hardship to the debtor, along with supporting documentation.

(c) If a financial hardship is found, GSA will downwardly adjust, by an amount and for a period of time agreeable to the Agency, the amount garnished to reflect the debtor's financial condition. GSA will notify the employer of any adjustments to the amounts to be withheld.

§ 105–57.011 Ending garnishment.

(a) Once GSA has fully recovered the amounts owed by the debtor, including interest, penalties, and administrative costs consistent with the FCCS, the Agency will send the debtor's employer notification to discontinue wage withholding.

(b) At least annually, GSA will review its debtors' accounts to ensure that garnishment has been terminated for accounts that have been paid in full.

§ 105–57.012 Actions prohibited by the employer.

An employer may not discharge, refuse to employ, or take disciplinary action against the debtor due to the issuance of a withholding order under this part. See 31 U.S.C. 3720D(e).

§ 105–57.013 Refunds.

(a) If a hearing official, at a hearing held pursuant to § 105–57.005 of this part, determines that a debt is not legally due and owing to the United States, GSA will promptly refund any amount collected by means of administrative wage garnishment.

(b) Unless required by Federal law or contract, refunds under this part will not bear interest.

§ 105–57.014 Right of action.

GSA may sue any employer for any amount that the employer fails to withhold from wages owed and payable to an employee in accordance with §§ 105–057.006 and 105–57.008 of this part, plus attorney's fees, costs, and if applicable, punitive damages. However, a suit may not be filed before the termination of the collection action involving a particular debtor, unless earlier filing is necessary to avoid expiration of any applicable statute of limitations period. For purposes of this part, ''termination of the collection action'' occurs when GSA has terminated collection action in accordance with the FCCS or other applicable standards. In any event, termination of the collection action will have been deemed to occur if GSA has not received any payments to satisfy the debt from the particular debtor whose wages were subject to garnishment, in whole or in part, for a period of one (1) year.

[FR Doc. 03–17400 Filed 7–10–03; 8:45 am]

BILLING CODE 6820–34–P

Notices

Federal Register
Vol. 68, No. 133
Friday, July 11, 2003

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.

ADVISORY COUNCIL ON HISTORIC PRESERVATION

Final Amendment to the Army Alternate Procedures

AGENCY: Advisory Council on Historic Preservation.

ACTION: Notice of adoption of amendment to the Army alternate procedures.

SUMMARY: On June 30, 2003, the Advisory Council on Historic Preservation (''ACHP'') adopted an amendment to the Army Alternate Procedures (''AAP'') setting a process for technical and administrative amendments to the AAP.

DATES: The approved amendment went into effect on June 30, 2003.

FOR FURTHER INFORMATION CONTACT: Mr. David Berwick, Army Program Manager, Advisory Council on Historic Preservation, 202–606–8531.

SUPPLEMENTARY INFORMATION: A notice of intent to amend the AAP was published in the **Federal Register** on Friday, May 16, 2003 (68 FR 95). No comments were received from the general public during the 30-day comment period. Accordingly, no changes were made to the original proposed language.

The approved amendment will allow the Chairman of the ACHP to approve administrative and technical amendments to the AAP:

7.1(d) Upon request by Headquarters, Department of the Army, the Council may adopt technical and/or administrative amendments to the Army Alternate Procedures. Such amendments will take effect upon approval by the Council's Chairman. The Council shall publish in the **Federal Register** a notice of such amendment within 30 days after their approval. Technical and administrative amendments shall not modify the role of consulting parties in the Army Alternate Procedures.

Authority: 36 CFR 800.14(a)

Dated: July 7, 2003.

Sharon Conway,

Acting Executive Director.

[FR Doc. 03–17544 Filed 7–10–03; 8:45 am]

BILLING CODE 4310–10–M

DEPARTMENT OF AGRICULTURE

Forest Service

Sheep Creek Fire Salvage, Beaverhead-Deerlodge National Forest, Beaverhead County, Montana

AGENCY: Forest Service, USDA.

ACTION: Notice of intent to prepare an environmental impact statement.

SUMMARY: The USDA, Forest Service, will prepare an environmental impact statement (EIS) to disclose the environmental effects of the salvage harvest of timber killed as a result of fire in the Canyon Creek, Boulder Creek, Cascade Creek, Sage Creek, and Runaway Creek drainages (herein referred to as the Sheep Creek Project). The project area is located 15 miles west of Wisdom, Montana, north of State Highway 43, just west of the Placer Creek Road. The project area is outside of inventoried roadless areas.

DATES: Comments concerning the scope of the analysis must be postmarked within 30 days of the date of publishing of this legal notice. The draft environmental impact statement is expected February, 2004 and the final environmental impact statement is expected June of 2004.

ADDRESSES: Written comments concerning this notice or a request to be placed on the project mailing list should be addressed to Chris Tootell, TEAMS, 200 East Broadway, suite 251, Missoula, Montana, 59807. Comments may also be sent via e-mail to *r1_b–d_comments@fs.fed.us.* (Please not that there is a ''one'' after the letter r, not an ''L.'') The subject line in the e-mail message should contain the title ''Sheep Creek Fire Salvage Project.'' If you choose to comment by e-mail, please include your name and regular mailing address with the comment. Comments may also be sent via facsimile to (406) 689–3245, C/O Dennis Havig, Wisdom Ranger District.

All comments, including names and addresses when provided, are placed in the record and are available for public inspection and copying. The public may inspect comments received at the Wisdom Ranger District, Wisdom, MT. Visitors are encouraged to call ahead to (406) 689–3243 to facilitate entry to the building.

FOR FURTHER INFORMATION CONTACT: Chris Tootell, Environmental Resource Coordinator, TEAMS Enterprise unit, USDA Forest Service (406) 329–3459. Individuals who use telecommunication devices for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 between 8 a.m. to 8 p.m., Eastern Standard Time, Monday through Friday.

SUPPLEMENTARY INFORMATION: The proposed project area is located within sections 4, 5, 6, 7, 8, 9 & 18, T.2S., R.17W., and sections 1, 12 and 13. T.2S., R.18W.

Purpose and Need for Action

The purpose and need for the proposed action is to move toward the desired conditions as described in the Beaverhead National Forest Land and Resource Management Plan (LRMP). The proposed action is located on lands classified as ''available and suitable for timber production'' (LRMP, p. III–48 and III–63). Congress has recognized the treatments; the estimated timber volume to make available from the project area; the estimated amount of temporary road construction needed; and mitigation measures and monitoring requirements.

Scoping Process

Public participation is important to this analysis. Part of the goal of public involvement is to identify additional issues and to refine the general, tentative issues. The Beaverhead-Deerlodge National Forest has developed a listing of individuals and organizations that have expressed an interest in being informed of and providing input to vegetation management and fuel redcution projects. This list of individuals and organizations include private citizens, businesses, various organizations, Native American groups, and federal, state and county agencies. All of these contacts will be sent the initial scoping document.

Preliminary Issues

The following list of preliminary issues was developed for the project area by the Forest Service

Interdisciplinary Team (ID Team). This list was developed after review of issues from previous post fire management projects, including previous public involvement, and specific internal agency scoping. General categories have been used to focus key topics. This list will be amended and/or expanded after review of the Sheep Creek Project public comments. During the analysis, alternatives to the proposed action will be developed responding to the final list of issues. In response to the issues, the alternatives developed may include different levels of activity and may include different prescriptions.

- Timber sale value.
- Potential reduction of big game ''security cover'' within harvest units may result in a need for a nonsignificant site specific Forest Plan amendment for elk effective cover standards.
- Loss of future potential Lynx denning habitat by removal of heavy fuels.
- Potential for introduction and spread of noxious weeds from logging and log hauling.
- Potential soil disturbance.
- Residual fuel loads exceeding desired thresholds within treatment units.
- Potential for introduction of sediment to streams impacting fish species.
- Loss of habitat for snag dependent and cavity nesting species.

Comment Requested

This notice of intent initiates the scoping process which guides the development of the draft environmental impact statement, including the identification of the range of alternatives to be considered. While public participation is strictly optional at this stage, the Forest Service believes that it is important to give reviewers notice of several court rulings related to public participation in the subsequent environmental review process. First, reviewers of draft statements must structure their participation in the environmental review of the proposal so that it is meaningful and alerts an agency to the reviewer's position and contentions. *Vermont Yankee Nuclear Power Corp.* v. *NRDC,* 435 U.S. 519, 553 (1978). Also, environmental objections that could be raised at the draft environmental impact statement stage but that are not raised until after completion of the final environmental impact statement may be waived or dismissed by the courts. *City of Angoon* v. *Hodel,* 803 F.2d 1016, 1022 (9th Cir. 1986) and *Wisconsin Heritages, Inc.* v. *Harris,* 490 F. Supp. 1334, 1338 (E.D. Wis. 1980).

Because of these court rulings, it is very important that those interested in this proposed action participate by the close of the 45 day draft environmental impact statement comment period so that substantive comments and objections are made available to the Forest Service at a time when it can meaningfully consider them and respond to them in the final environmental impact statement. To assist the Forest Service in identifying and considering issues and concerns on the proposed action, comments on the draft environmental impact statement should be as specific as possible. It is also helpful if comments refer to specific pages or chapters of the draft statement. Comments also may address the adequacy of the draft environmental impact statement or the merits of the alternatives formulated and discussed in the statement. In addressing these points, reviewers may wish to refer to the Council on Environmental Quality regulations which implement the procedural provisions of the National Environmental Policy Act at 40 CFR 1503.3.

Dated: July 3, 2003.

Thomas K. Reilly,

Forest Supervisor.

[FR Doc. 03–17559 Filed 7–10–03; 8:45 am]

BILLING CODE 3410–11–M

DEPARTMENT OF AGRICULTURE

Forest Service

Meeting of the Land Between The Lakes Advisory Board

AGENCY: Forest Service, USDA.

ACTION: Notice of meeting.

SUMMARY: The Land Between The Lakes Advisory Board will hold a meeting on Wednesday, July 30, 2003. Notice of this meeting is given under the Federal Advisory Committee Act, 5 U.S.C. App.2.

The meeting agenda includes the following:

(1) Welcome/Introductions/Agenda.

(2) LBL Land and Resource Management Plan (LRMP).

(3) Board Discussion of Comments Received.

(4) Update on LBL Activities.

(5) Environmental Education Update.

The meeting is open to the public. Written comments are invited and may be mailed to: William P. Lisowsky, Area Supervisor, Land Between The Lakes, 100 Van Morgan Drive, Golden Pond, Kentucky 42211. Written comments must be received at Land Between The Lakes by July 22, 2003, in order for copies to be provided to the members at the meeting. Board members will review written comments received, and at their request, oral clarification may be requested at a future meeting.

DATES: The meeting will be held on Wednesday, July 30, 2003, 9 a.m. to 3 p.m., CDT.

ADDRESSES: The meeting will be held at Kentucky Dam Village State Resort Park, Village Green Meeting Room, Gilbertsville, KY, and will be open to the public.

FOR FURTHER INFORMATION CONTACT: Sharon Byers, Advisory Board Liaison, Land Between The Lakes, 100 Van Morgan Drive, Golden Pond, Kentucky 42211, 270–924–2002.

SUPPLEMENTARY INFORMATION: None.

Dated: July 7, 2003.

William P. Lisowsky,

Area Supervisor, Land Between The Lakes.

[FR Doc. 03–17558 Filed 7–10–03; 8:45 am]

BILLING CODE 3410–11–P

DEPARTMENT OF AGRICULTURE

National Agricultural Statistics Service

Notice of Intent to Discontinue an Information Collection

AGENCY: National Agricultural Statistics Service, USDA.

ACTION: Notice.

SUMMARY: This notice announces the intent of the National Agricultural Statistics Service (NASS) to discontinue information collection for the Monthly Hogs and Pigs Survey.

DATES: The Monthly Hogs and Pigs Report will be terminated on September 9, 2003.

ADDRESSES: Not open for comment.

FOR FURTHER INFORMATION CONTACT: Contact Dan Kerestes, Chief, Livestock Branch, National Agricultural Statistics Service, U.S. Department of Agriculture, Room 6435 South Building, 1400 Independence Avenue SW., Washington, DC 20250–2000, (202) 720–3570.

SUPPLEMENTARY INFORMATION:

Title: Monthly Hog Survey.

OMB Control Number: 0535–0241.

Expiration Date of Approval: 10/31/2003.

Type of Request: Intent to Discontinue an Information Collection.

Abstract: The primary objective of the National Agricultural Statistics Service is to prepare and issue State and National estimates of crop and livestock production. The Monthly Hog Surveys obtain basic agricultural statistics on

Hogs and Pigs inventory from producers throughout the nation. Data are gathered on total breeding herd inventory, number of sows farrowed, pigs weaned, and number of sows bred the previous month.

Authorized funding for implementation of the Monthly Hog Survey was specified in Title IX—Livestock Mandatory Reporting, Subtitle C—Related Swine Reporting Provisions, Section 931, Improvements of Hogs and Pigs Inventory Report, which passed as part of the Agriculture, Rural Development, Food and Drug Administration, and Related Agencies the Appropriation Act, 2000. The survey was requested by the National Pork Producers Council and others in the hog industry to aid in forecasting pig production and to provide the pork industry with more knowledge of and quicker realization of market conditions. The Monthly Hogs and Pigs Survey questionnaire was developed to be consistent with the Quarterly Hogs and Pigs Survey questionnaire. The questionnaire was pre-tested with hog producers by NASS staff in mid-2000. NASS began collecting hog information in October 2000. Monthly data were released in the December, 2000, Quarterly Hogs and Pigs report. The first published Monthly Hogs and Pigs report occurred in January 2001. Response rates for the Monthly Hogs and Pigs Survey deteriorated due to increased respondent burden. The continued deterioration in response rates impacted the monthly survey indication by causing a greater portion of the indication to be estimated. The increase in monthly estimation also raised concern that the monthly report adversely impacted response rates of the Quarterly Hogs and Pigs Survey. NASS will be discontinuing collection and publication of the monthly report.

Dated July 2, 2003, at Washington, DC

R. Ronald Bosecker,

Administrator, National Agricultural Statistics Service.

[FR Doc. 03–17546 Filed 7–10–03; 8:45 am]

BILLING CODE 3410–20–P

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List; Proposed Additions and Deletions

AGENCY: Committee for Purchase From People Who Are Blind or Severely Disabled.

ACTION: Proposed Additions to and Deletions from Procurement List.

SUMMARY: The Committee is proposing to add to the Procurement List products and services to be furnished by nonprofit agencies employing persons who are blind or have other severe disabilities, and to delete products previously furnished by such agencies.

COMMENTS MUST BE RECEIVED ON OR BEFORE: August 10, 2003.

ADDRESSES: Committee for Purchase From People Who Are Blind or Severely Disabled, Jefferson Plaza 2, Suite 10800, 1421 Jefferson Davis Highway, Arlington, Virginia 22202–3259.

FOR FURTHER INFORMATION CONTACT: Sheryl D. Kennerly, (703) 603–7740.

SUPPLEMENTARY INFORMATION: This notice is published pursuant to 41 U.S.C 47(a)(2) and 41 CFR 51–2.3. Its purpose is to provide interested persons an opportunity to submit comments on the proposed actions.

Additions

If the Committee approves the proposed additions, the entities of the Federal Government identified in this notice for each product or service will be required to procure the products and services listed below from nonprofit agencies employing persons who are blind or have other severe disabilities.

Regulatory Flexibility Act Certification

I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. If approved, the action will not result in any additional reporting, recordkeeping or other compliance requirements for small entities other than the small organizations that will furnish the products and services to the Government.

2. If approved, the action will result in authorizing small entities to furnish the products and services to the Government.

3. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 46–48c) in connection with the products and services proposed for addition to the Procurement List. Comments on this certification are invited. Commenters should identify the statement(s) underlying the certification on which they are providing additional information.

(End of Certification)

The following products and services are proposed for addition to Procurement List for production by the nonprofit agencies listed:

Products

Product/NSN: Belt, General Officers, Leather, Black

8440–00–205–2509—Size 44
8440–00–205–2510—Size 28
8440–00–205–2511—Size 29
8440–00–205–2512—Size 30
8440–00–205–2513—Size 31
8440–00–205–2514—Size 32
8440–00–205–2515—Size 33
8440–00–205–2516—Size 34
8440–00–205–2517—Size 35
8440–00–205–2518—Size 36
8440–00–205–2519—Size 37
8440–00–205–2520—Size 38
8440–00–205–2521—Size 39
8440–00–205–2522—Size 40
8440–00–205–2523—Size 41
8440–00–205–2524—Size 42
8440–00–205–2525—Size 43

NPA: Stone Belt ARC, Inc., Bloomington, Indiana
Contract Activity: Defense Supply Center Philadelphia, Philadelphia, Pennsylvania
Product/NSN: Document Protector, 7510–01–236–0059
NPA: L.C. Industries For The Blind, Inc., Durham, North Carolina
Contract Activity: Office Supplies & Paper Products Acquisition Center, New York, New York

Services

Service Type/Location: Commissary Custodial and Warehousing, Naval Education Training Center, Newport, Rhode Island
NPA: Newport County Chapter, Rhode Island Association for Retarded Citizens, Middletown, Rhode Island
Contract Activity: Defense Commissary Agency (DeCA)—East Region, Virginia Beach, Virginia
Service Type/Location: Custodial Services, Irvine-Tustin U.S. Army Reserve Center, Irvine, California
NPA: Elwyn, Inc, Aston, Pennsylvania—at its facility in Fountain Valley, California
Contract Activity: 63rd Regional Support Command, Los Alamitos, California
Service Type/Location: Document Destruction
At the following locations and provided by the Nonprofit Agencies indicated:
IRS Service Center, Albuquerque, New Mexico
NPA: Adelante Development Center, Inc, Albuquerque, New Mexico
IRS Service Center, Cheyenne, Wyoming
IRS Service Center, Colorado Springs, Colorado
IRS Service Center, Denver, Colorado
IRS Service Center, Englewood, Colorado
IRS Service Center, Lakewood, Colorado
IRS Service Center, Westminster, Colorado
NPA: Bayaud Industries, Inc., Denver, Colorado
IRS Service Center, Las Vegas, Nevada
NPA: Opportunity Village Association for Retarded Citizens, Las Vegas, Nevada
IRS Service Center, Oakland, California
IRS Service Center, San Jose, California
NPA: Hope Rehabilitation Services, Santa Clara, California
IRS Service Center, Ogden, Utah

NPA: Enable Industries Incorporated, Ogden, Utah
IRS Service Center, Salt Lake City, Utah
NPA: Community Foundation for the Disabled, Inc., Salt Lake City, Utah
IRS Service Center, Phoenix, Arizona
IRS Service Center, Tempe, Arizona.
NPA: The Centers for Habilitation/TCH, Tempe, Arizona
IRS Service Center, Seattle, Washington.
NPA: Northwest Center for the Retarded, Seattle, Washington.
Contract Activity: IRS—Western Area Procurement Branch—APFW, San Francisco, California
Service Type/Location: Janitorial/Custodial. Basewide, Fort McCoy, Wisconsin.
NPA: Challenge Unlimited, Inc., Alton, Illinois
Contract Activity: Department of the Army, Fort McCoy, Wisconsin.

Deletions

Regulatory Flexibility Act Certification

I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. If approved, the action will not result in any additional reporting, recordkeeping or other compliance requirements for small entities.

2. If approved, the action will result in authorizing small entities to furnish the products to the Government.

3. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 46–48c) in connection with the products proposed for deletion from the Procurement List. (End of Certification)

The following products are proposed for deletion from the Procurement List:

Products

Product/NSN: Dropcloth, 8340–01–444–3652, 8340–01–444–3653
NPA: East Texas Lighthouse for the Blind, Tyler, Texas.
Contract Activity: GSA, Southwest Supply Center, Fort Worth, Texas

Sheryl D. Kennerly,

Director, Information Management.

[FR Doc. 03–17596 Filed 7–10–03; 8:45 am]

BILLING CODE 6353–01–P

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List; Additions

AGENCY: Committee for Purchase from People Who Are Blind or Severely Disabled.

ACTION: Additions to Procurement List.

SUMMARY: This action adds to the Procurement List products and services to be furnished by nonprofit agencies employing persons who are blind or have other severe disabilities.

EFFECTIVE DATE: August 10, 2003.

ADDRESS: Committee for Purchase From People Who Are Blind or Severely Disabled, Jefferson Plaza 2, Suite 10800, 1421 Jefferson Davis Highway, Arlington, Virginia, 22202–3259.

FOR FURTHER INFORMATION CONTACT: Sheryl D. Kennerly, (703) 603–7740.

SUPPLEMENTARY INFORMATION: On March 7, March 28, April 18, April 25, May 2, and May 9, 2003, the Committee for Purchase From People Who Are Blind or Severely Disabled published notice (68 F.R. 11036, 15150, 19188, 20371, 23441, and 24919) of proposed additions to the Procurement List. After consideration of the material presented to it concerning capability of qualified nonprofit agencies to provide the products and services and impact of the additions on the current or most recent contractors, the Committee has determined that the products and services listed below are suitable for procurement by the Federal Government under 41 U.S.C. 46–48c and 41 CFR 51–2.4.

Regulatory Flexibility Act Certification

I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. The action will not result in any additional reporting, recordkeeping or other compliance requirements for small entities other than the small organizations that will furnish the products and services to the Government.

2. The action will result in authorizing small entities to furnish the products and services to the Government.

3. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 46–48c) in connection with the products and services proposed for addition to the Procurement List.

(End of Certification)

Accordingly, the following products and services are added to the Procurement List:

Products

Product/NSN: Blue & White Finishing Mops, 7920–00–NIB–0407 (Medium), 7920–00–NIB–0408 (Large).
NPA: New York City Industries for the Blind, Inc., Brooklyn, New York.
Contract Activity: Office Supplies & Paper Products Acquisition Center, New York, New York.
Product/NSN: U.S. Air Force Technical Manual Binder, 7510–00–241–4958.
NPA: York County Blind Center, York, Pennsylvania.
Contract Activity: Office Supplies & Paper Products Acquisition Center, New York, New York.

Services

Service Type/Location: Base Supply Center & Individual Equipment Element, Air Force Flight Test Center (AFFTC), Edwards AFB, California.
NPA: Industries for the Blind, Inc., Milwaukee, Wisconsin.
Contract Activity: 95th MSG/LGRQ, Edwards AFB, California.
Service Type/Location: Base Supply Center & Individual Equipment Element, Buckley Air Force Base, Colorado.
NPA: Envision, Inc., Wichita, Kansas.
Contract Activity: 460th Air Base Wing, Buckley AFB, Colorado.
Service Type/Location: Custodial Services, Overton Corners Border Station, Champlain, New York.
NPA: Clinton County Chapter, NYSARC, Inc., Plattsburgh, New York.
Contract Activity: GSA/PBS Upstate New York Service Center, Syracuse, New York.
Service Type/Location: Food Service, Michigan Army National Guard, Maneuver Training Center, Camp Grayling, Michigan.
NPA: G.W. Services of Northern Michigan, Inc., Traverse City, Michigan.
Contract Activity: U.S. Property and Fiscal Officer for Michigan, Lansing, Michigan.
Service Type/Location: Grounds Maintenance, U.S. Border Station, Old Champlain, New York.
NPA: Clinton County Chapter, NYSARC, Inc., Plattsburgh, New York.
Contract Activity: GSA/PBS Upstate New York Service Center, Syracuse, New York.
Service Type/Location: Grounds Maintenance, U.S. Border Station, Overton Corners, New York.
NPA: Clinton County Chapter, NYSARC, Inc., Plattsburgh, New York.
Contract Activity: GSA/PBS Upstate New York Service Center, Syracuse, New York.
Service Type/Location: Janitorial/Custodial, Abingdon Memorial USARC, Abingdon, Virginia.
NPA: Highlands Community Services Board, Bristol, Virginia.
Contract Activity: 99th Regional Support Command, Coraopolis, Pennsylvania.
Service Type/Location: Janitorial/Custodial, FAA Tower and Base Building, Bloomington-Normal Airport, Bloomington, Illinois.
NPA: Occupational Development Center, Inc., Bloomington, Illinois.
Contract Activity: Federal Aviation Administration, Des Plaines, Illinois.
Service Type/Location: Janitorial/Custodial, Naval & Marine Corps Reserve Center, Billings, Montana.
NPA: Community Option Resource Enterprises, Inc., Billings, Montana.
Contract Activity: Naval Facilities Engineering Command, Everett, Washington.

Service Type/Location: Janitorial/Custodial, NEX Norfolk Distribution Center, NEXCOM Corporate Accounting (CAC), NEX Norfolk Overseas Distribution, NEX Norfolk Ship Store, Norfolk, Virginia; NEXCOM Uniform Support Center, Bldg 1545, Chesapeake, Virginia.
NPA: Community Alternatives, Incorporated, Virginia Beach, Virginia.
Contract Activity: Navy Exchange Service Command (NEXCOM), Virginia Beach, Virginia.
Service Type/Location: Janitorial/Custodial, U.S. Customs Service, Seattle, Washington.
NPA: Northwest Center for the Retarded, Seattle, Washington.
Contract Activity: U.S. Customs Service, Indianapolis, Indiana.
Service Type/Location: Janitorial/Custodial, U.S. Marine Corps Reserve Center, Johnstown, Pennsylvania.
NPA: Goodwill Industries of the Conemaugh Valley, Inc., Johnstown, Pennsylvania.
Contract Activity: 99th Regional Support Command, Coraopolis, Pennsylvania.

This action does not affect current contracts awarded prior to the effective date of this addition or options that may be exercised under those contracts.

Sheryl D. Kennerly,

Director, Information Management.

[FR Doc. 03–17597 Filed 7–10–03; 8:45 am]

BILLING CODE 6353–01–P

DEPARTMENT OF COMMERCE

[I.D. 070703E]

Submission for OMB Review; Comment Request

The Department of Commerce has submitted to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35).

Agency: National Oceanic and Atmospheric Administration (NOAA).

Title: Atlantic Highly Migratory Species Recreational Landings Reports.

Form Number(s): None.

OMB Approval Number: 0648–0328.

Type of Request: Regular submission.

Burden Hours: 1,369.

Number of Respondents: 10,069.

Average Hours Per Response: 5 minutes for a telephone or Internet report; 10 minutes for a state landing card; 1hour for a state weekly report; and 4 hours for a state annual report.

Needs and Uses: This information collection consists of a mandatory catch reporting program in the recreational fishery for Atlantic bluefin tuna, Atlantic swordfish, Atlantic blue marlin, Atlantic white marlin, and Atlantic sailfish. Anglers harvesting these species must report through an automated phone system or an Internet site, or through landing card programs administered by some states. Catch monitoring and collection of catch and effort statistics in these fisheries are required under the Atlantic Tunas Convention Act and the Magnuson-Stevens Fishery Conservation and Management Act. The information collected through this program is essential for the United States to meet its reporting obligations to the International Commission for the Conservation of Atlantic Tunas (ICCAT) and to assure the harvest of these species remains within ICCAT required quotas.

Affected Public: Individuals or households; business or other for-profit organizations; and State, Local, or Tribal Government.

Frequency: On occasion, weekly, annually.

Respondent's Obligation: Mandatory.

OMB Desk Officer: David Rostker, (202) 395–3897.

Copies of the above information collection proposal can be obtained by calling or writing Diana Hynek, Departmental Paperwork Clearance Officer, (202) 482–0266, Department of Commerce, Room 6625, 14th and Constitution Avenue, NW, Washington, DC 20230 (or via the Internet at *dHynek@doc.gov*).

Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to David Rostker, OMB Desk Officer, Room 10202, New Executive Office Building, Washington, DC 20503.

Dated: July 3, 2003,

Gwellnar Banks,

Management Analyst, Office of the Chief Information Officer.

[FR Doc. 03–17623 Filed 7–10–03; 8:45 am]

BILLING CODE 3510–22–S

DEPARTMENT OF COMMERCE

[I.D. 070703D]

Submission for OMB Review; Comment Request

The Department of Commerce has submitted to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35).

Agency: National Oceanic and Atmospheric Administration (NOAA).

Title: Application for the Marine Mammal Authorization Program Under Section 118 of the Marine Mammal Protection Act.

Form Number(s): None.

OMB Approval Number: 0648-0293.

Type of Request: Regular submission.

Burden Hours: 2,800.

Number of Respondents: 12,000.

Average Hours Per Response: 15 minutes for a new application; and 9 minutes for a renewal application.

Needs and Uses: The Marine Mammal Protection Act (MMPA) requires any commercial fisher operating in a Category I or II fishery to register for a certificate of authorization that will allow the fisher to take marine mammals incidental to commercial fishing operations. Category I and II fisheries are those identified by NOAA as having either frequent or occasional takings of marine mammals.

Affected Public: Business or other for-profit organizations; and individuals or households.

Frequency: Annually.

Respondent's Obligation: Mandatory.

OMB Desk Officer: David Rostker, (202) 395-3897.

Copies of the above information collection proposal can be obtained by calling or writing Diana Hynek, Departmental Paperwork Clearance Officer, (202) 482-0266, Department of Commerce, Room 6625, 14th and Constitution Avenue, NW, Washington, DC 20230 (or via the Internet at *dHynek@doc.gov*).

Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to David Rostker, OMB Desk Officer, Room 10202, New Executive Office Building, Washington, DC 20503.

Dated: July 3, 2003.

Gwellnar Banks,

Management Analyst, Office of the Chief Information Officer.

[FR Doc. 03–17624 Filed 7–10–03; 8:45 am]

BILLING CODE 3510–22–S

DEPARTMENT OF COMMERCE

[I.D. 070803F]

Submission for OMB Review; Comment Request

The Department of Commerce has submitted to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35).

Agency: National Oceanic and Atmospheric Administration (NOAA).

Title: NOAA Coastal Ocean Program Grants Proposal Application Package.

Form Number(s): None.

OMB Approval Number: 0648–0384.

Type of Request: Regular submission.

Burden Hours: 1,100.

Number of Respondents: 300.

Average Hours Per Response: 30 minutes for a budget form; 30 minutes for a project summary; 5 hours for an annual report; 10 hours for a final report; and 10 minutes to provide the extra copies required.

Needs and Uses: The Coastal Ocean Program (COP) provides direct financial assistance for the management of coastal ecosystems. Applicants for assistance are required to provide information in addition to the Standard Forms and grant application information. These additional requirements include a COP summary proposal budget form and a COP project summary. Applicants may also be required to provide up to 20 copies of their proposals. Successful applicants must file annual progress reports and a project final report in accordance with COP formats.

Affected Public: Not-for-profit institutions (universities, colleges, junior colleges, technical schools, laboratories); State, Local, or Tribal Government.

Frequency: On occasion, annually.

Respondent's Obligation: Required to obtain or retain a benefit.

OMB Desk Officer: David Rostker, (202) 395–3897.

Copies of the above information collection proposal can be obtained by calling or writing Diana Hynek, Departmental Paperwork Clearance Officer, (202) 482–0266, Department of Commerce, Room 6625, 14th and Constitution Avenue, NW, Washington, DC 20230 (or via the Internet at dHynek@doc.gov).

Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to David Rostker, OMB Desk Officer, Room 10202, New Executive Office Building, Washington, DC 20503.

Dated: July 3, 2003.

Gwellnar Banks,

Management Analyst, Office of the Chief Information Officer.

[FR Doc. 03–17625 Filed 7–10–03; 8:45 am]

BILLING CODE 3510–22–S

DEPARTMENT OF COMMERCE

Census Bureau

Proposed Information Collection; Comment Request; 2004 Census Test

ACTION: Notice.

SUMMARY: The Department of Commerce, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(C)(2)(A)).

DATES: Written comments must be submitted on or before September 9, 2003.

ADDRESSES: Direct all written comments to Diana Hynek, Departmental Paperwork Clearance Officer, Room 6625, 14th and Constitution Avenue, NW., Washington, DC 20230 (or via the Internet at *dhynek@doc.gov*).

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection instruments and instructions should be directed to Edison Gore, U.S. Census Bureau, Building 2, Room 2012, Washington, DC 20233–9200, 301–763–3998.

SUPPLEMENTARY INFORMATION:

I. Abstract

The 2004 Census Test is part of an extended test cycle leading up to the next decennial census. This testing cycle is an opportunity to evaluate new methods, procedures, systems, questions, and instructions designed to improve coverage and data quality in order to select the most promising ones for use in Census 2010.

The test will be conducted in two sites—Queens, NY, and three rural counties in Georgia (Colquitt, Tift, and Thomas)—and will use two modes for data collection (paper and a Mobile Computing Device [MCD]). The 2004 Census Test will include an array of data collection, data capture, and data processing operations along with the associated support activities necessary for obtaining the data required for evaluation. No prototype data products or counts will be published.

The Census Bureau also will conduct a two-part assessment (the Race and Hispanic/Latino Response Evaluation) in conjunction with the 2004 Census Test. In the first part of the assessment, enumerator taping assistants (ETAs) will accompany enumerators during Nonresponse Followup ([NRFU]—See Definition of Terms) in order to record enumerator behavior and respondent reaction to the race and Hispanic questions. The second part will consist of telephone re-interviews. The Race and Hispanic/Latino Response Evaluation is scheduled to begin during the NRFU phase of the 2004 Census Test.

Our experience in Census 2000 taught us important lessons emphasizing the need to begin planning and development early in the decade. Consequently, the Census Bureau established a number of Census 2010 Planning Groups to investigate potential changes for the next decennial census. As part of the development cycle, the 2004 Census Test will evaluate the effectiveness of:

1. Methodological innovations (*e.g.*, changes in the residence rule instructions—*See Definition of Terms*),

2. Content modifications (*e.g.*, changes in the race and Hispanic origin questions and response categories, as well as dropping the ''Some other race'' option), and

3. Incorporation of evolving technologies (using an MCD for data collection during NRFU).

The Race and Hispanic/Latino Response Evaluation is intended to evaluate personal visit respondent reactions to removing the ''Some other race'' category. The primary vehicle for this evaluation will combine the ETA interviews taped as part of the personal visits during 2004 NRFU with the 2003 National Census Test results.

Approximately 175,000 housing units in the test sites will receive a census form by mail. These housing units are expected to complete these forms and mail them back (mailout/mailback universe, *i.e.* housing units that have city-style addresses such as 806 Main Street). Additionally, enumerators will deliver a form to approximately 25,000 housing units that have non city-style addresses such as Rt. 7, Box 433. These housing units are asked to complete the forms and mail them back (update/leave universe).

Beginning in June 2004, a sample of approximately 2,800 households in the Queens, NY site will be re-interviewed via telephone for the Hispanic/Latino Response Evaluation. (Although the Behavior Coding segment of the test will involve about 2,000 households, it will not involve an increase in respondent burden, since the coding will be done as the NRFU interview is conducted.)

II. Method of Collection

Prior to receiving the 2004 questionnaire, each housing unit included in the test will be mailed an advance letter informing respondents that they will soon receive a census form. A few days after the questionnaire packages are delivered, each household will receive a reminder postcard that asks respondents to fill out and return their questionnaires, if they have not already done so. The postcard also will thank respondents who have already returned their forms.

Census Day is scheduled for April 1, 2004. About 10 days after that date, each household in the mailout/mailback universe that did not return the initial form will receive a replacement questionnaire. After respondents have had a chance to complete and return their forms, enumerators will visit each housing unit that has not responded (NRFU). NRFU is scheduled to begin approximately three weeks after Census Day. Enumerators will use handheld MCDs rather than paper questionnaires for data collection during NRFU.

Although the 2004 mailback form is similar to the Census 2000 short form in both content and format, there are several significant differences. These include revised wording for residence rules instructions; the addition of two coverage questions; a revised race question that eliminates the ''Some other race'' option; revisions in wording in the Hispanic origin question; and a format that allows a respondent to record information for up to 12 household members.

Completing the paper questionnaire and responding to the questions again during the telephone section of the Race and Hispanic/Latino Response Evaluation will take approximately 10 minutes. Preliminary research indicates enumerator-filled forms (data collected using MCDs during NRFU) also will take about 10 minutes. All data capture operations will be conducted at the Census Bureau's National Processing Center (NPC) located in Jeffersonville, Indiana.

In order to conduct the 2004 Census Test, we hope to create content and wording that will allow data collection using the MCDs to be comparable to other modes of response. The Census Bureau is designing software for handheld devices that is intended to incorporate both Spanish and English language capabilities and that will result in MCDs that will be easy for enumerators to use.

The goal of the two-part Race and Hispanic/Latino Response Evaluation is to understand how changes to the Race and Hispanic origin questions affect response behavior. The evaluation will study missing data rates, NRFU response distributions, and behavior coding data gathered in the process of conducting some NRFU interviews.

The Behavior Coding section of the test will involve taping and coding the behavior of about 2,000 enumerators and respondents during the NRFU personal visit interviews in the Queens, NY site. An ETA who accompanies each enumerator will record the selected interviews using a handheld recorder. ETAs will be trained to use basic interviewing techniques, operate the recorder, and take notes on respondent and interviewer behavior during the interview. Behavior coding is intended to provide data about respondents' verbal reaction to the race and Hispanic origin question as well as information about interviewer behavior while asking these questions. These interviews will be conducted and voice-recorded with the respondent's permission.

The second section of the Race and Hispanic/Latino Response Evaluation—Re-interview Follow-up—also is restricted to the Queens, NY site. The 2004 Census Test questionnaire will be administered to selected respondents after the NRFU visit. We will re-administer the 2004 Census Test questionnaire by telephone in order to evaluate the response distribution of the race question. The resulting response distribution is intended to provide information for evaluating the effect of changes in the race and Hispanic origin questions and response categories, as well as dropping the ''Some other race'' option.

Employees from the NPC will contact a sample of approximately 2,800 households to re-administer the 2004 questionnaire beginning in June 2004. Data gathered as a result of these interviews will be processed at NPC. The goal for this segment of the Race and Hispanic/Latino Response Evaluation is 2,000 completed interviews.

Definition of Terms

Residence Rules—Rules that respondents and the Census Bureau use to determine where people should be counted. They are meant to insure that everyone is counted once and in the right place for the primary purposes of apportionment.

Nonresponse Followup (NRFU)—An operation developed to obtain completed questionnaires from housing units for which the Census Bureau did not receive a completed questionnaire in mail census areas (mailout/mailback, update/leave, and urban update/leave). Enumerators visit addresses to collect the information.

III. Data

OMB Control Number: None.

Form Number(s): DB–1 (2004 Census Test).

Type of Review: Regular.

Affected Public: Individuals and households.

Estimated Number of Respondents: Approximately 200,000 households for the 2004 Census Test. Approximately 2,800 households for Race and Hispanic/Latino Response Evaluation.

Estimated Time Per Response: 10 minutes.

Estimated Total Annual Burden Hours: 33,800.

Estimated Total Annual Cost: There is no cost to respondents except for their time to respond.

Respondent Obligation: Mandatory.

Legal Authority: Title 13 of the United States Code, sections 141 and 193.

IV. Request for Comments

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden (including hours and cost) of the proposed collection; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval of this information collection; they also will become a matter of public record.

Dated: July 7, 2003.

Gwellnar Banks,

Management Analyst, Office of the Chief Information Officer.

[FR Doc. 03–17545 Filed 7–10–03; 8:45 am]

BILLING CODE 3510–07–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–122–822]

Certain Corrosion-Resistant Carbon Steel Flat Products from Canada: Rescission, in Part, of Antidumping Duty Administrative Review

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

ACTION: Notice.

SUMMARY: In response to a timely request from petitioners, Bethlehem Steel Corp., National Steel Corp., and United States Steel Corp., the Department of Commerce (the Department) initiated an administrative review of Stelco Inc. (Stelco) and Dofasco Inc. (Dofasco) under the antidumping duty order on certain corrosion-resistant carbon steel flat products (CORE) from Canada covering the period August 1, 2001 through July 31, 2002. *See Initiation of Antidumping and Countervailing Duty Administrative Reviews, Requests for Revocation in Part and Deferral of Administrative Reviews,* 67 FR 60210 (September 25, 2002). Petitioners, which were the only parties to request this review, have now withdrawn their request for an administrative review with respect to Stelco. Accordingly, the Department is rescinding, in part, its review of CORE for Stelco in accordance with section 351.213(d)(1) of the Department's regulations.

EFFECTIVE DATE: July 11, 2003.

FOR FURTHER INFORMATION CONTACT: Christian Hughes or Elfi Blum-Page, AD/CVD Enforcement Group III, Office 7, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, N.W., Washington D.C. 20230; telephone (202) 482–0190 or (202) 482–0197, respectively.

SUPPLEMENTARY INFORMATION:

Background

The Department published in the **Federal Register** the antidumping duty order on CORE from Canada on August 19, 1993. *See Antidumping Duty Orders: Certain Corrosion-Resistant Carbon Steel Flat Products and Certain Cut-to-Length Carbon Steel Plate from Canada*, 58 FR 44162 (August 19, 1993). On August 6, 2002, the Department published an opportunity to request administrative review. *See Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation; Opportunity To Request Administrative Review*, 67 FR 50856 (August 6, 2002). On August 30, 2002, the Department received a timely request from petitioners to conduct an administrative review pursuant to section 351.213(b) of the Department's regulations. On September 25, 2002, the Department initiated the administrative review covering the period August 1, 2001 to July 31, 2002, for producers Stelco and Dofasco. *See Initiation of Antidumping and Countervailing Duty Administrative Reviews, Requests for Revocation in Part and Deferral of Administrative Reviews*, 67 FR 60210 (September 25, 2002). On April 24, 2003, petitioners withdrew their review request for this period with respect to Stelco in accordance with section 351.213(d)(1) of the Department's regulations. On May 1, 2003, Stelco filed comments in opposition to petitioners' withdrawal request, and requested the Department to continue the review.

Rescission, in Part, of the Antidumping Duty Administrative Review of CORE

The Department is rescinding the antidumping duty administrative review of Stelco, covering the period August 1, 2001 through July 31, 2002, in accordance with section 351.213(d)(1) of the Department's regulations. Although petitioners' withdrawal request for this review was not within the normal time limit as prescribed in section 351.213(d)(1) of the Department's regulations, we find that, under the circumstances of this review, it is appropriate to accept the withdrawal request and rescind the review with respect to Stelco. According to section 351.213(d)(1) of the Department's regulations, the Department will rescind an administrative review ''if a party that requested the review withdraws the request within 90 days of the date of publication of notice of initiation of the requested review.'' The regulations further provide that the Secretary ''may extend this time limit if the Secretary decides that it is reasonable to do so.'' In this case, petitioners' withdrawal request was not within the 90-day time limit. However, the Department has determined that rescinding the review is appropriate. Continuing this review would only require Stelco, the domestic industry and the Department to expend time and resources on a review in which the only parties that requested the review are no longer interested. The Department has not released supplemental questionnaires with respect to Stelco, nor conducted verification. Therefore, the Department does not believe the administrative review has proceeded to a point at which it would be ''unreasonable'' to rescind the review. Furthermore, there are no overarching policy issues which would warrant continuing with this review.

The Department, therefore, has determined that it is reasonable to extend the 90-day time limit and to rescind, in part, the administrative review of CORE for the period August 1, 2001 through July 31, 2002 with respect to Stelco. (For a full discussion of the comments filed with respect to whether to rescind this review, *see Memorandum to the File from Christian Hughes, Analyst, Re: Antidumping Duty Order on Certain Corrosion-Resistant Carbon Steel Flat Products from Canada: 08/01/01- 07/31/02; Rescission, in Part, of the Ninth Administrative Review with Respect to Stelco, Inc.*, July 3, 2003.) The Department will issue appropriate assessment instructions directly to the U.S. Bureau of Customs and Border Protection (BCBP) within 15 days of publication of this notice. The Department will direct the BCBP to assess antidumping duties for this company at the cash deposit rate in effect on the date of entry for entries during the period August 1, 2001 through July 31, 2002.

Notification to Parties

This notice serves as a reminder to importers of their responsibility under section 351.402(f) of the Department's regulations to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this period of time. Failure to comply with this requirement could result in the Secretary's presumption that reimbursement of antidumping duties occurred and subsequent assessment of double antidumping duties.

This notice also serves as a reminder to parties subject to administrative protective order (APO) of their responsibility concerning the disposition of proprietary information disclosed under APO in accordance with section 351.305(a)(3) of the Department's regulations. Timely written notification of the return or 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 determination and notice are issued and published in accordance with sections 351.213(d)(4) and sections 751(a)(2)(c) and 777(I)(1) of the Tariff Act of 1930, as amended.

Dated: July 3, 2003.

Joseph A. Spetrini,

Acting Assistant Secretary for Grant Aldonas, Under Secretary.

[FR Doc. 03–17626 Filed 7–10–03; 8:45 am]

BILLING CODE 3510–DS–S

DEPARTMENT OF COMMERCE

International Trade Administration

[A–533–813]

Certain Preserved Mushrooms From India: Final Results of Antidumping Duty Administrative Review

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

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

SUMMARY: On March 7, 2003, the Department of Commerce published the preliminary results of the third administrative review of the antidumping duty order on certain preserved mushrooms from India. The review covers three manufacturers/exporters. The period of review is February 1, 2001, through January 31, 2002.

Based on our analysis of the comments received, we have made changes in the margin calculations. Therefore, the final results differ from the preliminary results. The final weighted-average dumping margins for the reviewed firms are listed below in the section entitled ''Final Results of Review.''

EFFECTIVE DATE: July 11, 2003.

FOR FURTHER INFORMATION CONTACT: David J. Goldberger or Katherine Johnson, Office 2, AD/CVD Enforcement Group I, Import Administration—Room B099, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC 20230; telephone: (202) 482–4136 or (202) 482–4929, respectively.

SUPPLEMENTARY INFORMATION:

Background

The review covers three manufacturers/exporters: Agro Dutch Foods Ltd. (''Agro Dutch''), Himalya International Ltd. (''Himalya''), and Weikfield Agro Products Ltd. (''Weikfield''). The period of review is February 1, 2001, through January 31, 2002.

On March 7, 2003, the Department of Commerce published the preliminary results of the third administrative review of the antidumping duty order on certain preserved mushrooms from India (68 FR 11045). We invited parties to comment on the preliminary results of review. On April 7, 2003, we received a request for a public hearing from respondent Weikfield. We received case briefs from the petitioner,[1] Agro Dutch, and Weikfield on May 2, 2003. We received rebuttal briefs from the petitioner and Weikfield on May 13, 2003. On June 3, 2003, Weikfield withdrew its request for a public hearing. We have conducted this administrative review in accordance with section 751(a) of the Tariff Act of 1930, as amended (''the Act'').

Scope of the Order

The products covered by the order are certain preserved mushrooms, whether imported whole, sliced, diced, or as stems and pieces. The preserved mushrooms covered under the order are the species *Agaricus bisporus* and *Agaricus bitorquis*. ''Preserved mushrooms'' refer to mushrooms that have been prepared or preserved by cleaning, blanching, and sometimes slicing or cutting. These mushrooms are then packed and heated in containers including but not limited to cans or glass jars in a suitable liquid medium, including but not limited to water, brine, butter or butter sauce. Preserved mushrooms may be imported whole, sliced, diced, or as stems and pieces. Included within the scope of the order are ''brined'' mushrooms, which are presalted and packed in a heavy salt solution to provisionally preserve them for further processing.

Excluded from the scope of the order are the following: (1) All other species of mushroom, including straw mushrooms; (2) all fresh and chilled mushrooms, including ''refrigerated'' or ''quick blanched mushrooms''; (3) dried mushrooms; (4) frozen mushrooms; and (5) ''marinated,'' ''acidified'' or ''pickled'' mushrooms, which are prepared or preserved by means of vinegar or acetic acid, but may contain oil or other additives.

The merchandise subject to the order is classifiable under subheadings 2003.10.0127, 2003.10.0131, 2003.10.0137, 2003.10.0143, 2003.10.0147, 2003.10.0153, and 0711.51.0000 of the *Harmonized Tariff Schedule of the United States* (''HTSUS'')[2]. Although the HTSUS subheadings are provided for convenience and customs purposes, our written description of the scope of the order is dispositive.

Analysis of Comments Received

All issues raised in the case and rebuttal briefs by parties to this antidumping duty administrative review are addressed in the ''Issues and Decision Memorandum'' (''Decision Memo'') from Jeffrey May, Deputy Assistant Secretary for Import Administration, to Joseph A. Spetrini, Acting Assistant Secretary for Import Administration, dated July 7, 2003, which is hereby adopted by this notice. A list of the issues which parties have raised and to which we have responded, all of which are in the Decision Memo, is attached to this notice as an Appendix. Parties can find a complete discussion of all issues raised in this review and the corresponding recommendations in this public memorandum which is on file in the Central Records Unit, room B–099 of the main Department building. In addition, a complete version of the Decision Memo can be accessed directly on the Web at *http://ia.ita.doc.gov/*. The paper copy and electronic version of the Decision Memo are identical in content.

Changes From the Preliminary Results

Based on our analysis of comments received, we have made certain changes to the margin calculations, including:

- We revised the calculation for Weikfield's indirect selling expenses to exclude the amounts for commissions and discounts Weikfield and its affiliate paid to unaffiliated parties.
- We revised Weikfield's U.S. indirect selling expenses used as an offset to home market commissions to include inventory carrying expenses.
- We excluded a deduction from Weikfield's home market price for ''Discount Program 2.''
- We did not make a deduction for the Indian export tax to the price of one of Weikfield's U.S. sales.
- We revised Weikfield's reported general and administrative (G&A) expenses to include idle depreciation costs experienced during the POR.
- We revised Weikfield's reported financial expenses to exclude long-term financial and non-financial income. In addition, we included all financial expenses incurred during the POR, including certain expenses associated with debt restructuring. Finally, we

[1] The petitioner is the Coalition for Fair Preserved Mushroom Trade which includes the American Mushroom Institute and the following domestic companies: L.K. Bowman, Inc.; Modern Mushroom Farms, Inc.; Monterey Mushrooms, Inc.; Mount Laurel Canning Corp.; Mushrooms Canning Company; Southwood Farms; Sunny Dell Foods, Inc.; and United Canning Corp.

[2] Prior to January 1, 2002, the HTSUS numbers were as follows: 2003.10.0027, 2003.10.0031, 2003.10.0037, 2003.10.0043, 2003.10.0047, 2003.10.0053, and 0711.90.4000.

calculated the financial expense ratio based on the highest level of audited fiscal year financial statements prepared by Weikfield.

• As Agro Dutch had no comparison market during the POR, and its constructed value selling expenses and profit rate were based on the weighted-average selling and profit amounts incurred on home market sales by Himalya and Weikfield, we revised the selling expenses and profit used to calculate Agro Dutch's constructed value to account for the revisions to the Weikfield margin calculation outlined above. For a discussion of these changes, see the ''Margin Calculations'' section of the Decision Memo and the various comments discussed in the Decision Memo.

Final Results of Review

We determine that the following weighted-average margin percentages exist:

Manufacturer/Exporter	Margin (percent)
Agro Dutch Foods Ltd/Agro Dutch Industries Ltd	1.02
Himalya International Ltd (*de minimis*)	0.08
Weikfield Agro Products Ltd	34.66

Assessment

The Department shall determine, and the U.S. Bureau of Customs and Border Protection (BCBP) shall assess, antidumping duties on all appropriate entries. The Department will issue appropriate assessment instructions directly to BCBP within 15 days of publication of these final results of review. In accordance with 19 CFR 351.106(c)(1), we will instruct BCBP to assess antidumping duties on all appropriate entries covered by this review if any importer-specific assessment rate calculated in the final results of this review is above *de minimis* (*i.e.*, less than 0.50 percent). For assessment purposes, we do not have the actual entered value for Agro Dutch and Weikfield because these respondents are not the importers of record for the subject merchandise. Accordingly, we have calculated customer-specific assessment rates by aggregating the dumping margins calculated for all of Agro Dutch's and Weikfield's U.S. sales examined and dividing the respective amounts by the total quantity of the sales examined for each producer. With respect to Himalya, we calculated importer-specific assessment rates for the subject merchandise from Himalya by aggregating the dumping margins calculated for all of Himalya's U.S. sales examined and dividing this amount by the total entered value of the sales examined. To determine whether the duty assessment rates were *de minimis*, in accordance with the requirement set forth in 19 CFR 351.106(c)(2), we calculated customer-or importer-specific *ad valorem* ratios based on export prices.

Cash Deposit Requirements

The following cash deposit requirements will be effective for all shipments of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the publication date of the final results of this administrative review, as provided by section 751(a)(1) of the Act: (1) The cash deposit rates for the reviewed companies will be those established in the final results of this review, except if the rate is less than 0.50 percent, and therefore, *de minimis* within the meaning of 19 CFR 351.106(c)(1), in which case the cash deposit rate will be zero; (2) for previously reviewed or investigated companies not listed above, the cash deposit rate will continue to be the company-specific rate published for the most recent period; (3) if the exporter is not a firm covered in this review, a prior review, or the original less-than-fair-value (LTFV) investigation, but the manufacturer is, the cash deposit rate will be the rate established for the most recent period for the manufacturer of the merchandise; and (4) the cash deposit rate for all other manufacturers or exporters will continue to be 11.30 percent. This rate is the ''All Others'' rate from the LTFV investigation. These deposit requirements shall remain in effect until publication of the final results of the next administrative review.

This notice also serves as a final reminder to importers of their responsibility under 19 CFR 351.402(f) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in the Secretary's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of doubled antidumping duties.

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(a)(3). Timely written 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. We are issuing and publishing this determination and notice in accordance with sections 751(a)(1) and 777(i) of the Act.

Dated:July 7, 2003.

Jeffrey May,

Acting Assistant Secretary for Grant Aldonas, Under Secretary.

Appendix—List of Issues

Company-Specific Comments:

Agro Dutch

Comment 1: Calculation of the Work-in-Process Offset
Comment 2: Application of Adverse Facts Available

Weikfield

Comment 3: Home Market Quantity Discounts
Comment 4: Affiliated Party Commissions
Comment 5: Home Market Indirect Selling Expenses
Comment 6: U.S. Indirect Selling Expenses for Commission Offset
Comment 7: Calculation of U.S. Credit Expense
Comment 8: CESS for Observation 33
Comment 9: Offset to Direct Materials Cost
Comment 10: Depreciation of Idle Assets
Comment 11: Addition of WPCL General and Administrative Expenses
Comment 12: Weikfield General and Administrative Expense Calculation
Comment 13: Gain on Debt Restructuring as Offset to Financial Expenses
Comment 14: Interest Expenses from ICICI Loan
Comment 15: Cost of Goods Sold for the Financial Expense Ratio
Comment 16: Offsetting Positive Margins with Negative Margins

[FR Doc. 03–17627 Filed 7–10–03; 8:45 am]

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DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–851]

Certain Preserved Mushrooms From the People's Republic of China: Final Results and Partial Rescission of the New Shipper Review and Final Results and Partial Rescission of the Third Antidumping Duty Administrative Review

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

ACTION: Notice of final results and partial rescission of the new shipper review and final results and partial

rescission of the third antidumping duty administrative review.

SUMMARY: On March 6, 2003, the Department of Commerce published the preliminary results and partial rescission of the new shipper review and the third antidumping duty administrative review of the antidumping duty order on certain preserved mushrooms from the People's Republic of China. *See Certain Preserved Mushrooms from the People's Republic of China: Preliminary Results of New Shipper Review and Preliminary Results and Partial Rescission of Third Antidumping Duty Administrative Review,* 68 FR 10694 (March 6, 2003) (*Preliminary Results*). The new shipper review covers three exporters and the administrative review covers four exporters (see ''Background'' section below for further discussion). The period of review is February 1, 2001, through January 31, 2002.[1] We gave interested parties an opportunity to comment on our preliminary results.

Based on the additional publicly available information used in these final results and the comments received from the interested parties, we have made changes in the margin calculations for certain respondents in these reviews. The final weighted-average dumping margins for the reviewed firms in these reviews are listed below in the section entitled ''Final Results of Reviews.''

EFFECTIVE DATE: July 11, 2003.

FOR FURTHER INFORMATION CONTACT: Brian Smith or Davina Hashmi, Import Administration, International Trade Administration, U.S. Department of Commerce, Washington, DC 20230; telephone: (202) 482–1766 or (202) 482–0984, respectively.

SUPPLEMENTARY INFORMATION:

Background

While the Department initiated an administrative review of 7 companies,[2] based on a request by the petitioners [3] and certain exporters, this administrative review now covers only the following four exporters: (1) Gerber; (2) Green Fresh; (3) Shantou Hongda; and (4) Shenxian Dongxing (see ''Partial Rescission of Administrative Review'' section below of this notice for further discussion).

On March 6, 2002, the Department published in the **Federal Register** the preliminary results of the new shipper review and the third antidumping duty administrative review of the antidumping duty order on certain preserved mushrooms from the People's Republic of China (''PRC'') (*see Preliminary Results*, 67 FR at 10128).

On March 7, 2003, after determining that the 2001–2002 financial report submitted for one Indian producer contained in Gerber's February 5, 2003, submission was incomplete, we requested that Gerber provide the complete financial report for that Indian producer in order to further consider the data for the final results. In response to our request, the petitioners provided this data on April 18, 2003, for the Department's consideration in the final results.

On March 10, 2003, the petitioners placed information on the record indicating that one of Guangxi Yulin's owners may have made shipments of subject merchandise during the period of investigation (''POI'') [4] and therefore may not be eligible for a new shipper review. On March 20, 2003, Guangxi Yulin submitted rebuttal comments. On April 15, 2003, we placed on the record the results of our data query on this matter (see April 15, 2003, Memorandum from Sophie Castro, Case Analyst to the File, entitled ''Results of Data Queries Conducted in Response to Allegations and Information Submitted in March of 2003 Regarding Guangxi Yulin Oriental Food Co., Ltd.'').

On March 31, 2003, in accordance with 19 CFR 351.301(c)(3), we received additional publicly available information from two respondents, Gerber and Green Fresh.

On April 25, 2003, we placed on the record additional publicly available information on truck freight rates for consideration in the final results.

The petitioners and three respondents, Gerber, Guangxi Yulin and Shenzhen Qunxingyuan Trading Co., Ltd. (''Shenzhen Qunxingyuan'') submitted their case briefs on April 30, 2003. On May 7, 2003, the petitioners and two respondents, Gerber and Guangxi Yulin, submitted rebuttal briefs. The other respondents participating in these reviews did not submit case or rebuttal briefs.

On May 7, 2003, we determined that the petitioner and Shenzhen Qunxingyuan had submitted new factual information in their case briefs in violation of the regulatory requirement provided in 19 CFR 351.301(c)(3)(ii), and requested these parties to remove this data and resubmit their case briefs. On May 19, 2003, we determined that the petitioner had also submitted new factual information in its rebuttal brief and requested the petitioner to remove this data as well and resubmit its rebuttal brief. Also, on May 19, 2003, the petitioner requested a meeting with the Department to discuss the relationship between Gerber and Green Fresh during the period of review (''POR'') as discussed in its case brief. On May 22, 2003, Gerber and Green Fresh requested a similar meeting. On June 11, and June 27, 2003, we held *ex-parte* meetings with the petitioners' and respondents' counsels, respectively, to discuss the relationship between Gerber and Green Fresh during the POR and the new shipper claims made by Shenzhen Qunxingyuan and Guangxi Yulin (*see ex-parte* memoranda to the file dated June 12, and June 30, 2003).

On June 5, 2003, we placed on the record additional publicly available price information on copper wire scrap, water, and the components included in laterite, and additional public financial data from an Indian producer submitted in this review for consideration in the final results of this review. On June 19, 2003, Gerber and Green Fresh submitted comments on the publicly available information we had placed on the record on June 5, 2003.

No party requested a hearing, as specified under 19 CFR 351.310(c).

The Department has conducted these reviews in accordance with section 751 of the Act.

Scope of the Order

The products covered by this order are certain preserved mushrooms whether imported whole, sliced, diced, or as stems and pieces. The preserved mushrooms covered under this order are the species *Agaricus bisporus* and *Agaricus bitorquis.* ''Preserved mushrooms'' refer to mushrooms that have been prepared or preserved by cleaning, blanching, and sometimes slicing or cutting. These mushrooms are then packed and heated in containers including, but not limited to, cans or glass jars in a suitable liquid medium, including, but not limited to, water, brine, butter or butter sauce. Preserved mushrooms may be imported whole,

[1] The POR for both the new shipper and administrative review is the same.

[2] The petitioners' request for review included the following companies: (1) China Processed Food Import & Export Company (''China Processed''); (2) Shantou Hongda Industrial General Corporation (''Shantou Hongda''); (3) Shenxian Dongxing Foods Co., Ltd. (''Shenxian Dongxing''); (4) Gerber Food Yunnan Co., Ltd. (''Gerber''); (5) Green Fresh Foods (Zhangzhou) Co., Ltd. (''Green Fresh''); (6) Raoping Xingyu Foods Factory Co., Ltd. (''Raoping Xingyu''); (7) Compania Envasador Del Atlantico (''Compania Envasador'').

[3] The petitioners are the Coalition for Fair Preserved Mushroom Trade which includes the American Mushroom Institute and the following domestic companies: L.K. Bowman, Inc., Modern Mushroom Farms, Inc., Monterey Mushrooms, Inc., Mount Laurel Canning Corp., Mushrooms Canning Company, Southwood Farms, Sunny Dell Foods, Inc., and United Canning Corp.

[4] The POI covers the period of July 1, 1997 though December 31, 1997.

sliced, diced, or as stems and pieces. Included within the scope of this order are ''brined'' mushrooms, which are presalted and packed in a heavy salt solution to provisionally preserve them for further processing.

Excluded from the scope of this order are the following: (1) All other species of mushroom, including straw mushrooms; (2) all fresh and chilled mushrooms, including ''refrigerated'' or ''quick blanched mushrooms''; (3) dried mushrooms; (4) frozen mushrooms; and (5) ''marinated,'' ''acidified'' or ''pickled'' mushrooms, which are prepared or preserved by means of vinegar or acetic acid, but may contain oil or other additives.[5]

The merchandise subject to this order is classifiable under subheadings: 2003.10.0127, 2003.10.0131, 2003.10.0137, 2003.10.0143, 2003.10.0147, 2003.10.0153 and 0711.51.0000 of the Harmonized Tariff Schedule of the United States[6] (''HTS''). Although the HTSUS subheadings are provided for convenience and customs purposes, the written description of the scope of this order is dispositive.

Partial Rescission of Administrative Review

We have rescinded this review with respect to China Processed, Compania Envasador, and Raoping Xingyu pursuant to 19 CFR 351.213(d)(1), because the petitioners withdrew their request for review and no other interested party requested a review of these companies. *See Certain Preserved Mushrooms from the People's Republic of China: Notice of Partial Rescission of Antidumping Duty Administrative Review,* 67 FR 53914 (August 20, 2002).

Facts Available—Shenxian Dongxing

In the *Preliminary Results,* 67 FR at 10697, the Department determined that the use of adverse facts available was warranted in accordance with section 776(b) of the Tariff Act of 1930, as amended (''the Act''), to calculate the dumping margin for Shenxian Dongxing. Because Shenxian Dongxing failed to provide usable transaction-specific sales quantities for purposes of calculating its weighted-average dumping margin, we determined that Shenxian Dongxing did not cooperate to the best of its ability. Since the preliminary results, nothing has changed to reverse our preliminary decision regarding Shenxian Dongxing and Shenxian Dongxing has filed no comments on the record addressing the Department's calculation. Therefore, pursuant to section 776(b) of the Act, we have continued to make an adverse inference with respect to Shenxian Dongxing by assigning to its exports of the subject merchandise a rate of 61.37 percent, which is the highest rate calculated for any of its U.S. sales transactions based on the use of additional publicly available information and the comments received from the interested parties since the preliminary results (*see* ''Changes Since the Preliminary Results'' section below for further discussion).

Facts Available—Gerber/Green Fresh

In the *Preliminary Results,* 67 FR at 10697, the Department determined that the business relationship which existed between Gerber and Green Fresh resulted in evasion of antidumping cash deposits during the POR. (*See* February 28, 2003, memorandum from Office Director to the Acting Deputy Assistant Secretary entitled ''Cash Deposit Rate for Gerber Food (Yunnan) Co., Ltd. and Green Fresh Foods (Zhangzhou) Co., Ltd.'' (''Gerber-Green Fresh memo'') for further discussion). Consequently, as adverse facts available, the Department preliminarily assigned to each of these respondents for future cash deposit purposes the higher of the rates calculated for each of them in this review.[7] The preliminary calculated margins for Gerber and Green Fresh were 1.17 percent and 46.41 percent, respectively. However, as adverse facts available for cash deposit purposes, we assigned both companies Green Fresh's calculated margin of 46.41 percent. We invited comments on our preliminary results.

After considering the comments submitted by the parties on this matter, we find that our preliminary decision with respect to Gerber and Green Fresh did not sufficiently address the fact that both companies withheld crucial information prior to verification and actively colluded to circumvent the cash deposit rates in effect during the POR. After a re-examination of the facts on the record of this review, we find that the use of total adverse facts available is warranted in this case with respect to determining Gerber's and Green Fresh's cash deposit and assessment rates for the reasons stated below.

With respect to Gerber, we find that Gerber continually misrepresented in its questionnaire responses the true nature of its relationship with Green Fresh during the POR. In its questionnaire responses, which were accompanied by a certification from Gerber officials attesting to the validity and truthfulness of these responses, Gerber claimed that Green Fresh acted as an agent on its behalf by arranging for the shipment on some of its reported U.S. sales of self-produced subject merchandise during the POR (see May 23, 2003, Section A response at A–11). Moreover, Gerber indicated that Green Fresh acted as its agent from September 2001 to May 2002 and Gerber paid it a commission for each container of Gerber-produced merchandise which Green Fresh shipped to the U.S. market on Gerber's behalf (see September 11, 2002, submission at 6).

Based on this information, the Department was led to believe prior to verification that Gerber's business with Green Fresh was at arms-length, and constituted a *bona fide* business arrangement under which Green Fresh did, in fact, operate as the exporter of the merchandise. However, an examination of sales and export documentation at verification revealed that Gerber in fact arranged shipment of all of its sales of subject merchandise and paid Green Fresh a fee to use Green Fresh's sales invoices for this purpose in order to take advantage of Green Fresh's comparatively low cash deposit rate during the POR (see February 12, 2003, Gerber verification report at 5–7 and exhibits 4D through 4K)). Absent verification, the Department would never have discovered that Gerber used Green Fresh's sales invoices in order to benefit from Green Fresh's lower cash deposit rate.

Gerber's misrepresentations were highly material to the Department's analysis and call into question the veracity of other responses provided by Gerber. Despite Gerber's pre-verification claims to the contrary, Green Fresh never acted as Gerber's agent for most of the Gerber/Green Fresh reported transactions. Green Fresh had at most negligible commercial involvement with the specific transactions involving the export of Gerber's merchandise to the United States from the PRC using its invoices. Although the nature of this relationship came to light at verification, the Department deems it critical to the resolution of this issue the

[5] On June 19, 2000, the Department affirmed that ''marinated,'' ''acidified,'' or ''pickled'' mushrooms containing less than 0.5 percent acetic acid are within the scope of the antidumping duty order. *See* ''Recommendation Memorandum-Final Ruling of Request by Tak Fat, *et al.* for Exclusion of Certain Marinated, Acidified Mushrooms from the Scope of the Antidumping Duty Order on Certain Preserved Mushrooms from the People's Republic of China,'' dated June 19, 2000.

[6] Prior to January 1, 2002, the HTS subheadings were as follows: 2003.10.0027, 2003.10.0031, 2003.10.0037, 2003.10.0043, 2003.10.0047, 2003.10.0053, and 0711.90.4000.

[7] For assessment purposes, we preliminarily stated that we intended to calculate importer-specific duty assessment rates based on the data provided by these two companies, as adjusted, to reflect verification findings.

fact that Gerber certified as truthful false information it provided to the Department, in numerous questionnaire responses.

Under these circumstances, section 776(a)(2) of the Act states that the Department may use ''facts available'' if an interested party (A) withholds information that has been requested by the Department, (C) significantly impedes a proceeding under this title or (D) provides such information but the information cannot be verified. All of these provisions apply in this case. Because the Department relies on original sales invoices to verify the accuracy of the sales listing, the information Gerber mis-characterized and withheld was fundamental and material to the Department's analysis. Gerber's actions now lead us to question our verification findings which were predicated on the reliability of Gerber's own information and records. Gerber's consistent mis-characterization of the facts on the record impeded a proper review of Gerber's transactions. This is particularly true, given that the vast majority of Gerber's reported U.S. sales were made using Green Fresh's sales invoices. Without the necessary information pertaining to these transactions, the Department could not realistically conduct an accurate review of Gerber. Clearly in this case, Gerber did not act to the best of its ability by providing the Department with incorrect and misleading mis-characterizations of its agreement with Green Fresh and misusing Green Fresh's invoices to evade the payment of cash deposits during the POR.

For these reasons, the Department has determined that it will apply total adverse facts available to Gerber in this case. Thus, as adverse facts available, in light of record evidence of material misrepresentations by Gerber as noted above and the potential for future misconduct, the assignment of a cash deposit and assessment rate equal to the PRC-wide rate of 198.63 percent is appropriate. The application of this cash deposit rate reflects the Department's best estimate as to what the company's ultimate assessed duty liability would be in the next stage of the proceeding, given the uncertainty created by the misconduct that has characterized the parties' behavior to date. The Department considers the assignment of this rate to Gerber sufficient to encourage it to cooperate with the Department in future reviews, and to ensure that Gerber cannot undermine the efficacy of the antidumping duty law by posting insufficient and improper deposits.

With respect to Green Fresh, its misrepresentations on the record significantly impeded this proceeding as well. Like Gerber, Green Fresh also stated in its questionnaire responses that it acted as an agent for sales made and produced by Gerber, whereby it received a commission for exporting that merchandise on Gerber's behalf to the U.S. market during the POR (see May 23, 2002, submission at 11). In describing its role as Gerber's agent, Green Fresh indicated that it provided Gerber with specific export documents (*i.e.*, an invoice, PRC Customs and quarantine inspection form, packing list, VAT refund form, and PRC Customs declaration form) for only a portion of Gerber's sales transactions during the POR (*see* December 23, 2003, submissions at 1 and 2). Moreover, Green Fresh indicated that it had the data for these affected sales transactions and separately reported them in its supplemental response (*see* December 23, 2002, submission at 3). With respect to these affected sales transactions which it claimed it acted as Gerber's shipping agent, Green Fresh did not reveal to the Department until verification that it merely provided Gerber with blank sales invoices for purposes of enabling Gerber to ship its merchandise to the U.S. market during the POR at a lower cash deposit rate. Furthermore, although Green Fresh claimed that it actually arranged for the shipment of Gerber-produced merchandise included in these affected sales transactions (which were reported by both companies in their respective Section C sales listings), Green Fresh was unable to provide complete documentation for all of the affected sales transactions to support its claim that it served as a *bona fide* shipping agent on behalf of Gerber with respect to these sales (*see* February 12, 2003, Green Fresh verification report at 6–7 and exhibit 6P). Because these affected sales transactions were documented with invoices issued by Green Fresh and not by Gerber but could not be tied to records prepared by Green Fresh in the ordinary course of business, we were unable to verify the extent of Green Fresh's involvement with respect to these sales or to corroborate Green Fresh's statements. Therefore, given the fact that the sales in question were made using Green Fresh's invoices and that Green Fresh was unable to provide its own supporting documentation for all but one of these sales transactions, we question the reliability of Green Fresh's reported sales data, its sales documentation, and the additional data it provided at verification.

Furthermore, the willingness of Green Fresh to assist another company to evade the payment of legally required cash deposits, as well as its consistent mis-characterization of the facts on the record (despite its representatives' certification of the facts contained in multiple submissions to the Department as truthful when they were not), leads us again to question the validity of the books and records examined by the Department at verification. Thus, consistent with our analysis for Gerber, we do not believe that Green Fresh's reported information can be relied upon by the Department in calculating an antidumping duty margin and cash deposit/assessment rates. Consequently, pursuant to sections 776(a)(2)(A), (C) and (D) of the Act, the Department is applying total facts available to Green Fresh. Furthermore, pursuant to section 776(b) of the Act, an adverse inference is warranted because Green Fresh's sale of invoices for purposes of aiding Gerber to evade cash deposits, as well as its mis-characterization of the facts in this case, clearly demonstrate that Green Fresh did not act to the best of its ability during this administrative review.

Thus, as adverse facts available, in light of record evidence of material misrepresentations by Green Fresh as noted above and the potential for future misconduct, the assignment of a cash deposit and assessment rate equal to the PRC-wide rate of 198.63 percent is appropriate. (*See* Issues and Decision Memorandum (''Decision Memo'') from Jeffrey May, Deputy Assistant Secretary for Import Administration, to Joseph A. Spetrini, Acting Assistant Secretary for Import Administration at Comment 1 for further discussion).

Corroboration of Facts Available

Section 776(c) of the Act provides that where the Department selects from among the facts otherwise available and relies on ''secondary information,'' the Department shall, to the extent practicable, corroborate that information from independent sources reasonably at the Department's disposal. The Statement of Administrative Action, H.R. Doc. 103–316 (''SAA''), states that ''corroborate'' means to determine that the information used has probative value. *See* SAA at 870. To corroborate secondary information, the Department will, to the extent practicable, examine the reliability and relevance of the information to be used.

In this segment of the proceeding, in accordance with Department practice, as adverse facts available, we have assigned to exports of the subject merchandise by Gerber and Green Fresh the PRC-wide rate of 198.63 percent, a

rate that was calculated based on information contained in the petition. When using a previously calculated margin as facts available, for purposes of corroboration the Department will consider, in the context of the current review, whether that margin is both reliable and relevant. With respect to the relevancy aspect of corroboration, the Department stated in *Tapered Roller Bearings and Parts Thereof, Finished and Unfinished, from Japan, and Tapered Roller Bearings, Four Inches or Less in Outside Diameter, and Components Thereof, from Japan; Preliminary Results of Antidumping Duty Administrative Reviews and Partial Termination of Administrative Reviews,* 61 FR 57391, 57392 (November 6, 1996) (''TRBs''), that it will ''consider information reasonably at its disposal as to whether there are circumstances that would render a margin irrelevant. Where circumstances indicate that the selected margin is not appropriate as adverse facts available, the Department will disregard the margin and determine an appropriate margin.'' *See also Fresh Cut Flowers from Mexico; Preliminary Results of Antidumping Duty Administrative Review,* 61 FR 6812, 6814 (February 22, 1996) (disregarding the highest margin in the case as best information available because the margin was based on another company's uncharacteristic business expense resulting in an extremely high margin).

We corroborated the petition information, and found that we had not received any information that warranted revisiting the issue. *See Notice of Preliminary Determination of Sales at Less-Than-Fair-Value: Certain Preserved Mushrooms from the People's Republic of China*, 63 FR 41794, 417988 (August 5, 1998). Similarly, no information has been presented in the current review that calls into question the reliability or the relevance of the information contained in the petition. Therefore, we have applied, as adverse facts available, the PRC-wide rate from prior administrative reviews of this order and have satisfied the corroboration requirements under section 776 of the Act. See *Persulfates from the People's Republic of China: Preliminary Results of Antidumping Duty Administrative Review*, 66 FR 18439, 18441 (April 9, 2001) (employing a petition rate used as adverse facts available in a previous segment as the adverse facts available in the current review). We have determined that this rate has probative value and, therefore, is an appropriate rate to be applied in this review to exports of subject merchandise by Gerber and Green Fresh as facts otherwise available.

Partial Rescission of New Shipper Review

A. Zhangzhou Jingxiang

We have rescinded this new shipper review with respect to Zhangzhou Jingxiang because it failed to provide us with the necessary documentation for determining which entity or entities own it and because it was unable to explain whether or not its owner was affiliated with any PRC exporters or producers of the subject merchandise (*see Preliminary Results*, 67 FR at 10696).

B. Shenzhen Qunxingyuan

In the preliminary results, we determined that the sole U.S. sale of subject merchandise made by Shenzhen Qunxingyuan during the POR was not *bona fide* primarily because it was made at an aberrationally high price and an unreasonably low quantity relative to other commercial transactions involving comparable merchandise during the POR. In addition, Shenzhen Qunxingyuan did not have any other business activity or income beyond this sale during the POR or after the POR (at least until the date of verification). We also noted other questionable factors with respect to Shenzhen Qunxingyuan's customer. Based on the totality of the circumstances, we found that the quantity and value reported by Shenzhen Qunxingyuan did not provide a reasonable or reliable basis for the Department to calculate a dumping margin and we rescinded the new shipper review with respect to Shenzhen Qunxingyuan. *See* Memorandum from Louis Apple, Office Director, to Susan Kuhbach, Acting Deputy Assistant Secretary for Import Administration, Fourth New Shipper Review of Certain Preserved Mushrooms from the People's Republic of China: Whether the Sale Made by Shenzhen Qunxingyuan Trading Co., Ltd. Is *Bona Fide* (February 28, 2003) (''Preliminary Price and Quantity Analysis Memorandum'').

We are also rescinding the new shipper review with respect to Shenzhen Qunxingyuan because we find that it did not have a *bona fide* U.S. sale during the POR, as required by 19 CFR 351.214(b)(2)(iv)(c), based on the totality of the facts on the record. In determining whether a sale was *bona fide,* the Department normally considers factors such as, *inter alia,*: (1) The timing of the sale, (2) the sale price and quantity, (3) the expenses arising from the sales transaction, (4) whether the sale was sold to the customer at a loss, and (5) whether the sales transaction between the exporter and importer was executed on an arm's-length basis. *See American Silicon Technologies* v. *United States*, 110 F. Supp. 2d 992, 996 (CIT 2000); *see also Final Results of First New Shipper Review and First Antidumping Duty Administrative Review: Certain Preserved Mushrooms From the People's Republic of China*, 66 FR 31204 (June 11, 2001) and the accompanying issues and decision memorandum. An examination of whether a sale is a *bona fide* transaction may be extensive and thus, may include a variety of these factors and others given the nature and circumstances of each company and its corresponding sales practices. In Shenzhen Qunxingyuan's case, we focused on the commercial income and viability of the company, the profitability of the sale in question, and its sale price relative to AUVs.

In this case, we find that the price of its single reported sale was aberrationally high relative to the average unit value of all U.S. imports of comparable canned mushroom imports during the POR. More importantly, with respect to the commercial legitimacy of the one reported U.S. sale, we continue to find that Shenzhen Qunxingyuan had no other sales of any merchandise, subject or non-subject, during or after the POR and therefore, had no commercial income during this period. In addition, it appears that Shenzhen Qunxingyuan's reported U.S. sale incurred a loss. Therefore, we determine that the record evidence does not support a finding that this company is a *bona fide* commercial entity. Consequently, for the reasons discussed above, the Department finds that Shenzhen Qunxingyuan's sole U.S. sale during the POR was *not* a *bona fide* commercial transaction and does not provide a reasonable or reliable basis for the Department to calculate a dumping margin. *See Decision Memo* at Comment 2 for additional discussion.

Non-Adverse Facts Available

For the final results of these reviews, we have determined it appropriate to treat water as a factor of production separate from factory overhead consistent with the Department's current practice (*see Fresh Garlic From the People's Republic of China: Final Results of Antidumping New Shipper Review*, 67 FR 72139 (December 4, 2002) and accompanying Issues and Decision Memorandum at Comment 7 (''*Garlic*'')).

Shantou Hongda and Shenxian Dongxing reported water consumption data which appeared to be erroneous

when compared to the amount reported by Guangxi Yulin and verified by the Department. With respect to Shenxian Dongxing, because originally we did not consider its reported water consumption factor to be necessary for valuation purposes, we did not examine its water consumption data at verification. In the case of Shantou Hongda, we examined its water consumption at verification but it contained errors which rendered this data unreliable (*see* exhibit 12 of the Department's February 14, 2002, verification report for Shantou Hongda).

Because Shantou Hongda and Shenxian Dongxing provided the Department with incomplete and/or unreliable information which could not be verified, use of facts available is appropriate pursuant to section 776(a)(2)(D) of the Act. We believe that Shantou Hongda and Shenxian Dongxing were unaware at the time the Department requested this information that it would be necessary to use the water consumption data in its margin calculation because the Department had not separately valued this input in any prior segment of this proceeding. Thus, in order to account for water consumption usage by each of these respondents in the final results, as non-adverse facts available, we have used the water factor reported by Guangxi Yulin, the only other respondent under review (for which we are calculating a margin in the final results) which reported a correct and complete water factor (as verified by the Department), and valued water for the other respondents using Guangxi Yulin's reported water factor. *See Decision Memo* at Comment 5.

Analysis of Comments Received

All issues raised in the case briefs are addressed in the *Decision Memo*, which is hereby adopted by this notice. A list of the issues raised, all of which are in the *Decision Memo*, is attached to this notice as an Appendix. Parties can find a complete discussion of all issues raised in the briefs and the corresponding recommendations in this public memorandum which is on file in the Central Records Unit, room B–099 of the main Department building. In addition, a complete version of the *Decision Memo* can be accessed directly on the Web at *http://ia.ita.doc.gov.* The paper copy and electronic version of the *Decision Memo* are identical in content.

Changes Since the Preliminary Results

Based on the use of additional publicly available information and the comments received from the interested parties, we have made changes in the margin calculation for each respondent. For a discussion of these changes, *see* the ''Margin Calculations'' section of the *Decision Memo.*

For the final results, we calculated average surrogate percentages for factory overhead, SG&A expenses, and profit using the 2001–2002 financial reports of Agro Dutch Foods Ltd. (''Agro Dutch'') and Flex Foods Ltd. (''Flex Foods''). *See Decision Memo* at Comment 4.

We used freight rates published in the February 2002–June 2002 issues of *Chemical Weekly* and obtained distances between cities from the following Web sites: *http://www.infreight.com* and *http://www.sitaindia.com/Packages/CityDistance.php.*

We treated water as a separate factor of production. To value water, we used 1995–1996 and 1996–1997 data from the *Second Water Utilities Data Book.* Since this value was not contemporaneous with the POR, we adjusted this value for inflation based on wholesale price indices published in the International Monetary Fund's *International Financial Statistics.* As discussed above, two respondents (*i.e.*, Shantou Hongda and Shenxian Dongxing) did not provide the Department with complete and/or reliable water consumption information which could be verified. Therefore, as facts available, we have used the amount reported by Guangxi Yulin, the only respondent under review which reported a correct and complete water factor (as verified by the Department), and applied it to the surrogate value for water for the two respondents at issue. *See* ''Non-Adverse Facts Available'' section above and *Decision Memo* at Comment 5.

To value tin can sets (*i.e.*, the can with the lid) for the respondents which produced their cans during the POR (*i.e.*, Guangxi Yulin and Shenxian Dongxing), we used 2001–2002 actual can-size-specific price data submitted by Agro Dutch in the 3rd antidumping duty administrative review of certain preserved mushrooms from India. However, for the respondents which only purchased their cans during the POR (*i.e.*, Shantou Hongda), we continued to use 2000–2001 price data from the May 21, 2001, public version response submitted by Agro Dutch in the 2nd antidumping duty administrative review of certain preserved mushrooms from India, and relied on the petitioners' methodology contained in its September 6, 2002, publicly available information submission for purposes of deriving per-unit, can-size-specific prices. *See Decision Memo* at Comment 6.

To value urea (carbamide), we used data in the 2001–2002 financial report of Flex Foods and February 2001–January 2002 data in *Chemical Weekly.*

To value super phosphate and grain, we used data in the 2001–2002 financial report of Flex Foods.

To value spawn, cow manure and straw, we used price data contained in the 2001–2002 financial reports of Flex Foods and Agro Dutch.

To value gypsum, we used the 2001–2002 financial report of Flex Foods and April 2001–December 2001 data from *Monthly Statistics of the Foreign Trade of India (''Monthly Statistics*'').

To value copper wire scrap, we used April 2001–December 2001 data from *Monthly Statistics* because this value is more specific to the product than the value used in the preliminary results. *See Decision Memo* at Comment 8.

We corrected a programming error by including Guangxi Yulin's tape cost only in its total packing costs (and not in its material costs).

We corrected a calculation error by including the total surrogate cost for seal glue in Guangxi Yulin's total material costs.

Final Results of Reviews

We determine that the following weighted-average margin percentages exist for the period February 1, 2001, through January 31, 2002:

Exporter	Margin (percent)
Gerber Food (Yunnan) Co., Ltd	198.63
Green Fresh Foods (Zhangzhou) Co., Ltd	198.63
Guangxi Yulin Oriental Food Co., Ltd. (''Guangxi Yulin'')	0.00
Guangxi Yulin/All Others	198.63
Shantou Hongda Industrial General Corporation	122.07
Shenxian Dongxing Foods Co., Ltd	61.37
PRC-Wide Rate	198.63

Assessment Rates

The Department shall determine, and the U.S. Bureau of Customs and Border Protection (''BCBP'') shall assess, antidumping duties on all appropriate entries. The Department will issue appropriate appraisement instructions for the companies subject to these reviews directly to the BCBP within 15 days of publication of the final results of these reviews. For assessment purposes, we do not have the actual entered value for any of the respondents for which we calculated a margin because it is not the importer of record for the subject merchandise. Therefore, we have calculated individual importer- or customer-specific assessment rates by aggregating the dumping margins calculated for all of the U.S. sales

examined and dividing that amount by the total quantity of the sales examined. For Shenxian Dongxing, however, because we find that its quantity data is unreliable, we will instruct the BCBP to apply Shenxian Dongxing's margin to the entered value of its subject merchandise as reported to the BCBP during the POR. To determine whether the duty assessment rates are *de minimis* (*i.e.*, less than 0.50 percent), in accordance with the requirement set forth in 19 CFR 351.106(c)(2), we have calculated importer- or customer-specific *ad valorem* ratios based on export prices. We will instruct the BCBP to assess antidumping duties on all appropriate entries covered by these reviews if any importer or customer-specific assessment rate calculated in the final results of these reviews is above *de minimis*. For entries of the subject merchandise during the POR from companies not subject to these reviews, we will instruct the BCBP to liquidate them at the cash deposit in effect at the time of entry.

Cash Deposit Requirements

Bonding will no longer be permitted to fulfill security requirements for shipments from Guangxi Yulin, Shenzhen Qunxingyuan, or Zhangzhou Jingxiang of certain preserved mushrooms from the PRC entered, or withdrawn from warehouse, for consumption on or after the publication date of these final results.

The following deposit rates shall be required for merchandise subject to the order entered or withdrawn from warehouse, for consumption on or after the publication date of these final results, as provided by section 751(a)(1) and 751(a)(2)(B) of the Act: (1) The cash deposit rates for Gerber, Green Fresh, Guangxi Yulin (*i.e.*, for subject merchandise both manufactured and exported by Guangxi Yulin), Shantou Hongda, and Shenxian Dongxing will be the rates indicated above; (2) the cash deposit rate for PRC exporters for whom the Department has rescinded the review or for which a review was not requested (*e.g.*, China Processed, Compania Envasador, and Raoping Xingyu) will continue to be the rate assigned in an earlier segment of the proceeding or the PRC-wide rate of 198.63 percent, whichever applicable; (3) the cash deposit rate for the PRC NME entity (including Shenzhen Qunxingyuan and Zhangzhou Jingxiang) and for subject merchandise exported but not manufactured by Guangxi Yulin will continue to be the PRC-wide rate of 198.63 percent; and (4) the cash deposit rate for non-PRC exporters of subject merchandise from the PRC will be the rate applicable to the PRC supplier of that exporter. These deposit requirements shall remain in effect until publication of the final results of the next administrative review.

This notice also serves as a final reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in the Secretary's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of doubled antidumping duties.

This notice also serves as the only reminder to parties subject to administrative protective orders (APO) of their responsibility concerning the return or destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a). Timely written notification of the return/destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and terms of an APO is a violation which is subject to sanction.

We are issuing and publishing these determinations and notice in accordance with sections 751(a)(1), 751(a)(2)(B), and 777(i) of the Act and 19 CFR 351.213 and 351.214.

Dated: July 3, 2003.

Joseph A. Spetrini,

Acting Assistant Secretary for Grant Aldonas, Under Secretary.

Appendix—Issues in Decision Memo

Comments

1. The Application of Facts Available to Gerber and Green Fresh.
2. The *Bona Fides* of Shenzhen Qunxingyuan's U.S. Sale.
3. The Rescission of the New Shipper Review for Guangxi Yulin.
4. The Use of Himalya's Financial Data to Derive Surrogate Percentages.
5. The Valuation of Water.
6. Surrogate Value for Cans.
7. The Treatment of Tin Scrap as an Offset.
8. Surrogate Value for Copper Wire Scrap.

[FR Doc. 03–17628 Filed 7–10–03; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE
International Trade Administration

[C–507–501]

Certain In-Shell Pistachios From the Islamic Republic of Iran: Final Results of Countervailing Duty Administrative Review

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

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

SUMMARY: On April 4, 2003, the Department of Commerce (the Department) published in the **Federal Register** its preliminary results in the countervailing duty (CVD) administrative review of certain in-shell pistachios from Iran. *See Certain In-shell Pistachios from the Islamic Republic of Iran: Preliminary Results of Countervailing Duty Administrative Review,* 68 FR 16473 (April 4, 2003) (*Preliminary Results*). The Department has now completed this administrative review in accordance with section 751(a) of the Tariff Act of 1930, as amended (the Act).

Based on our analysis of the comments received, the Department has revised the net subsidy rate for the Rafsanjan Pistachios Producers Cooperative (RPPC). The revised final net subsidy rate for the reviewed company is listed below in the ''Final Results of Review'' section of this notice.

EFFECTIVE DATE: July 11, 2003.

FOR FURTHER INFORMATION CONTACT: Darla Brown or Eric B. Greynolds, AD/CVD Enforcement, Office VI, Group II, Import Administration, U.S. Department of Commerce, Room 4012, 14th Street and Constitution Avenue, NW., Washington, DC 20230; telephone (202) 482–2849 or (202) 482–6071, respectively.

SUPPLEMENTARY INFORMATION:

Background

On March 11, 1986, the Department published in the **Federal Register** the countervailing duty order on certain in-shell pistachios from Iran. *See Final Affirmative Countervailing Duty Determination and Countervailing Duty Order: In-shell Pistachios from Iran,* 51 FR 8344 (March 11, 1986) (*In-shell Pistachios*).

We published the *Preliminary Results* of the instant administrative review in the **Federal Register** on April 4, 2003 (68 FR 16473). We invited interested parties to comment on the results. On

May 5, 2003, we received a case brief from petitioners.[1] In their May 5, 2003, case brief, petitioners requested a hearing. On May 14, 2003, petitioners withdrew their request for a hearing. We did not receive case or rebuttal briefs from respondents.

In accordance with 19 CFR 351.213 (2002), this administrative review covers only those producers or exporters for which a review was specifically requested. Accordingly, this administrative review covers RPPC and nine programs for the period of review (POR) January 1, 2001, through December 31, 2001.

Scope of Review

The product covered by this administrative review is in-shell pistachio nuts from which the hulls have been removed, leaving the inner hard shells and edible meat, as currently classifiable in the Harmonized Tariff Schedules of the United States (HTSUS) under item number 0802.50.20.00. The HTSUS subheadings are provided for convenience and customs purposes. The written description of the scope of this proceeding is dispositive.

Use of Facts Available

During the course of this proceeding, we have repeatedly sought information pertaining to all companies that are cross-owned and/or affiliated with RPPC, the producer of subject merchandise, and RPPC's shareholders. In addition, we have repeatedly requested information concerning the total sales and sales of subject merchandise made by RPPC during the POR. Moreover, we have repeatedly asked for specific information concerning RPPC's and its members' usage of the following programs: Provision of Fertilizer and Machinery, Provision of Water and Irrigation Equipment, Duty Refunds on Imported Raw or Intermediate Materials Used in the Production of Exported Goods, Program to Improve the Quality of Exports of Dried Fruit, Tax Exemptions, Technical Assistance from the GOI, and Provision of Credit. *See Preliminary Results.*

Section 776(a) of the Act requires the use of facts available when an interested party withholds information that has been requested by the Department, or when an interested party fails to provide the information requested in a timely manner and in the form required. As described in the paragraph above and in our *Preliminary Results,* RPPC and the GOI have failed to provide information regarding cross-ownership, affiliation, sales, and the programs named above in the manner explicitly and repeatedly requested by the Department; therefore, we must resort to the facts otherwise available.

Furthermore, section 776(b) of the Act provides that in selecting from among the facts available, the Department may use an inference that is adverse to the interests of a party if it determines that a party has failed to cooperate to the best of its ability. The Department finds that by not providing necessary information specifically requested by the Department, despite numerous opportunities, the GOI and RPPC have failed to cooperate to the best of their ability. Therefore, in selecting from among the facts available, the Department determines that an adverse inference is warranted.

When employing an adverse inference in an administrative review, the statute indicates that the Department may rely upon information derived from (1) the petition, a final determination in a countervailing duty or an antidumping investigation, any previous administrative review, new shipper review, expedited antidumping review, section 753 review, or section 762 review; or (2) any other information placed on the record. *See* section 776(b) of the Act. Thus, in applying adverse facts available, we have used information on the record of this administrative review as well as information regarding the programs and exchange rates from the final determinations of *In-shell Pistachios* and *Certain In-shell Pistachios and Certain Roasted In-shell Pistachios from the Islamic Republic of Iran: Final Results of New Shipper Countervailing Duty Reviews,* 68 FR 4997 (January 31, 2003) (*Pistachios New Shipper Reviews*).

Specifically, for the Export Certificate Voucher Program, we used publicly available data from the *Pistachios New Shipper Reviews* in order to calculate a benefit. With respect to the other seven programs determined to confer subsidies, we relied on the rates calculated for each of those programs in the original investigation of *In-shell Pistachios.* The Department's selection of the information used as adverse facts available is discussed in more detail in the program-specific sections of the ''Issues and Decision Memorandum: Final Results of Countervailing Duty Administrative Review: Certain In-Shell (Raw) Pistachios from the Islamic Republic of Iran'' (Decision Memorandum) dated August 2, 2003, which is hereby adopted by this notice.

If the Department relies on secondary information (*e.g.*, data from a petition) as facts available, section 776(c) of the Act provides that the Department shall, ''to the extent practicable,'' corroborate such information using independent sources reasonably at its disposal.[2] The SAA further provides that to corroborate secondary information means that the Department will satisfy itself that the secondary information to be used has probative value. *See also,* 19 CFR 351.308(d).

Thus, in those instances in which it determines to use secondary information, the Department, in order to satisfy itself that such information has probative value, will examine, to the extent practicable, the reliability and relevance of the information used. *See Final Affirmative Countervailing Duty Determination: Certain Hot-Rolled Carbon Steel Flat Products From Argentina,* 66 FR 37007 (July 16, 2001). However, unlike other types of information, such as publicly available data on the national inflation rate of a given country or national average interest rates, there typically are no independent sources for data on company-specific benefits resulting from countervailable subsidy programs. The only source for such information normally is administrative determinations. In the instant case, no evidence has been presented or obtained which contradicts the reliability of the evidence relied upon in previous segments of this proceeding.

With respect to the relevance aspect of corroboration, the Department will consider information reasonably at its disposal as to whether there are circumstances that would render benefit data not relevant. *See Cotton Shop Towels from Pakistan: Final Results of Countervailing Duty Administrative Review,* 66 FR 42514 (August 13, 2001) at ''Use of Facts Available Section'' of the Final Issues and Decision Memorandum (where the Department used the subsidy rate found for a program in the last administrative review conducted for the order). Where circumstances indicate that the information is not appropriate as adverse facts available, the Department will not use it. *See Fresh Cut Flowers from Mexico; Final Results of Antidumping Duty Administrative Review,* 61 FR 6812 (February 22, 1996) (where the Department disregarded the highest dumping margin as best

[1] Petitioners include the California Pistachios Commission and its members and a domestic interested party, Cal Pure Pistachios, Inc.

[2] The Statement of Administrative Action accompanying the URAA clarifies that information from the petition is ''secondary information.'' *See* Statement of Administrative Action, accompanying H.R. 5110 (H. Doc. No. 103–316) (1994) (SAA) at 870.

information available because the margin was based on another company's uncharacteristic business expense resulting in an unusually high margin). In the instant case, no evidence has been presented or obtained which contradicts the relevance of the benefit data relied upon in previous segments of this proceeding. Thus, in the instant case, the Department finds that the information used has been corroborated to the extent practicable.

Analysis of Comments Received

All issues raised in the case and rebuttal briefs by parties to this review are addressed in the Decision Memorandum. A list of issues which parties have raised and to which we have responded, all of which are in the Decision Memorandum, is attached to this notice as Appendix I. Parties can find a complete discussion of all issues raised in this review and the corresponding recommendations in this public memorandum, which is on file in room B–099 of the Main Commerce Building. In addition, a complete version of the Decision Memorandum can be accessed directly on the World Wide Web at *http://ia.ita.doc.gov,* under the heading ''**Federal Register** Notices.'' The paper copy and electronic version of the Decision Memorandum are identical in content.

Final Results of Review

In accordance with section 705(c)(1)(B)(i) of the Act, we determined an ad valorem subsidy rate for RPPC.

Producer/Exporter	Cash deposit rate
Rafsanjan Pistachio Producers Cooperative (RPPC).	60.77 percent *ad valorem.*

Under section 351.526 of the Department's regulations, the Department can adjust cash deposit rates to account for program-wide changes. During the recently-completed new shipper reviews of in-shell pistachios and in-shell roasted pistachios from Iran, the Department verified that the export certificate voucher program has been terminated subsequent to the POR (*see Pistachios New Shipper Reviews* and the accompanying Issues and Decision Memorandum at Comment 13). Therefore, we are adjusting the cash deposit rate to take into account this program-wide change. Thus, in determining the cash deposit rate listed below, we have deducted the subsidies found for this program from the overall subsidy rate calculated for RPPC.

Producer/Exporter	Cash deposit rate
Rafsanjan Pistachio Producers Cooperative (RPPC).	49.77 percent *ad valorem.*

We will instruct the U.S. Bureau of Customs and Border Protection (Customs) to assess countervailing duties as indicated above. The Department will instruct Customs to collect cash deposits of estimated countervailing duties in the percentage detailed above of the f.o.b. invoice prices on all shipments of the subject merchandise from the producers/exporters under review, entered, or withdrawn from warehouse, for consumption on or after the date of publication of the final results of this administrative review.

Because the URAA replaced the general rule in favor of a country-wide rate with a general rule in favor of individual rates for investigated and reviewed companies, the procedures for establishing countervailing duty rates, including those for non-reviewed companies, are now essentially the same as those in antidumping cases, except as provided for in section 777A(e)(2) of the Act. The requested review will normally cover only those companies specifically named. *See* 19 CFR 351.213(b). Pursuant to 19 CFR 351.212(c), for all companies for which a review was not requested, duties must be assessed at the cash deposit rate, and cash deposits must continue to be collected, at the rate previously ordered. As such, the countervailing duty cash deposit rate applicable to a company can no longer change, except pursuant to a request for a review of that company. *See Federal-Mogul Corporation and The Torrington Company* v. *United States,* 822 F. Supp. 782 (CIT 1993) and *Floral Trade Council* v. *United States,* 822 F. Supp. 766 (CIT 1993). Therefore, the cash deposit rates for all companies except those covered by this review will be unchanged by the results of this review.

We will instruct Customs to continue to collect cash deposits for non-reviewed companies at the most recent company-specific or country-wide rate applicable to the company. Accordingly, the cash deposit rates that will be applied to non-reviewed companies covered by this order will be the rate for that company established in the most recently completed administrative proceeding conducted under the URAA. If such a review has not been conducted, the rate established in the most recently completed administrative proceeding pursuant to the statutory provisions that were in effect prior to the URAA amendments is applicable. *See Stainless Steel Sheet and Strip in Coils from the Republic of Korea: Amended Final Results of Countervailing Duty Administrative Review,* 67 FR 8229 (February 22, 2002). This rate shall apply to all non-reviewed companies until a review of a company assigned this rate is requested. In addition, for the period January 1, 2001 through December 31, 2001, the assessment rates applicable to all non-reviewed companies covered by this order are the cash deposit rates in effect at the time of entry.

This notice also serves as a final reminder to importers of their responsibility under 19 CFR 351.402(f) to file a certificate regarding the reimbursement of duties prior to liquidation of the relevant entries during this review period.

This notice serves as a 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(a)(3). Timely written 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 administrative review and notice are issued and published in accordance with section 751(a)(1) of the Act.

Dated: July 2, 2003.

Joseph A. Spetrini,

Acting Assistant Secretary for Grant Aldonas, Under Secretary.

Appendix I—Issues and Decision Memorandum

I. Methodology and Background Information Use of Facts Available.
II. Analysis of Programs
A. Programs Determined to Confer Subsidies
1. Export Certificate Voucher Program.
2. Provision of Fertilizer and Machinery.
3. Provision of Water and Irrigation Equipment.
4. Program to Improve Quality of Exports of Dried Fruit.
5. Duty Refunds on Imported Raw or Intermediate Materials Used in the Production of Exported Goods.
6. Tax Exemptions.
7. Technical Assistance from the GOI.
8. Provision of Credit.
B. Program Determined To Be Not Countervailable
Price Supports and/or Guaranteed Purchase of All Production.
III. Total AD Valorem Rate
IV. Analysis of Comments
Comment 1: Use of Adverse Facts Available.

Comment 2: Export Certificate Voucher Program.

Comment 3: Price Supports Program.

[FR Doc. 03–17629 Filed 7–10–03; 8:45 am]

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DEPARTMENT OF COMMERCE

International Trade Administration

North American Free-Trade Agreement, Article 1904 NAFTA Panel Reviews; Request for Panel Review

AGENCY: NAFTA Secretariat, United States Section, International Trade Administration, Department of Commerce.

ACTION: Notice of first request for panel review.

SUMMARY: On July 2, 2003, Camara Nacional de la Industria de Aceites, Grasas, Jabones y Detergentes (CANAJAD) filed a First Request for Panel Review with the Mexican Section of the NAFTA Secretariat pursuant to Article 1904 of the North American Free Trade Agreement. Panel review was requested of the final countervailing duty determination made by the Secretaria de Economia, respecting Sodium Hydroxide (Caustic Soda) in Aqueous Solution, Originating in the United States of America independently of the country of origin. This determination was published in the *Diario Oficial de la Federacion del,* on June 6,2003. The NAFTA Secretariat has assigned Case Number MEX–USA–2003–1904–01 to this request.

FOR FURTHER INFORMATION CONTACT: Caratina L. Alston, United States Secretary, NAFTA Secretariat, Suite 2061, 14th and Constitution Avenue, Washington, DC 20230, (202) 482–5438.

SUPPLEMENTARY INFORMATION: Chapter 19 of the North American Free-Trade Agreement (''Agreement'') establishes a mechanism to replace domestic judicial review of final determinations in antidumping and countervailing duty cases involving imports from a NAFTA country with review by independent binational panels. When a Request for Panel Review is filed, a panel is established to act in place of national courts to review expeditiously the final determination to determine whether it conforms with the antidumping or countervailing duty law of the country that made the determination.

Under Article 1904 of the Agreement, which came into force on January 1, 1994, the Government of the United States, the Government of Canada and the Government of Mexico established *Rules of Procedure for Article 1904 Binational Panel Reviews* (''Rules''). These Rules were published in the **Federal Register** on February 23, 1994 (59 FR 8686).

A first Request for Panel Review was filed with the Mexican Section of the NAFTA Secretariat, pursuant to Article 1904 of the Agreement, on July 2, 2003, requesting panel review of the final determination described above.

The Rules provide that:

(a) A Party or interested person may challenge the final determination in whole or in part by filing a Complaint in accordance with Rule 39 within 30 days after the filing of the first Request for Panel Review (the deadline for filing a Complaint is August 1, 2003);

(b) A Party, investigating authority or interested person that does not file a Complaint but that intends to appear in support of any reviewable portion of the final determination may participate in the panel review by filing a Notice of Appearance in accordance with Rule 40 within 45 days after the filing of the first Request for Panel Review (the deadline for filing a Notice of Appearance is August 18, 2003); and

(c) The panel review shall be limited to the allegations of error of fact or law, including the jurisdiction of the investigating authority, that are set out in the Complaints filed in the panel review and the procedural and substantive defenses raised in the panel review.

Dated: July 7, 2003.

Caratina L. Alston,

United States Secretary, NAFTA Secretariat.

[FR Doc. 03–17547 Filed 7–10–03; 8:45 am]

BILLING CODE 3510–GT–P

DEPARTMENT OF COMMERCE

National Institute of Standards and Technology

Advanced Technology Program Advisory Committee

AGENCY: National Institute of Standards and Technology, Department of Commerce.

ACTION: Notice of renewal.

SUMMARY: In accordance with the provisions of the Federal Advisory Committee Act, 5 U.S.C. App. 2, and the General Services Administration (GSA) rule on Federal Advisory Committee Management, 41 CFR part 101–6, and after consultation with GSA, the Secretary of Commerce has determined that the renewal of the Advanced Technology Program Advisory Committee is in the public interest in connection with the performance of the duties imposed on the Department by law.

The Committee was first established in July 1999 to advise ATP regarding their programs, plans, and policies. In renewing the Board, the Secretary has established it for an additional two years. During the next two years, the Committee plans to study and make recommendations regarding a number of issues related to further improving the effectiveness of the program, such as, but not limited to, strengthening ties between the ATP and state technology programs and further encouraging the involvement of universities.

The Committee will consist of not fewer than 6 nor more than 12 members to be appointed by the Director of the National Institute of Standards and Technology to assure a balanced membership that will represent the views and needs of customers, providers, and others involved in industrial extension throughout the United States.

The Committee will function solely as an advisory body and in compliance with the provisions of the Federal Advisory Committee Act. Copies of the renewed charter will be filed with the appropriate committees of the Congress and with the Library of Congress.

FOR FURTHER INFORMATION CONTACT: Marc Stanley, Director, Advanced Technology Program, National Institute of Standards and Technology, 100 Bureau Drive, Stop 4700, Gaithersburg, Maryland 20899–4700; telephone: 301–975–2162.

Dated: June 30, 2003.

Karen H. Brown,

Deputy Director.

[FR Doc. 03–17636 Filed 7–10–03; 8:45 am]

BILLING CODE 3510–13–P

DEPARTMENT OF COMMERCE

National Institute of Standards and Technology

Announcing a Workshop on Building Secure Configurations/Security Settings/Security Checklists for Information Technology Products Widely Used in the Federal Government

AGENCY: National Institute of Standards and Technology (NIST).

ACTION: Notice of public workshop.

SUMMARY: The Cyber Security Research and Development Act of 2002 tasks National Institute of Standards and Technology (NIST) to ''develop, and revise as necessary, a checklist setting forth settings and option selections that

minimize the security risks associated with each computer hardware or software system that is, or is likely to become widely used within the Federal Government.'' Various Federal organizations (NIST, NSA, DISA, etc.), consortia (*e.g.*, Center for Internet Security), and some commercial vendors produce these checklists. Such checklists when combined with well-developed guidance, leveraged with high-quality security expertise, vendor product knowledge, operational experience, and accompanied with tools can markedly reduce the vulnerability exposure of an organization. To meet this challenging requirement to produce checklists for the spectrum of IT products widely used in the government, NIST has developed a proposal to solicit from IT vendors, consortia, industry and government organizations, and others in the public and private sector to produce additional checklists and associated guidance material to NIST. These materials would then be made available for display and downloading from the NIST Computer Security Resource Center (CSRC) Web site (*http://csrc.nist.gov*). To gather feedback on the proposed approach, NIST is announcing a workshop to identify current and planned Federal government checklist activities and related needs, existing and planned voluntary efforts for building security checklists, and current industry capabilities for the development of checklists and the associated templates that describe sets of security configurations for IT products widely used in the United States Government (USG).

It is anticipated that the workshop will support the development of a standard Extensible Markup Language (XML) template for security configuration checklist descriptions, and a guideline on producing consensus checklists that can be searched, compared, shared freely, and used by the USG and Internet community at large. The goal of this initial workshop is to collect suggestions from organizations that have already developed or are involved in the development of such checklists to gain their input on key items that should be included within the template. The detailed draft agenda and supporting documentation for the workshop will be available prior to the workshop from the NIST CSRC Web site at *http://csrc.nist.gov/checklists* by July 31, 2003.

DATES: The workshop will be held on September 25 and 26, 2003, from 9 a.m. to 5 p.m.

ADDRESSES: The workshop will be held in the Lecture Room B, Bldg 101 at the National Institute of Standards and Technology, Gaithersburg, MD.

FOR FURTHER INFORMATION CONTACT: Additional information, when available, may be obtained from the Computer Security Resource Center Web site at *http://csrc.nist.gov/checklists* or by contacting John Wack, National Institute of Standards and Technology, Building 100 Bureau Drive, Stop 8930, Gaithersburg, MD 20899–8930; telephone 301–975–3411; Fax 301–948–0279, or e-mail: *checklists@nist.gov.*

SUPPLEMENTARY INFORMATION:

NIST will lead an effort in coordination with other agencies and private industry to develop and disseminate a standard template designed to describe security checklists. Examples of key IT product technology areas include: operating systems, database systems, web servers, e-mail servers, firewalls, routers, intrusion detection systems, virtual private Networks, biometric devices, smart cards, telecommunication switching devices and web browsers.

Vendors, agencies, consortia, and other reputable sources will be encouraged to submit checklists and related information called for by the template to populate a public web-based repository. The template will provide a standardized method of centrally cataloging, describing, and categorizing existing and newly developed security checklists for IT products. The XML template will be used to populate an online database hosted by NIST that will provide the USG and Internet community with a centralized database used to consolidate information about IT product security checklists.

The initial workshop is being held to identify the key fields of the template. Workshop topics are planned to include:

- Target environments,
- Risk levels,
- Methods to gain wide agency and vendor support,
- Methods and incentives to encourage vendors' submissions adhering to the proposed template.

Vendors, agencies, and other reputable sources currently developing checklists for IT products are encouraged to present information at the workshop describing their checklist development and testing process. Speakers wishing to formally present information at the workshop should submit proposals to *checklists@nist.gov* by September 1, 2003.

Because of NIST security regulations, advance registration is mandatory; there will be no on-site, same-day registration. To register, please register via the Web at *http://www.nist.gov/conferences* or fax the registration form with your name, address, telephone, fax and e-mail address to 301–948–2067 (Attn: Workshop on Building Secure Configurations/Security Settings/ Security Checklists for Federal Government Systems) by September 22, 2003. The registration fee will be $85. Payment can be made by credit card, check, purchase order, and government training form. Registration questions should be addressed to Kimberly Snouffer on 301–975–2776 or *kimberly.snouffer@nist.gov.*

Authority

This work effort is being initiated pursuant to NIST's responsibilities under the Cyber Security Research and Development Act of 2002.

Dated: July 7, 2003.

Arden L. Bement, Jr.,

Director.

[FR Doc. 03–17635 Filed 7–10–03; 8:45 am]

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DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[I.D. 021203A]

Small Takes of Marine Mammals Incidental to Specified Activities; Oceanographic Surveys in the Hess Deep, Eastern Equatorial Pacific Ocean

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

ACTION: Notice of issuance of an incidental harassment authorization.

SUMMARY: In accordance with provisions of the Marine Mammal Protection Act (MMPA) as amended, notification is hereby given that an Incidental Harassment Authorization (IHA) to take small numbers of marine mammals, by harassment, incidental to conducting oceanographic surveys in the Hess Deep in international waters of the Eastern Equatorial Pacific Ocean has been issued to Lamont-Doherty Earth Observatory (L-DEO).

DATES: Effective from July 3, 2003, through June 30, 2004.

ADDRESSES: The application, a list of references used in this document, and/or the IHA are available by writing to Kaja A. Brix, Acting Chief, Marine Mammal Conservation Division, Office of Protected Resources, National Marine

Fisheries Service, 1315 East-West Highway, Silver Spring, MD 20910–3225, or by telephoning the contact listed here.

FOR FURTHER INFORMATION CONTACT: Kenneth R. Hollingshead, Office of Protected Resources, NMFS, (301) 713–2055, ext 128,

SUPPLEMENTARY INFORMATION:

Background

Sections 101(a)(5)(A) and (D) of the MMPA (16 U.S.C. 1361 *et seq.*) direct the Secretary of Commerce to allow, upon request, the incidental, but not intentional, taking of marine mammals by U.S. citizens who engage in a specified activity (other than commercial fishing) within a specified geographical region if certain findings are made and either regulations are issued or, if the taking is limited to harassment, a notice of a proposed authorization is provided to the public for review.

Permission may be granted if NMFS finds that the taking will have a negligible impact on the species or stock(s) and will not have an unmitigable adverse impact on the availability of the species or stock(s) for subsistence uses and that the permissible methods of taking and requirements pertaining to the monitoring and reporting of such takings are set forth. NMFS has defined ''negligible impact'' in 50 CFR 216.103 as ''...an impact resulting from the specified activity that cannot be reasonably expected to, and is not reasonably likely to, adversely affect the species or stock through effects on annual rates of recruitment or survival.

Subsection 101(a)(5)(D) of the MMPA established an expedited process by which citizens of the United States can apply for an authorization to incidentally take small numbers of marine mammals by harassment. Under section 18(A), the MMPA defines ''harassment'' as:

> any act of pursuit, torment, or annoyance which (i) has the potential to injure a marine mammal or marine mammal stock in the wild [Level A harassment]; or (ii) has the potential to disturb a marine mammal or marine mammal stock in the wild by causing disruption of behavioral patterns, including, but not limited to, migration, breathing, nursing, breeding, feeding, or sheltering [Level B harassment].

Subsection 101(a)(5)(D) establishes a 45–day time limit for NMFS review of an application followed by a 30–day public notice and comment period on any proposed authorizations for the incidental harassment of small numbers of marine mammals. Within 45 days of the close of the comment period, NMFS must either issue or deny issuance of the authorization.

Summary of Request

On January 29, 2003, NMFS received an application from L-DEO for the taking, by harassment of several species of marine mammals incidental to conducting a seismic survey program in the Hess Deep portion of the Eastern Equatorial Pacific Ocean about 600 nautical miles (nm)(690 land miles; 1111.2 km) west of the Galapagos Islands during March and April 2003, but rescheduled for July, 2003. The purpose of this survey is to obtain information on movements of the earth's plates and on formations associated with those movements. More specifically, the Hess Deep survey will obtain information on the geologic nature of boundaries of the earth's crust at fast-spreading and intermediate-spreading ridges at the boundaries of tectonic plates.

Description of the Activity

The seismic survey will involve a single vessel, the *R/V Maurice Ewing* (*Ewing*), which will deploy and retrieve the Ocean Bottom Seismometers (OBSs) and conduct the seismic work. The Ewing will deploy an array of airguns as an energy source, plus a 6–km (3.2–nm) towed streamer containing hydrophones to receive the returning acoustic signals.

Water depths in the Hess Deep survey area will range from approximately 2,000 to 3,400 m (6,560 to 11,150 ft). A total of 912 km (492 nm) of MCS (Multi Channel Seismic) surveys using a 10–gun array and 189 km (102 nm) of OBS surveys using a 12–gun array are planned to be conducted. These line-kilometer figures represent the planned production surveys. There will be additional operations associated with equipment testing, startup, line changes, and repeat coverage of any areas where initial data quality is sub-standard.

The procedures to be used for the 2003 seismic survey will be similar to those used during previous seismic surveys by L-DEO, (e.g., in the equatorial Pacific Ocean (Carbotte et al., 1998, 2000)). The proposed program will use conventional seismic methodology with a towed airgun array as the energy source and a towed streamer containing hydrophones as the receiver system, sometimes in combination with OBS receivers placed on the bottom. The energy to the airgun array is compressed air supplied by compressors on board the source vessel. In addition, a multi-beam bathymetric sonar will be operated from the source vessel at most times during the Hess Deep survey.

The *Ewing* will be used as the source vessel. It will tow the airgun array (either 10 or 12 guns) and a streamer containing hydrophones along predetermined lines. The vessel will travel at 4–5 knots (7.4–9.3 km/hr), and seismic pulses will be emitted at intervals of 60–90 seconds (OBS lines) and approximately 20 seconds (all other lines). The 20–sec spacing corresponds to a shot interval of about 50 m (164 ft). The 60–90 sec spacing along OBS lines is to minimize previous shot noise during OBS data acquisition, and the exact spacing will depend on water depth. The 10–gun array will be used during MSC surveys and the 12 gun-array will be used during OBS surveys. The airguns will be widely spaced in an approximate rectangle with dimensions 35 m (114.9 ft)(across track) by 9 m (29.5 ft)(along track). Individual airguns range in size from 80 to 850 in3, with total volumes of the arrays being 3050 and 3705 in3 for the 10- and 12–gun arrays, respectively.

The 10–airgun array will have a peak sound source level of 248 dB re 1 μPa or 255 dB peak-to-peak (P-P). The 12–airgun array will have a peak sound source level of 250 dB re 1 μPa or 257 dB P-P. These are the nominal source levels for the sound directed downward, and represent the theoretical source level close to a single point source emitting the same sound as that emitted by the array of 10 or 12 sources. Because the actual source is a distributed sound source (10 or 12 guns) rather than a single point source, the highest sound levels measurable at any location in the water will be less than the nominal source level. Also, because of the downward directional nature of the sound from these airgun arrays, the effective source level for sound propagating in near-horizontal directions will be substantially lower than sounds projected directly beneath the array.

Along selected lines, OBSs will be positioned by the *Ewing* prior to the time when it begins airgun operations in that area. After OBS lines are shot, the *Ewing* will retrieve the OBSs, download the data, and refurbish the units.

Along with the airgun operations, one additional acoustical data acquisition activity will occur throughout most of the cruise. The ocean floor will be mapped with an Atlas Hydrosweep DS–2, multi-beam 15.5–kHz bathymetric sonar (Atlas Hydrosweep). The Atlas Hydrosweep is mounted in the hull of the *Ewing*, and it operates in three modes, depending on the water depth. The first mode is when water depth is <400 μ(<1312.3 ft). The source output is 210 dB re 1 μPa-m rms and a single 1–

millisec (msec) pulse or ''ping'' per second is transmitted, with a beam-width of 2.67 degrees fore-aft and 90 degrees in beam-width. The beam-width is measured to the 3 dB point, as is usually quoted for sonars. The other two modes are deep-water modes: The Omni mode is identical to the shallow-water mode except that the source output is 220 dB rms. The Omni mode is normally used only during start up. The Rotational Directional Transmission (RDT) mode is normally used during deep-water operation and has a 237 dB rms source output. In the RDT mode, each ''ping'' consists of five successive transmissions, each ensonifying a beam that extends 2.67 degrees fore-aft and approximately 30 degrees in the cross-track direction. The five successive transmissions (segments) sweep from port to starboard with minor overlap, spanning an overall cross-track angular extent of about 140 degrees, with tiny (<1 μs) gaps between the pulses for successive 30–degree segments. The total duration of the ''ping'', including all 5 successive segments, varies with water depth but is 1 msec in water depths <500 m (<1640.4 ft) and 10 msec in the deepest water. Additional information on the airgun array and Atlas Hydrosweep specifications is contained in the application, which is available upon request (see **ADDRESSES**).

Comments and Responses

A notice of receipt of the L-DEO application and proposed IHA was published in the **Federal Register** on April 14, 2003 (68 FR 17909). That notice described in detail the proposed activity, including the characteristics of the Ewing's acoustic sources, the marine mammal species that may be affected by the activity, and the anticipated effects on marine mammals. That information is not repeated here. During the 30–day public comment period, comments were received from the Marine Mammal Commission (Commission) and the Center for Biological Diversity (CBD).

Activity Concerns

Comment 1: The CBD believes that the proposed authorization is flawed because it lacks a disclosure and analysis of the impacts of the multi-beam bathymetric sonar planned for use on this voyage. The proposed authorization indicates that the dB level of this sonar is 210–220 dB rms, yet concludes without sufficient analysis that the sonar is unlikely to result in any take by harassment.

Response: A complete description of the Atlas Hydrosweep is contained in the proposed IHA document (68 FR 17916, April 14, 2003), pages 54–56 of the L-DEO application, and pages 65–66 of the National Science Foundation (NSF) Environmental Assessment (EA). The reason for concluding that the Atlas Hydrosweep is unlikely to result in a take by harassment is contained in those documents. In summary, any given marine mammal at depth near the Ewing trackline would be in the main beam for only 1/5th or at most 2/5th of the 1 10 msec duration of the signal. The Atlas Hydrosweep is less powerful, has a shorter pulse duration and projects downwards as compared to standard Navy sonars that have been linked to avoidance reactions and stranding of cetaceans. Also, because the area of possible influence of the Atlas Hydrosweep is much smaller (a narrow band below the source vessel), marine mammals that encounter the Atlas Hydrosweep at close range are unlikely to be subjected to repeated pulses because of the narrow fore-aft width of the beam, and will receive only limited amounts of pulse energy because of the short pulses. This effectively eliminates a marine mammal receiving the additional acoustic stimulus needed to induce a significant behavioral response.

Marine Mammal Impact Concerns

Comment 2: The CBD notes that the proposed IHA **Federal Register** document states that approximately 8,901 marine mammals will be taken by the 10–gun and 12–gun array with peak source levels of 255 dB P-P (peak-to-peak) and 257 dB P-P (or approximately 239 rms (root-mean-squared) and 241 rms). According to the CBD, this does not constitute ''small numbers'' of marine mammals.

Response: Section 101(a)(5)(D) of the MMPA authorizes takings of marine mammals incidental to an applicant's activity if, among other things, the incidental taking, by harassment, is of small numbers of marine mammals of a species or population stock. The regulations at 50 CFR 216.103 define ''small numbers'' to mean ''a portion of a marine mammal species or stock whose taking would have a negligible impact on that species or stock.'' An activity would affect ''small numbers'' of a species or stock when it is determined that the total taking (of the species or stock by the activity over the period of the authorization) will be small relative to the estimated population size and relevant to the behavioral, physiological, and life history characteristics of the species. In other words, NMFS considers the kind of take (e.g., mortality, injury, or harassment); an individual mammal's hearing ability, and the affected species hearing capability in the frequency of the subject anthropogenic sounds; and the robustness of the affected marine mammal populations when determining whether the incidental taking would be small. There is no requirement that the total cumulative taking of all species be small.

Table 7 in the application (and referenced in the proposed authorization notice) provides an estimate of the number of animals that might be exposed to a sound pressure level (SPL) of 160 dB (RMS) or greater. This does not necessarily mean that 100 percent of all marine mammals exposed to seismic sounds will have a significant disruption in a biologically important activity at 160 dB. It is likely that some lower percentage would be affected either because of the hearing ability of the affected species or an individual animal to the projected frequencies. For example, Table 7 provides estimates of the number of animals of the 13 species of Delphinidae that might be exposed to received levels ≥ 160 dB. However, the Delphinidae have their best hearing in the higher frequencies and are unlikely to be as sensitive as the mysticete whales to the low frequency of the airgun array. Therefore, they are less likely to experience Level B harassment at 160 dB. A more likely threshold for Delphinidae for onset of Level B harassment in response to seismic sounds is at about 170 dB.

However, based on either sound pressure level, Level B harassment take levels for almost every species would be significantly less than 1 percent of the affected stock and one could reach a level of 2 percent. Since this activity will not result in mortality or serious injury of any marine mammals and has the potential to result in the incidental behavioral (Level B) harassment of only a small percentage of the estimated population size of affected stocks, NMFS has concluded that the takings will be small.

Comment 3: The CBD states that NMFS has not demonstrated that the level of take will have a ''negligible impact.'' The drafters of the MMPA's small take provision defined ''negligible impact'' as an impact that is ''so small or unimportant or of so little consequence as to warrant little or no attention'' (H. Rept. 228, 97th Cong. 1st sess. 19 (1981)). According to the proposed IHA, animals subjected to sound levels above 160 dB may alter their behavior and distribution. The take by harassment of 8,901 marine mammals by underwater noise far exceeding the thresholds for harassment and injury is not negligible. The *Ewing* should not be permitted to use the 10–

gun and 12–gun array at the planned levels.

Response: The definition quoted in the comment was modified by Public Law 99–659 when Congress expanded the small take authorization to include marine mammal species listed under the ESA. NMFS interprets negligible impact to mean that the impact resulting from the specified activity cannot reasonably be expected to, and is not reasonably likely to, adversely affect the species or stock through effects on reproduction or survival. NMFS believes that this definition of negligible impact captures Congressional intent since it adopted, substantially without change, the definition set out in the Senate's ''Section-by-Section Analysis'' (132 Cong. Rec. S16305 (October 15, 1986)).

Discussion regarding the potential for taking by Level B harassment of up to 8,901 marine mammals is provided in the previous response. As required by the MMPA, L-DEO has provided significant documentation in its application that the harassment of marine mammals incidental to conducting a scientific survey using a seismic array will have a negligible impact on affected species and stocks of marine mammals. NMFS concurs with this finding and believes that the information contained in the L-DEO application and the NSF EA is a compilation of the best scientific information available on this subject. NMFS is unaware of additional scientifically-based information on which to make an alternative decision and the commenter has not provided any information to support the statement. Refer to the proposed authorization notice (68 FR 17909, April 14, 2003) for discussion on potential seismic noise impacts on marine mammals.

Mitigation Concerns

Comment 4: The CBD states that while the proposed IHA notice outlines several mitigation measures the action will include, these measures do not ensure the ''least practicable adverse impact'' as required by the MMPA. It is unclear from the proposed IHA that the safety radii dB levels are sufficient to protect marine mammals (from injury). It appears that L-DEO determined the safety radii based on exposure to 180 dB (cetaceans) and 190 dB (pinnipeds). These levels are far too high to be deemed ''safety'' radii and should be modified accordingly.

Response: The safety radii are based on the findings of two public workshops (High-Energy Seismic Survey (HESS) Workshop, June 12–13, 1997; NMFS Acoustic Criteria Workshop, September, 1998). A panel of nine experts in marine biology and acoustics sponsored by Southern California's HESS Team convened to develop marine mammal exposure criteria (Knastner, 1998). The consensus of the experts was that they were

> apprehensive about levels above 180 dB re 1 μPa (rms) with respect to overt behavioral, physiological, and hearing effects on marine mammals in general. Therefore, the 180–dB radius, as initially defined by transmission loss model and verified on-site, is recommended as the safety zone distance to be used for all seismic surveys within the southern California study area.

The 1998 NMFS workshop clarified that, because pinniped hearing is different from that of cetaceans, 190 dB would be a safe level preventing pinniped injury from exposure to impulse sounds.

While there is limited empirical evidence on injury at levels below 180 dB, the 180- and 190–dB levels make sense, given that Frankel (1994) estimated the source level for singing humpback whales to be between 170 and 175 dB while Au and Andrews (2001) measured humpback whale calls off Hawaii at 189 dB; the average call source level for blue whales was calculated by McDonald et al. (2001) to be 186 dB; Watkins et al. (1987) and Charif et al. (2002) found source levels for fin whales up to 186 dB; and M hl et al. (2000) recorded source levels for sperm whale clicks up to 223 dB. If marine mammals vocalize at these levels, it is realistic to believe that these species have also evolved mechanisms to protect themselves and conspecifics from high SPLs.

Comment 5: The CBD states that it is far from clear that the vessel-based observers will detect marine mammals in the area in order to trigger the necessary shutdown of operations. For example, Cuvier's beaked whales in the vicinity of the airgun array and sonar are likely to escape observance due to the documented extreme difficulty in detecting this species.

Response: The MMPA requires NMFS to ensure that takings are at the lowest level practicable. The mitigation measures, which include (1) course alteration; (2) power-down procedures; (3) ramp-up procedures; and (4) vessel-based observers, are discussed in detail later in this document (see Mitigation). In combination, they are more likely to be effective mitigation than the use of observers alone. These same measures are included in the Interim Operational Guidelines for High-Energy Seismic Surveys off Southern California (HESS, 1999) and are standard mitigation measures for high-energy seismic sources used in the Beaufort Sea and other areas. NMFS reviewed the practicality of adding other mitigation measures, and has added an additional measure discussed later in this document (see Monitoring Concerns) and clarified timing for events such as ramp-up and observation periods (see Mitigation). Other mitigation measures, such as aircraft overflights and limiting operations to daylight hours, are not practicable. Overflights, for example, in addition to the prohibitive cost, would be unable to spend much time in the area for observation after flying 600 nm (1111.2 km) from the Galapagos Islands. Therefore, NMFS determined that the takings, by Level B harassment, are at the lowest level practicable without compromising the ability of L-DEO to obtain the scientific information on movements of the earth's plates and on formations associated with those movements at the Hess Deep.

Monitoring Concerns

Comment 6: The Commission believes that NMFS' preliminary determinations are reasonable, provided NMFS is satisfied that the proposed mitigation and monitoring activities are adequate to detect marine mammals in the vicinity of the proposed operations and ensure that marine mammals are not being taken in unanticipated ways or numbers. In this regard, NMFS' **Federal Register** notice and the application state that ''[v]essel-based observers will monitor marine mammals near the seismic source vessel during all daylight airgun operations and during any nighttime startups of the airguns;'' and that bridge personnel will watch for marine mammals during nighttime activities but that ''[o]bservers will not be on duty during ongoing seismic operations at night.'' The **Federal Register** notice states that an image-intensifier night-vision devices (NFDs) will be available for use at night, although past experience has shown that NFDs are of limited value for this purpose.'' Thus it is unclear that, for nighttime activities, the monitoring effort will be sufficient to determine that no marine mammals are within the safety zones at start-up or will be an effective means of detecting when marine mammals enter the safety zones during operations such that activities are suspended before received levels of 180 and 190 dB (rms) are reached.

Response: As part of the IHA, NMFS is requiring that if the airguns are started up at night, two marine mammal observers will monitor for marine mammals within the safety radii for 30 minutes prior to start up using night vision devices as described later (see Monitoring and Reporting). If the entire

safety radii is not visible for 30 minutes prior to ramp-up in either daylight or nighttime, ramp-up may not commence unless at least one airgun has maintained an SPL of at least 180 dB (rms) during the interruption of seismic survey operations. This latter IHA condition ensures that marine mammals will have sufficient opportunity to move away from the track of the Ewing prior to receiving high dB levels. The combination of the two conditions ensures, to the greatest extent practicable, that no mammals will be within the appropriate safety zones whenever the airguns are turned on, either in daylight or nighttime.

However, it is noted that at times, pinnipeds and even some small cetaceans will actively approach a vessel during transmissions (the vessel itself moving forward at about 3–5 knots) from the side of the vessel or the stern, meaning that the animal is voluntarily approaching a noise source that is increasing in strength as the animal gets closer. Experience indicates that pinnipeds will come from great distances to scrutinize seismic-reflection operations. Seals have been observed swimming within airgun bubbles only 10 m (33 ft) away from active arrays. Also, Canadian scientists, who were using a high-frequency seismic system that produced sound frequencies closer to pinniped hearing than those used by the Ewing, describe how seals frequently approached close to the seismic source, presumably out of curiosity. Therefore, because at least pinnipeds indicated no adverse behavioral reaction to seismic noise, NMFS has concluded that the above-mentioned mitigation requirement is reasonable because the bridge-watch will be concentrating on marine mammals approaching the vessel from the bow. Also, the night-vision ability of the trained bridge-watch staff will be better than observers elsewhere on the vessel where normal ship-board lighting is more likely. Finally, an observer is still required to be on standby, meaning his/her presence would be in the vicinity of the bridge and is not precluded from conducting observations during night-time.

Comment 7: The Commission notes that there is no discussion on why nighttime operations are considered necessary.

Response: The daily cost to the Federal government to operate the Ewing is approximately $33,000-$35,000/day, or approximately $350,000 for this 10–day research cruise (Ljunngren, pers. comm. May 28, 2003). If the Ewing is prohibited from operating during nighttime, the 10–day trip would require an additional 3–5 days, or up to $105,000–175,000 more, depending upon average daylight at the time of the work.

Therefore, because NMFS has determined that the safety zone must be visible during ramp-up, and because once the Ewing is underway and ramp-up completed, mammals will have sufficient notice of a vessel approaching (at least one hour) to avoid the approaching array if the sounds are annoying, NMFS determined that it is neither practical nor necessary to limit seismic operations to daylight hours since marine mammal are unlikely to be injured. Finally, with an extension of the time needed to complete the work if limited to daylight only operations, ship time would likely be limited for scheduled future research projects, possibly resulting in the utilization of alternative vessels.

Comment 8: The Commission notes that it is unclear whether vessel-based passive acoustic monitoring will be conducted as an adjunct to visual monitoring during daytime and particularly during nighttime operations to detect, locate, and identify marine mammals, and, if not, why not.

Response: The passive acoustical monitoring equipment that was used onboard the Ewing during the 2003 Gulf of Mexico (GOM) Sperm Whale Seismic Study (SWSS), is not the property of L-DEO or the Ewing, and therefore is not available for the Hess Deep cruise. As a result of this comment, L-DEO is evaluating the scientific results of the passive sonar from the SWSS trip to determine whether it is practical to incorporate into future seismic research cruises. NMFS expects a report on this analysis within 90 days of completion of the SWSS cruise.

Comment 9: The Commission asks whether conducting monitoring for at least 30 minutes prior to the planned start of airgun operations during the day and at night is sufficient, particularly for detecting the presence of species that make long dives.

Response: A 30–minute observation period is practical and NMFS believes it is unnecessary to lengthen this period considering that the ramp-up period will increase SPLs at a rate no greater than 6 dB per 5–minutes for a total ramp-up duration of approximately 18–20 min for the 10–12 gun arrays. Also, while some whale species may dive for up to 45 minutes, it is unlikely that the ship's bridge watch would miss a large whale surfacing from its previous dive if it is within a mile or two of the vessel.

Endangered Species Act (ESA) Concerns

Comment 10: The CBD believes that NMFS and NSF have not yet completed consultation under section 7 of the ESA. As this research voyage will impact endangered species, including blue and sperm whales, the CBD expects that NMFS and NSF will complete consultation prior to authorizing this action and will forward a copy of the resulting documentation to the CBD.

Response: NMFS has completed consultation on this action and has forwarded a copy of the Biological Opinion, the NSF EA, and the L-DEO application to the CBD as requested in its letter.

Mitigation

For the seismic operations in the Hess Deep, a 12–gun array with a total volume of 3705 in3 and a 10–gun array of 3050 in3 will be used. The airguns comprising these arrays will be spread out horizontally, so that the energy from the array will be directed mostly downward. The directional nature of the two alternative airgun arrays to be used in this project is an important mitigating factor, resulting in reduced sound levels at any given horizontal distance than would be expected at that distance if the source were omnidirectional with the stated nominal source level. Also, the use of the 10- or 12–gun array of 3,050 or 3,705 in3 rather than the largest airgun array that the L-DEO's source vessel can deploy (20 airguns totaling almost 8,600 in3) is another significant mitigation measure.

Safety Radii

Modeled results for the 10- and 12–gun arrays indicate that the 180–dB (re 1 μPa (rms)) isopleths (i.e., the current potential injury threshold for cetaceans) are 830 and 880 m (2,723 and 2,887 ft), respectively. The radii around the 10- and 12–gun arrays corresponding to the 190 dB (re 1 μPa (rms)) isopleths (the current potential injury threshold for pinnipeds), are estimated as 250 and 300 m (820 and 984 ft), respectively. A calibration study was conducted prior to this survey to determine the actual radii corresponding to each sound level. These actual radii will be implemented for this study. Until then, or if those measurements appear defective, L-DEO will use a precautionary 1.5 times the 180–dB and 190–dB radii predicted by the model as the safety radii. Under those circumstances, the safety radii for cetaceans would be 1,245 and 1,320 m (4,085 and 4,331 ft), respectively, for the 10- and 12–gun arrays, and the safety radii for pinnipeds would be 375 and 450 m (1,230 and 1,476 ft), respectively.

Power-down Procedures

Vessel-based observers will monitor marine mammals near the seismic vessel during daylight and for 30 minutes prior to start up during darkness throughout the program. Airgun operations will be suspended immediately when marine mammals are observed within, or about to enter, designated safety zones where there is a potential for injury (based on the 180- and 190–dB criteria). The power-down procedure should be accomplished within several seconds or a single seismic ''ping'' of the determination being made that a marine mammal is within or about to enter the safety zone.

Restart Procedures

After a power-down of the airguns, the observer(s) will maintain watch to determine when the animal is outside the safety radius. Airgun transmissions can commence/ resume after the mammal(s) is observed to have left the safety zone or 15 minutes (for small odontocetes and pinnipeds) or 30 minutes (for mysticetes/large odontocetes (sperm, pygmy sperm, dwarf sperm, beaked, and bottlenose whales)) from the last visual detection of the mammal(s) within the safety zone. Once the safety zone is clear of marine mammals, the observer will advise that restart procedures can commence.

A 30–minute pre-ramp-up observation period must be conducted after a shutdown (but not after power-down) of the array for a length of time greater than it would take a seismic vessel to travel the distance to the 160–dB isopleth at the time of shutdown. For example, traveling at 4.0 knots (4.0 nm/hr), the Ewing would need about 1 hr to reach that isopleth while operating the 10–gun array and 1.25 hrs when using the 12–gun array. For this cruise, the IHA requires the 30–minute observation period to take place after a shut-down of 1 hour or more. The ''ramp-up'' procedure will then be followed.

Ramp-up Procedure

L-DEO will use the standard ''ramp-up'' (soft-start) procedure when the airgun arrays begin operating after a period without any airgun operations as specified in this paragraph. From a shut-down, ramp-up will begin with the smallest gun in the array that is being used (80 in3 for the 10- and 12–gun arrays), and guns will be added in a sequence such that the source level of the array will increase at a rate no greater than 6 dB per 5–minutes for a total ramp-up duration of approximately 18–20 min (10–12 gun arrays). Under normal operational conditions (vessel speed 4–5 knots), a ramp-up would be required after a ''no shooting'' period lasting 2 minutes or longer. At 4 knots, the source vessel would travel 247 m (810 ft) during a 2–minute period. If the towing speed is reduced to 3 knots or less, as sometimes required when maneuvering in shallow water (not a factor in Hess Deep), ramp-up is required after a ''no shooting'' period lasting 3 minutes or longer. At towing speeds not exceeding 3 knots, the source vessel would travel no more than 277 m (909 ft) in 3 minutes. These procedures would require modification if the normal seismic shot interval were more than 2 or 3 min, but that is not expected to occur during the Hess Deep project.

Course Alteration

If a marine mammal is detected outside its safety radius and, based on its position and relative motion, is likely to enter the safety radius, alternative ship tracks will be plotted against anticipated mammal locations. The vessel's direct course and/or speed will be changed to avoid the marine mammal entering the safety radius, but in a manner that also minimizes the effect to the planned science objectives. The marine mammal activities and movements relative to the seismic vessel will be closely monitored to ensure that the marine mammal does not approach within the safety radius. If the mammal appears likely to enter the safety radius, further mitigative actions will be taken, i.e., either further course alterations or power-down of the airguns. The Ewing is required to adopt this mitigation measure during the Hess Deep seismic survey program provided that doing so will not compromise operational safety requirements.

Marine Mammal Monitoring

L-DEO will conduct marine mammal monitoring during its seismic program in the Hess Deep in order to verify that the taking of marine mammals, by harassment, incidental to conducting the seismic survey will have a negligible impact on marine mammal stocks and to ensure that these harassment takings are at the lowest level practicable.

A minimum of two marine mammal observers will be onboard the *Ewing* to monitor marine mammals near the seismic vessel. Observers will watch for marine mammals during all daylight periods with seismic shooting, and for at least 30 minutes prior to any start-up of airgun operations after shutdown. At least one observer must have previous observation experience. Prior to seismic operations commencing, observers must complete a 1–day training/refresher course on marine mammal monitoring procedures, given by a contract employee experienced in vessel-based seismic monitoring projects. The *Ewing* is considered a suitable platform for marine mammal observations. The observer's eye level will be approximately 11 m (36 ft) above sea level when stationed on the bridge, allowing for good visibility within a 210° arc for each observer. Airgun operations will be suspended and the source powered-down whenever marine mammals are observed within, or about to enter, designated safety zones.

Observers will be on duty in shifts of duration no longer than 4 hours. The second observer will also be on watch part of the time, including the 30–minute periods preceding startup of the airguns and during ramp ups. Use of two simultaneous observers will decrease the potential that marine mammals near the source vessel will be missed. Bridge personnel that are additional to the dedicated observers will also assist in detecting marine mammals and implementing mitigation requirements, and before the start of the seismic survey will be given proper instruction for observing and reporting marine mammals and sea turtles.

Observers will not normally be on duty during ongoing seismic operations at night; bridge personnel will watch for marine mammals during this period and will immediately call for the airguns to be powered down and the stand-by observer will be notified if marine mammals are observed in or about to enter the safety radii. However, if the airguns are started up at night after a shutdown duration of 1 hour or greater, two observers will monitor for marine mammals within the safety radii for 30 minutes prior to beginning ramp-up using night vision devices (NVDs), although NMFS notes that past experience has shown that NVDs are of limited value for this purpose. If the complete safety radii are not visible for at least 30 minutes prior to ramp-up in either daylight or nighttime, ramp-up may not commence unless the seismic source has maintained an SPL of at least 180 dB during the interruption of seismic survey operations. While the 30–minute observation period is only required prior to commencing seismic operations following an extended shut down period, if ramp-up procedures must be performed at night, the two observers must be on duty 30 minutes prior to the start of seismic shooting and during the ramp-up procedures.

The observer(s) will watch for marine mammals from the bridge, the highest practical vantage point on the vessel. The observer(s) will systematically scan

the area around the vessel with 7 X 50 Fujinon reticle binoculars or with the naked eye during the daytime. At night, NVDs will be available (ITT F500 Series Generation 3 binocular image intensifier or equivalent), and used, if necessary. Laser rangefinding binoculars (Bushnell Lytespeed 800 laser rangefinder with 4 optics or equivalent) will be available to assist with distance estimation.

The vessel-based monitoring will provide data required to estimate the numbers of marine mammals exposed to various received sound levels, to document any apparent disturbance reactions, and thus to estimate the numbers of mammals potentially taken by Level B harassment. It will also provide the information needed in order to power-down the airguns at times when mammals are present in or near the safety zone. Results from the vessel-based observations will provide (1) the basis for real-time mitigation (airgun power-down); (2) information needed to estimate the number of marine mammals potentially taken by harassment, which must be reported to NMFS; (3) data on the occurrence, distribution, and activities of marine mammals in the area where the seismic study is conducted; (4) information to compare the distance and distribution of marine mammals relative to the source vessel at times with and without seismic activity; and (5) data on the behavior and movement patterns of marine mammals seen at times with and without seismic activity.

Reporting

When a mammal sighting is made, the following information about the sighting will be recorded: (1) Species, group size, age/size/sex categories (if determinable), behavior when first sighted and after initial sighting, heading (if consistent), bearing and distance from seismic vessel, sighting cue, apparent reaction to seismic vessel (e.g., none, avoidance, approach, paralleling, etc.), and behavioral pace; and (2) time, location, heading, speed, activity of the vessel (shooting or not), sea state, visibility, cloud cover, and sun glare. The data listed under (2) will also be recorded at the start and end of each observation watch and during a watch, whenever there is a change in one or more of the variables.

All mammal observations and airgun power-downs will be recorded in a standardized format. Data will be entered into a custom database using a laptop computer when observers are off-duty. The accuracy of the data entry will be verified by computerized validity data checks as the data are entered and by subsequent manual checking of the database. These procedures will allow initial summaries of data to be prepared during and shortly after the field program, and will facilitate transfer of the data to statistical, graphical or other programs for further processing and archiving.

A draft report will be submitted to NMFS for review within 90 days after the end of the seismic program in the Hess Deep area which is predicted to occur on or about July 28, 2003. The draft report will cover the seismic surveys in the Hess Deep area and will provide full documentation of methods, results, and interpretation pertaining to all monitoring tasks. The draft report will summarize the dates and locations of seismic operations, sound measurement data, marine mammal sightings (dates, times, locations, activities, associated seismic survey activities), and estimates of the amount and nature of potential ''take'' of marine mammals by harassment or in other ways. The draft report will be considered the final report unless comments and suggestions are provided by NMFS within 60 days of its receipt of the draft report.

Estimates of Take by Harassment for the Hess Deep Cruise

As described previously (see 68 FR 17909, April 14, 2003) and in the L-DEO application, animals subjected to sound levels above 160 dB may alter their behavior or distribution, and therefore might be considered to be taken by Level B harassment.

Based on summer marine mammal survey data collected by NMFS and density calculations by Ferguson and Barlow (2001), L-DEO used their average marine mammal density to compute a ''best estimate'' of the number of marine mammals that may be exposed to seismic sounds ≥160 dB re 1μPa (rms). The average densities were then multiplied by the proposed survey effort (912 and 189 km for the 10–gun and 12–gun array, respectively) and twice the 160 dB safety radius from the source vessel (the 160–dB radius was 6.5 and 7.25 km for the 10–gun and 12–gun array, respectively) to estimate the ''best estimate'' of the numbers of animals that might be exposed to sound levels ≥160 dB re 1μPa (rms) during the proposed seismic survey program. Separate estimates were made for the 10–gun and 12–gun arrays because the 160–dB radius was different for the two arrays (see Tables 5 and 6 in L-DEO (2003)). Based on this method, Table 7 in LDEO (2003) provided a ''best estimate'' of the number of marine mammals (by species) that would be exposed to ≥160 dB (rms), and thus potentially taken by Level B harassment, during the proposed survey, by both the 10–gun and 12–gun arrays. Twelve animals would be endangered species, sperm whales (11) and a single blue whale, while two stocks of dolphins would account for 96 percent of the overall estimate for potential taking by harassment.

Conclusions

Effects on Cetaceans

Strong avoidance reactions by several species of mysticetes to seismic vessels have been observed at ranges up to 6 to 8 km (3.2–4.3 nm) and occasionally as far as 20–30 km (10.8–16.2 nm) from the source vessel. Some bowhead whales avoided waters within 30 km (16.2 nm) of the seismic operation. However, reactions at such long distances appear to be atypical of other species of mysticetes, and even for bowheads may only apply during migration.

Odontocete reactions to seismic pulses, or at least those of dolphins, are expected to extend to lesser distances than are those of mysticetes. Odontocete low-frequency hearing is less sensitive than that of mysticetes, and dolphins are often seen from seismic vessels. In fact, there are documented instances of dolphins approaching active seismic vessels. However, dolphins as well as some other types of odontocetes sometimes show avoidance responses and/or other changes in behavior when near operating seismic vessels.

Taking account of the mitigation measures that are planned, effects on cetaceans are expected to be limited to avoidance of the area around the seismic operation and short-term changes in behavior, falling within the MMPA definition of ''Level B harassment.'' In the cases of mysticetes, these reactions are expected to involve small numbers of individual cetaceans because few mysticetes occur in the areas where seismic surveys are proposed. L-DEO's ''best estimate'' is that 10 Bryde's whales, or 0.1 percent of the estimated Eastern Equatorial Bryde's whale population, will be exposed to sound levels ≥160 dB re 1 μPa (rms) and potentially affected, and 1 blue whale, or 0.1 percent of the endangered ETP blue whale population, would receive ≥160 dB. Therefore, these potential takings by Level B harassment will have a negligible impact on their populations.

Larger numbers of odontocetes may be affected by the seismic survey activities, but the population sizes of the main species are large and the numbers potentially affected are small (<0.1 percent) relative to the population sizes. The total number of odontocetes that might be exposed to ≥160 dB (re 1 μPa

(rms)) in the Hess Deep area is estimated as 8,890. Of these, 8,532 are delphinids, and of these about 3,076 might be exposed to ≥170 dB. Both estimates are <0.1 percent of the eastern equatorial populations of these species.

As noted earlier in this document, NMFS believes that Level B harassment take levels would, for almost every affected stock, be significantly less than 1 percent of the stock and only a single stock has the potential of reaching a level of 2 percent for Level B harassment.

Effects on Pinnipeds

Very few if any pinnipeds are expected to be encountered in the Hess Deep area. Thus, a maximum of 20 pinnipeds in the Hess Deep area may be affected by the proposed seismic surveys. If pinnipeds are encountered, the proposed seismic activities would have, at most, a short-term effect on their behavior and no long-term impacts on individual seals or their populations. Responses of pinnipeds to acoustic disturbance are variable, but usually quite limited. Effects are expected to be limited to short-term and localized behavioral changes falling within the MMPA definition of Level B harassment.

Determinations

Based on the information contained in the L-DEO application, the NSF EA, the April 14, 2003, proposed authorization notice (68 FR 17909) and this document, NMFS has determined that conducting a seismic survey by the *Ewing* at the Hess Deep in the eastern equatorial Pacific Ocean in 2003 by L-DEO would result in the harassment of small numbers of marine mammals; would have no more than a negligible impact on the affected marine mammal species or stocks; and would not have an unmitigable adverse impact on the availability of stocks for subsistence uses. This activity will result, at worst, in a temporary modification in behavior by affected species of marine mammals. While behavioral modifications may be made by these species as a result of seismic survey activities, this behavioral change is expected to result n no more than a negligible impact on the affected species. Also, while the number of actual incidental harassment takes will depend on the distribution and abundance of marine mammals in the vicinity of the survey activity, the number of potential harassment takings is estimated to be small. In addition, no take by injury and/or death is anticipated, and the potential for temporary or permanent hearing impairment is low and will be avoided through the incorporation of the mitigation measures mentioned in this document and required under the IHA. For these reasons therefore, NMFS has determined that the requirements of section 101(a)(5)(D) of the MMPA have been met and the authorization can be issued.

Consultation

NMFS has concluded consultation under section 7 of the ESA on NMFS' issuance of an IHA to take small numbers of marine mammals, by harassment, incidental to conducting calibration measurements of its seismic array in the Hess Deep by L-DEO. The finding of that consultation was that this study is not likely to jeopardize the continued existence of marine species listed as threatened or endangered under the ESA. No critical habitat has been designated for these species in the equatorial Pacific Ocean; therefore, none will be affected. A conservation recommendation was made to ensure that the safety zone is clear of sea turtles prior to ramp up. This recommendation has been implemented through the IHA to L-DEO. A copy of the Biological Opinion is available upon request (see **ADDRESSES**).

National Environmental Policy Act (NEPA)

On March 18, 2003, the NSF made a determination, based on information contained within its EA that implementation of the subject action is not a major Federal action having significant effects on the environment within the meaning of Executive Order 12114. NSF determined therefore, that an environmental impact statement would not be prepared. On April 14, 2003 (68 FR 17909), NMFS noted that the NSF had prepared an EA for the Hess Deep survey. In accordance with section 6.01 of the NOAA Administrative Order 216–6 (Environmental Review Procedures for Implementing the National Environmental Policy Act, May 20, 1999), NMFS has reviewed the information contained in NSF's EA and determined that the NSF EA accurately and completely describes the proposed action alternative, reasonable additional alternatives, and the potential impacts on marine mammals, endangered species, and other marine life that could be impacted by the preferred alternative and the other alternatives. As a result, NMFS has determined that it is not necessary to issue either a new EA or a Supplemental EA for the issuance of an IHA to L-DEO for this activity. Therefore, based on this review and analysis, NMFS is adopting the NSF EA under NEPA. A copy of the NSF EA for this activity is available upon request (see **ADDRESSES**).

Authorization

NMFS has issued an IHA to take small numbers of marine mammals, by harassment, incidental to conducting a seismic survey by the *Ewing* in the eastern equatorial Pacific Ocean to L-DEO for a 1–year period, provided the mitigation, monitoring, and reporting requirements described in this document and the IHA are undertaken.

Dated: July 3, 2003.

Laurie K. Allen,

Acting Director, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 03–17622 Filed 7–10–03; 8:45 am]

BILLING CODE 3510–22–S

DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[OMB Control No. 9000–0011]

Federal Acquisition Regulation; Information Collection; Preaward Survey Forms (Standard Forms 1403, 1404, 1405, 1406, 1407, and 1408)

AGENCIES: Department of Defense (DOD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

ACTION: Notice of request for public comments regarding an extension to an existing OMB clearance (9000–0011).

SUMMARY: Under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the Federal Acquisition Regulation (FAR) Secretariat will be submitting to the Office of Management and Budget (OMB) a request to review and approve an extension of a currently approved information collection requirement concerning preaward survey forms (Standard Forms 1403, 1404, 1405, 1406, 1407, and 1408). This clearance currently expires October 31, 2003.

Public comments are particularly invited on: Whether this collection of information is necessary for the proper performance of functions of the FAR, and whether it will have practical utility; whether our estimate of the public burden of this collection of information is accurate, and based on valid assumptions and methodology; ways to enhance the quality, utility, and clarity of the information to be

collected; and ways in which we can minimize the burden of the collection of information on those who are to respond, through the use of appropriate technological collection techniques or other forms of information technology.

DATES: Submit comments on or before September 9, 2003.

ADDRESSES: Submit comments, including suggestions for reducing this burden to the General Services Administration, FAR Secretariat (MVA), 1800 F Street, NW., Room 4035, Washington, DC 20405.

FOR FURTHER INFORMATION CONTACT: Victoria Moss, Acquisition Policy Division, GSA, (202) 501–4764.

SUPPLEMENTARY INFORMATION:

A. Purpose

To protect the Government's interest and to ensure timely delivery of items of the requisite quality, contracting officers, prior to award, must make an affirmative determination that the prospective contractor is responsible, *i.e.*, capable of performing the contract. Before making such a determination, the contracting officer must have in his possession or must obtain information sufficient to satisfy himself that the prospective contractor (i) has adequate financial resources, or the ability to obtain such resources, (ii) is able to comply with required delivery schedule, (iii) has a satisfactory record of performance, (iv) has a satisfactory record of integrity, and (v) is otherwise qualified and eligible to receive an award under appropriate laws and regulations. If such information is not in the contracting officer's possession, it is obtained through a preaward survey conducted by the contract administration office responsible for the plant and/or the geographic area in which the plant is located. The necessary data is collected by contract administration personnel from available data or through plant visits, phone calls, and correspondence and entered on Standard Forms 1403, 1404, 1405, 1406, 1407, and 1408 in detail commensurate with the dollar value and complexity of the procurement. The information is used by Federal contracting officers to determine whether a prospective contractor is responsible. Due to improved technology, increased sharing of information among agencies and the increasing reliance on commercial items, for which preaward surveys are not required, the annual burden related to this clearance has been reduced.

B. Annual Reporting Burden

Respondents: 5,478.
Responses Per Respondent: 1.
Total Responses: 5,478.
Hours Per Response: 20.8.
Total Burden Hours: 113,942.
Obtaining Copies of Proposals: Requesters may obtain a copy of the information collection documents from the General Services Administration, FAR Secretariat (MVA), 1800 F Street, NW., Room 4035, Washington, DC 20405, telephone (202) 501–4755. Please cite OMB Control No. 9000–0011, Preaward Survey Forms (Standard Forms 1403, 1404, 1405, 1406, 1407, and 1408), in all correspondence.

Dated: July 8, 2003.

Ralph J. DeStefano,

Acting Director, Acquisition Policy Division.

[FR Doc. 03–17609 Filed 7–10–03; 8:45 am]

BILLING CODE 6820–EP–P

DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[OMB Control No. 9000–0047]

Federal Acquisition Regulation; Information Collection; Place of Performance

AGENCIES: Department of Defense (DOD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

ACTION: Notice of request for public comments regarding an extension to an existing OMB clearance (9000–0047).

SUMMARY: Under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35), the Federal Acquisition Regulation (FAR) Secretariat will be submitting to the Office of Management and Budget (OMB) a request to review and approve an extension of a currently approved information collection requirement concerning place of performance. The clearance currently expires on October 31, 2003.

Public comments are particularly invited on: Whether this collection of information is necessary for the proper performance of functions of the FAR, and whether it will have practical utility; whether our estimate of the public burden of this collection of information is accurate, and based on valid assumptions and methodology; and ways to enhance the quality, utility, and clarity of the information to be collected. When the On-Line Representation and Certifications Application (ORCA) becomes available, contractors will be able to complete the provision electronically; however, because the data being collected could change for a specific solicitation, contractor's will still be required to submit place of performance information on an exception basis; that is, whenever the place of performance for a specific solicitation is different from the place of performance shown in ORCA.

DATES: Submit comments on or before September 9, 2003.

ADDRESSES: Submit comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to the General Services Administration, FAR Secretariat (MVA), 1800 F Street, NW., Room 4035, Washington, DC 20405

FOR FURTHER INFORMATION CONTACT: Gerald Zaffos, Acquisition Policy Division, GSA (202) 208–6091.

SUPPLEMENTARY INFORMATION:

A. Purpose

The information relative to the place of performance and owner of plant or facility, if other than the prospective contractor, is a basic requirement when contracting for supplies or services (including construction). This information is instrumental in determining bidder responsibility, responsiveness, and price reasonableness. A prospective contractor must affirmatively demonstrate its responsibility. Hence, the Government must be apprised of this information prior to award. The contracting officer must know the place of performance and the owner of the plant or facility to (1) determine bidder responsibility; (2) determine price reasonableness; (3) conduct plant or source inspections; and (4) determine whether the prospective contractor is a manufacturer or a regular dealer. The information is used to determine the firm's eligibility for awards and to assure proper preparation of the contract.

B. Annual Reporting Burden

Respondents: 79,397.
Responses Per Respondent: 14.
Total Responses: 1,111,558.
Hours Per Response: .07.
Total Burden Hours: 77,810.
Obtaining Copies of Proposals: Requesters may obtain a copy of the information collection documents from the General Services Administration, FAR Secretariat (MVA), Room 4035, 1800 F Street, NW., Washington, DC 20405, telephone (202) 501–4755. Please cite OMB Control No. 9000–0047, Place of Performance, in all correspondence.

Dated: July 8, 2003.

Ralph J. Destefano,

Acting Director, Acquisition Policy Division.

[FR Doc. 03–17610 Filed 7–10–03; 8:45 am]

BILLING CODE 6820–EP–P

DEPARTMENT OF DEFENSE

Department of the Air Force

Performance Review Boards List of 2003 Members

Below is a list of individuals who are eligible to serve on the Performance Review Boards for the Department of the Air force in accordance with the Air Force Senior Executive Appraisal and Awards System.

Mr. Roger Blanchard, AF/DP
MG Ronald J. Bath, AF/XPX
Mr. David Hamilton, AF/TE
Mr. Grover L. Dunn, AF/ILI
Ms. Patricia J. Zarodkiewicz, AFMC/FM
Ms. Barbara Westgate, AF/XPP
Mr. Frank O. Tuck, ASC/FB
Mr. James R. Speer, SAF/AG
MG Stephen R. Lorenz, SAF/FMB
Mr. Blaise J. Durante, SAF/AQX
Mr. Fred Kuhn, SAF/IEI
Mr. Garry B. Richey, AMC/LG
Mr. Michael A. Aimone, SAF/IEB
Ms. Donna J. Back, ASC/FM
Mr. Michael Aimone, SAF/IEB
Mr. William Davidson, SAF/AA
MG Joseph B. Sovey, SAF/USA
Ms. Cheryl Roby, DASD/Resources
Mr. W. Kipling Atlee, Jr., SAF/GCM
Mr. David Burtt, CIFA
Mr. Wilson, USI

Pamela D. Fitzgerald,

Air Force Federal Register Liaison Officer.

[FR Doc. 03–17537 Filed 7–10–03; 8:45 am]

BILLING CODE 5001–05–P

DEPARTMENT OF DEFENSE

Department of the Army, Corps of Engineers

Availability of the Final Environmental Impact Statement for the Proposed Rueter-Hess Reservoir, Parker, CO

AGENCY: Department of the Army, U.S. Army Corps of Engineers, DoD.

ACTION: Notice of availability.

SUMMARY: In accordance with the National Environmental Policy Act (NEPA) of 1969, as amended, and the U.S. Army Corps of Engineers' (Corps) regulations for NEPA implementation (33 CFR part 230 and 325, Appendices B and C), the Corps has issued a Final Environmental Impact Statement (FEIS) to disclose environmental impacts from constructing and operating the proposed Rueter-Hess Reservoir near the town of Parker, in Douglas County, CO. The project proponent is the Parker Water and Sanitation District (District). The basic purpose of the proposed action is to provide a safe, adequate and sustainable municipal water supply to the District, which is capable of meeting peak demands within the District's currently zoned boundary for the next 50 years. The construction of the proposed project would result in direct impacts to 6.7 acres of wetlands and 5 miles of other waters of the United States, and would require a section 404 permit.

DATES: Written comments on the FEIS will be accepted for a period of 30 days following **Federal Register** publication of the Notice of Availability by the Environmental Protection Agency (EPA). The anticipated date of EPA **Federal Register** publication is July 11, 2003. Comments should be submitted to Rodney Schwartz, Corps—Omaha District (see contact information below).

ADDRESSES: Copies of the FEIS will be available for review at the following locations:

1. Parker Library, 10851 South Crossroad Drive, Parker, CO 80134.

2. Parker Water and Sanitation District, 19801 East Mainstreet, Parker, CO 80138.

3. U.S. Army Corps of Engineers, Denver Regulatory Office, 9307 South Wadsworth Blvd., Littleton, CO 80128.

Copies can also be obtained from the Corps' third-party contractor, URS Corporation, attention: Paula Daukas, 8181 East Tufts Avenue, Denver, CO 80237; 303–740–3896; Fax 303–694–3946, *paula_daukas@urscorp.com.*

FOR FURTHER INFORMATION CONTACT: Rodney Schwartz, Senior Project Manager, U.S. Army Corps of Engineers, Omaha District-Regulatory Branch, Rm. 151, 12565 West Center Road, Omaha, NE., 68144–3869, Phone: 402–221–4143, Fax: 402–221–4939, *rodney.j.schwartz@usace.army.mil*

SUPPLEMENTARY INFORMATION: The purpose of the FEIS is to provide decision makers and the public with information pertaining to the proposed action, and to disclose environmental impacts and identify mitigation measures to reduce impacts. The FEIS analyzes the Parker Water and Sanitation District's proposal to construct and operate Rueter-Hess Reservoir and the associated water delivery system. The proposed reservoir would be located in Douglas County, CO approximately 12 miles southeast of Denver and 3 miles southwest of the town of Parker. The reservoir would be located on Newlin Gulch with a diversion structure along Cherry Creek. The project would include a 16,200 acre-foot (AF) reservoir inundating 470 acres, a 5,300-foot long and 135-foot high dam, two pipelines, a water treatment plant and booster pump station, a diversion structure along Cherry Creek with a pump station, and 16 Denver Basin extraction wellfields.

The proposed water supply system would rely upon renewable sources of water, including the capability of capturing, storing, and reusing seasonal high flows in nearby Cherry Creek, and Advanced Wastewater Treatment (AWT) return flows currently discharged into Cherry Creek. The water from the reservoir would be used primarily to help satisfy the District's peak seasonal demands, thereby reducing the loading on nonrenewable Denver Basin aquifer groundwater and maximizing use of renewable water resources. The reservoir is needed by the District to provide operational flexibility to ensure a long-term, reliable water supply. In addition to the proposed action, the FEIS analyzes two alternatives: (1) the Reduced Capacity Reservoir (11,200 AF), and (2) the No Action.

The Draft Environmental Impact Statement (DEIS) was published in February 2002. A combined public hearing on the DEIS and section 404 permit application was held on March 12, 2002 in Parker, CO. The comments and responses are included in the FEIS.

Rodney J. Schwartz,

Senior Project Manager, Regulatory Branch.

[FR Doc. 03–17520 Filed 7–10–03; 8:45 am]

BILLING CODE 3710–62–P

DEPARTMENT OF EDUCATION

RIN 1810–ZA08

Migrant Education Program Consortium Incentive Grant Program

AGENCY: Office of Elementary and Secondary Education, Department of Education.

ACTION: Notice of proposed requirements.

SUMMARY: The Department proposes requirements for the Migrant Education Program (MEP) Consortium Incentive Grant program. Under the authority of section 1308(d) of Title I of the Elementary and Secondary Education Act of 1965 (ESEA), as amended by the No Child Left Behind Act of 2001, the Department would award incentive grants to State educational agencies (SEAs) in high-quality consortium arrangements. The Department may use

these requirements for competitions in Fiscal Year (FY) 2003 and later years.

DATES: We must receive your comments on or before August 11, 2003.

ADDRESSES: All comments concerning these proposed requirements should be addressed to: Elsa Chagolla, Office of Migrant Education, Office of Elementary and Secondary Education, 400 Maryland Avenue, Room 3E257, FOB–6, SW., Washington, DC 20202–6135. Telephone: (202) 260–2823. If you prefer to send your comments through the Internet, use the following address: *elsa.chagolla@ed.gov.*

If you want to comment on the information collection requirements, you must send your comments to the Office of Management and Budget at the address listed in the Paperwork Reduction Act section of this preamble. You may also send a copy of these comments to the Department representative named in this section.

FOR FURTHER INFORMATION CONTACT: Elsa Chagolla, Telephone: (202) 260–2823, or via Internet: *elsa.chagolla@ed.gov.*

If you use a telecommunications device for the deaf (TDD), you may call the Federal Information Relay Service (FIRS) at 1–800–877–8339.

Individuals with disabilities may obtain this document in an alternative format (*e.g.*, Braille, large print, audiotape, or computer diskette) on request to the contact person listed under **FOR FURTHER INFORMATION CONTACT.**

SUPPLEMENTARY INFORMATION:

Invitation To Comment

We invite you to submit comments regarding these proposed requirements. During and after the comment period, you may inspect all public comments about these proposed requirements in room 3E257, 400 Maryland Avenue, Washington, DC, between the hours of 8:30 a.m. and 4 p.m., Eastern time, Monday through Friday of each week except Federal holidays.

Assistance to Individuals With Disabilities in Reviewing the Rulemaking Record

On request, we will supply an appropriate aid, such as a reader or print magnifier, to an individual with a disability who needs assistance to review the comments or other documents in the public rulemaking record for these proposed regulations. If you want to schedule an appointment for this type of aid, please contact the person listed under **FOR FURTHER INFORMATION CONTACT.**

Background

The Migrant Education Program (MEP), authorized in Title I, Part C of the Elementary and Secondary Education Act of 1965 (ESEA), as amended by the No Child Left Behind Act of 2001, is a State-operated and State-administered formula grant program. The MEP provides assistance to State educational agencies (SEAs) to support high-quality and comprehensive educational programs that provide migratory children appropriate educational and supportive services that address their special needs in a coordinated and efficient manner, and give migratory children the opportunity to meet the same challenging State academic content and student academic achievement standards that all children are expected to meet.

Section 1308(d) of the ESEA authorizes the Secretary to ''reserve not more than $3 million to award grants of not more than $250,000 [each] on a competitive basis to SEAs that propose a consortium arrangement with another State or other appropriate entity that the Secretary determines, pursuant to criteria that the Secretary shall establish, will improve the delivery of services to migratory children whose education is interrupted.''

Through this notice, the Department proposes the new requirements, criteria, and procedures to award consortium incentive grants in Fiscal Year (FY) 2003 and subsequent years. In brief, the Department proposes to change: (1) The way proposed consortia are evaluated by using application selection criteria; and (2) the funding formula under which the incentive grants are awarded to SEAs that participate in consortia whose applications are ranked as being of sufficiently high quality. The Department proposes these changes for two reasons. First, it will promote implementation of consortia that will achieve meaningful results. Second, since section 1308(d) now permits the Department to award consortium incentive grants without SEAs having to demonstrate resulting MEP administrative or program function cost savings, the Department will be able to implement a grant selection process that focuses much more on the quality of proposed consortium arrangements.

Proposed Definition for Eligibility for Consortium Incentive Grants

Section 1308(d) permits an SEA to enter into a consortium arrangement with another State or other appropriate entity. The Department proposes that the term ''other appropriate entity'' would mean any public or private agency or organization. However, under section 1308(d), only SEAs are eligible applicants to receive consortium incentive grants.

Proposed Application Requirements

An application for an incentive grant would be submitted by an SEA that will act as the ''lead SEA'' for the proposed consortium. This application would include—

1. The identity of the lead SEA for the consortium arrangement and of each other SEA or entity participating in the consortium arrangement;

2. The goals and measurable outcomes of the consortium arrangement, and the activities that each participating SEA or entity in the consortium will conduct during each project year to improve the delivery of services to migratory children whose education is interrupted;

3. A concise and cogent explanation of the need for and value of the proposed consortium arrangement to each participating SEA;

4. A description of the process each participating SEA will use for evaluating its progress in achieving the measurable outcomes of the consortium arrangement; and

5. A signed statement from the Chief State School Officer (or his/her authorized representative) of each SEA that is participating in the proposed consortium arrangement of his/her SEA's commitment to implement its activities as described in the application.

Proposed Absolute Priorities

Section 75.105(c)(3) of the Education Department General Administrative Regulations (EDGAR) authorizes the Department to establish absolute preferences under which all of a program's funding is reserved for applicants that meet this priority. For competitions in FY 2003 and later years, the Department proposes the following seven absolute priorities that promote key national objectives of the MEP. In order for SEAs to be considered for incentive grants, a proposed consortium arrangement would need to address one or more of the following absolute priorities:

1. Services designed to improve the proper and timely identification and recruitment of eligible migratory children whose education is interrupted;

2. Services designed (based on review of scientifically based research) to improve the school readiness of pre-school age migratory children whose education is interrupted;

3. Services designed (based on review of scientifically based research) to improve the reading proficiency of migratory children whose education is interrupted;

4. Services designed (based on review of scientifically based research) to improve the mathematics proficiency of migratory children whose education is interrupted;

5. Services designed (based on review of scientifically based research) to decrease the dropout rate of migratory students (*i.e.* grades 7 to 12) whose education is interrupted and improve high school completion rates;

6. Services designed (based on review of scientifically based research) to strengthen the involvement of migratory parents in the education of migratory students whose education is interrupted; and

7. Services designed (based on review of scientifically based research) to expand access to innovative educational technologies intended to increase the academic achievement of migratory students whose education is interrupted.

Specifically, an SEA wishing to receive an incentive grant would need to be a partner within a consortium that focuses on one or more of these seven key priorities. The Department believes that these seven priorities reflect the most pressing needs of migratory students that warrant particular attention through work in consortium arrangements.

The area of identification and recruitment is a critical first component of any migrant education program, and one in which consortium activities have proven useful and effective. The areas of early childhood education, reading and mathematics achievement, parental involvement, and reduction in the migrant dropout rate are critical to ensuring that migratory students stay in school and achieve to high academic content and academic performance standards. However, to date, these areas have not been a primary focus of consortia efforts. As school interruption and low levels of student achievement continue to be dominant characteristics of the migrant student population, finding innovative uses of electronic technologies to assist students away from home to continue to master State content and academic achievement standards also remains a priority.

In proposing these particular priorities to govern receipt of consortium incentive grants, the Department understands that migratory students have other significant needs that also warrant the focused attention of interstate and interagency consortia. These efforts, in areas such as improving the responsiveness of teachers to migrant student needs, transfer of key education and health records, and increasing the numbers of migratory students who take and pass State assessments, are clearly important and should continue. However, the Department believes that migratory students will be better served at this time by targeting special financial incentives to SEAs that participate in high-quality consortia that focus on one or more of the proposed seven absolute priorities.

Proposed Amount and Duration of Incentive Grants

The Department proposes that an SEA that participates in a high-quality consortium arrangement, as determined by use of the program's selection criteria, would receive only one incentive grant award regardless of the number of high-quality consortia in which it participates.

Rather than determine the amount of grant awards on the basis of a cost analysis as described in section 75.232 of the EDGAR, the Department would make awards to SEAs participating in these consortia on the basis of the following two-tiered formula: For each project period, SEAs whose MEP allocations are $1 million or less would receive a grant award that is twice the amount of the award provided to SEAs whose MEP allocations are greater than $1 million. Within each tier, awards would be of equal size. However, no SEA would receive an incentive grant award that exceeds the amount of its Title I, Part C MEP formula grant or $250,000, whichever is less.

It should be noted that, because these requirements would prohibit an SEA from receiving a consortium incentive grant award that exceeds its MEP formula allocation, some SEAs with MEP allocations of $1 million or less may not receive a consortium incentive grant award that is twice the amount of the award provided to SEAs whose MEP allocations are greater than $1 million.

In proposing to award only one incentive grant per SEA and to utilize a two-tiered formula, subject to the limitations discussed above, for making incentive grants, the Department is recognizing that these awards are by law, only ''incentives'' for SEAs to enter into high-quality consortium arrangements, and as such are not necessarily intended to pay the costs of consortium activities.

While the award of these grants offers all SEAs an incentive to participate in consortium arrangements, the use of this two-tiered formula would recognize the particular resource needs of SEAs whose MEPs are $1 million or less. Section 1303(d)(1) directs the Department to specifically consult with SEAs that receive MEP allocations of $1 million or less in order to determine whether their participation in consortium arrangements would result in the delivery of MEP services in a more effective and efficient manner.

On February 25, 2003, officials of the Department's Office of Migrant Education (OME) met with the MEP Directors from those SEAs that receive an MEP allocation of $1 million or less in order to discuss their States' special needs. One of the foremost concerns these State MEP Directors raised was the need to receive a consortium incentive grant fund amount large enough to encourage and enable their State MEPs' full participation in consortium arrangements. Responding to a possible option of having all SEAs that participated in high-quality consortia receive the same size consortium incentive grant, participants recommended that the Department consider awarding a higher consortium incentive grant amount to those States that receive MEP grants of $1 million or less.

The idea of awarding a higher level of consortium incentive grant funds to SEAs that receive MEP allocations of $1 million or less was later proposed to all the State MEP Directors in attendance at the February 26–27, 2003 Annual Meeting of State MEP Directors, and no objections were raised.

In short, the proposed two-tiered approach for awarding consortium incentive grants eliminates the costs and burdens associated with the individual SEAs and consortia preparing and reviewing their estimated cost savings, as was required under this program in prior years.

Based on these consultations with the State MEP Directors, the Department believes that the proposed two-tiered funding formula offers two advantages over other proposals. First, with little burden on SEAs, it provides a reasonable and efficient basis for awarding consortium incentive grant funds. In addition, it will assist those SEAs that receive MEP allocations of $1 million or less obtain the funds they need to participate effectively in consortium arrangements, while also administering and operating their State MEPs.

For FY 2003, the Department proposes to reserve $2.5 million for consortium incentive awards. The amount of awards in future years would vary and would be announced prior to any future competition. With a $2.5

million reservation of funds, the annual award to SEAs participating in consortium arrangements would vary from $35,738 (if all 52 SEAs received grants under this competition) to $250,000 (the statutory maximum). Based on the number of States that received consortium incentive grants (39) in FY 2002, the size of an annual award would be $45,997 for SEAs whose MEP allocations are greater than $1 million and $91,995 for SEAs whose MEP allocations are $1 million or less. The actual size of an SEA's award will depend on the number of SEAs that will participate in high-quality consortium arrangements as determined on the basis of this program's selection criteria, and the size of an SEA's MEP formula grant allocation.

Consortium incentive grants would be awarded for up to two years. (For example, the Department would not conduct a new incentive grant competition with FY 2004 funds; rather it would use FY 2004 funds for second-year continuation awards to those SEAs receiving FY 2003 incentive awards.) Pursuant to section 75.118 and 75.590 of EDGAR, each SEA that receives a consortium incentive grant award would submit a performance report (through the consortium's lead State) toward the end of the first project year, and a final evaluation report at the end of the second year. Eligibility of each SEA for second-year continuation funding would depend on that State's substantial performance of first-year consortium activities and attaining the outcomes identified in the approved consortium application.

Proposed Selection Criteria

The Department proposes to use the selection criteria from the general criteria for competitive grants contained in section 75.210 of EDGAR to evaluate applications for the incentive grants competition. The proposed selection criteria can be found in the application package, which is available on the following Web site: *http://www.ed.gov/offices/OESE/OME/index.html.* Applications would be reviewed and ranked on the basis of how well the information provided responds to these final selection criteria. Regardless of the number of consortium incentive grant applications ranked as being of sufficiently high quality in which an SEA participates, each SEA would receive only one incentive grant award.

Proposed Use of Consortium Incentive Grant Funds

An SEA that receives an incentive grant award would use this financial incentive to supplement its MEP formula grant funds provided under ESEA section 1303(a). Therefore, the SEA could use incentive grant funds to implement the consortium arrangement's activities or to carry out any other activities authorized under section 1306(b) of the ESEA. Moreover, general requirements governing the use and reporting of awarded funds would be governed by provisions of part 76 of EDGAR, which govern State-administered formula grant programs rather than provisions of part 75 of EDGAR, which govern discretionary grant programs.

Regulatory Flexibility Act Certification

The Department certifies that these proposed requirements would not have a significant economic impact on a substantial number of small entities. Entities that would be affected by these regulations are SEA. The information burden on each of these groups consists only of the time and resources needed to submit grant applications. Hence, the regulations would not have a significant impact on any entity because they would not impose excessive regulatory burden or require unnecessary Federal supervision.

Paperwork Reduction Act of 1995

The proposed criteria in this notice identified in the section entitled ''Application Requirements,'' contain information collection requirements. Under the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)), the Department of Education has submitted a copy of this notice and the information collection to the Office of Management and Budget (OMB) for its review.

Collection of Information: Migrant Education Program Consortium Incentive Grant program.

Applicants for MEP Consortium Incentive Grant funds would need to submit a program application that responds to the selection criteria announced in this notice. Applicants also would need to provide certain minimum information identified in the ''Application Requirements'' section of this notice.

We collect information once from applicants for this program. We estimate annual reporting and recordkeeping burden for this collection of information to average 50.67 hours for each application for 15 SEA respondents, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Thus, we estimate the total annual reporting and recordkeeping burden for this collection on all those preparing application under the State Program to be a total of 380 hours.

If you want to comment on the information collection requirements, please send your comments to the Office of Information and Regulatory Affairs, OMB, room 10235, New Executive Office Building, Washington, DC 20503; Attention: Desk Officer for U.S. Department of Education. You may also send a copy of these comments to the Department representative named in the **ADDRESSES** section of this preamble.

We consider your comments on this proposed collection of information in—

- Deciding whether the proposed collection is necessary for the proper performance of our functions, including whether the information will have practical use;
- Evaluating the accuracy of our estimate of the burden of the proposed collection, including the validity of our methodology and assumptions;
- Enhancing the quality, usefulness, and clarity of the information we collect; and
- Minimizing the burden on those who must respond. This includes exploring the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology; *e.g.*, permitting electronic submission of responses.

OMB is required to make a decision concerning the collections of information contained in these proposed regulations between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, to ensure that OMB gives your comments full consideration, it is important that OMB receives the comments within 30 days of publication. This does not affect the deadline for your comments to us on the proposed regulations.

Requests for copies of the proposed application packages for the Migrant Education Program Consortium Incentive Grant program may be accessed at *http://edicsweb.ed.gov*, or should be addressed to Vivian Reese, Department of Education, 400 Maryland Avenue, SW., Room 5624, Regional Office Building 3, Washington, D.C. 20202–4651. Requests may also be electronically mailed to the Internet address *OCIO_IMG_Issues@ed.gov* or faxed to 202–708–9346.

Intergovernmental Review

This program is subject to Executive Order 12372 and the regulations in 34 CFR Part 79. One of the objectives of the Executive order is to foster an intergovernmental partnership and a strengthened federalism. The Executive

order relies on processes developed by State and local governments for coordination and review of proposed Federal financial assistance.

This document is intended to provide early notification of our specific plans and actions for this program.

Electronic Access to This Document

You may view this document, as well as all other Department of Education documents published in the **Federal Register**, in text or Adobe Portable Document Format (PDF) on the Internet at the following site: *http://www.ed.gov/legislation/FedRegister.*

To use PDF you must have Adobe Acrobat Reader, which is available free at this site. If you have questions about using PDF, call the U.S. Government Printing Office (GPO), toll free, at 1–888–293–6498; or in the Washington, DC, area at (202) 512–1530.

You may also view this document in text at the following site: *http://www.ed.gov/offices/OESE/OME/index.html.*

Note: The official version of this document is the document published in the **Federal Register**. Free Internet access to the official edition of the **Federal Register** and the Code of Federal Regulations is available on GPO Access at: *http://www.access.gpo.gov/nara/index.html.*

(Catalog of Federal Domestic Assistance Number 84.144: (Migrant Education Coordination Program)

Dated: July 7, 2003.

Eugene W. Hickok,

Under Secretary of Education.

[FR Doc. 03–17532 Filed 7–10–03; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

[CFDA No. 84.358A]

Small, Rural School Achievement Program

AGENCY: Office of Elementary and Secondary Education, Department of Education.

ACTION: Notice announcing application deadline.

SUMMARY: Under the Small, Rural School Achievement Program (SRSA) Program, we will award grants on a formula basis to eligible local educational agencies (LEAs) to address the unique needs of rural school districts. An LEA that is eligible for fiscal year (FY) 2003 SRSA funding and that applied last year for FY 2002 SRSA funding does not have to submit another SRSA application in order to receive its FY 2003 grant award. An LEA that is eligible for FY 2003 SRSA funding but did not apply last year for FY 2002 SRSA funding is required to submit a FY 2003 SRSA application in order to receive its FY 2003 SRSA grant award. In this notice, we establish the deadline for submission of the FY 2003 SRSA grant applications.

Application Deadline: July 23, 2003, 4:30 p.m. Eastern time. (**Note:** The e-application has been open since May 27, 2003).

SUPPLEMENTARY INFORMATION: An LEA is eligible for an award under the SRSA Program if—

(a) The total number of students in average daily attendance at all of the schools served by the LEA is fewer than 600; *or* each county in which a school served by the LEA is located has a total population density of fewer than 10 persons per square mile; *and*

(b) All of the schools served by the LEA are designated with a school locale code of 7 or 8 by the Department's National Center for Education Statistics; *or* the Secretary has determined, based on a demonstration by the LEA and concurrence of the SEA, that the LEA is located in an area defined as rural by a governmental agency of the State.

Under the regulations at 34 CFR 75.104(a), the Secretary makes grants only to an eligible party that submits an application. The Secretary wants to minimize the burden on small, rural school districts and does not believe that it is necessary for eligible LEAs that applied for FY 2002 SRSA funding to submit another application for FY 2003 funding. Instead of requiring new applications from these LEAs, the Department is including as a condition of their FY 2003 grant award a requirement that they comply with the assurances that they filed as part of their FY 2002 applications. Those eligible LEAs that did not apply for FY 2002 funding will have to submit a FY 2003 SRSA application in order to receive their FY 2003 SRSA grant award.

We have provided on the Department's Web site at *http://www.ed.gov/offices/OESE/reap.html* a list of LEAs eligible for FY 2003 funds. The Web site also indicates which of these eligible LEAs must submit an application to receive their FY 2003 SRSA grant award, and which eligible LEAs do not have to re-apply for SRSA funding for FY 2003. Eligible LEAs that must submit an application in order to receive FY 2003 SRSA funding must do so electronically by the deadline established in this notice.

Electronic Submission of Applications: Unless it is listed on the Department's Web site as not required to re-apply for an SRSA FY 2003 funding, an eligible LEA must submit an electronic application for FY 2003 SRSA funding by July 23, 2003, 4:30 pm Eastern time. Submission of an electronic application involves the use of the Electronic Grant Application System (e-APPLICATION) portion of the Grant Administration and Payment System (GAPS).

You can access the electronic application for the SRSA Program at: *http://e-grants.ed.gov.*

Once you access this site, you will receive specific instructions regarding the information to include in your application.

The regular hours of operation of the e-Grants Web site are 6 a.m. Monday until 7 p.m. Wednesday; and 6 a.m. Thursday until midnight, Saturday (Washington, DC time). Please note that the system is unavailable on Sundays, Federal holidays, and after 7 p.m. on Wednesday for maintenance (Washington, DC time).

Waiver of Proposed Rulemaking: It is the Secretary's practice, in accordance with the Administrative Procedure Act (APA) (5 U.S.C. 553) to offer interested parties the opportunity to comment on proposed rules. Ordinarily, this practice would have applied to the rules in this notice. However, section 437(d)(2) of the General Education Provisions Act (GEPA) exempts from this rulemaking requirement those rules where the Secretary determines it would cause extreme hardship to the intended beneficiaries of the program that would be affected. In accordance with section 437(d)(2) of the GEPA, the Secretary has decided to forgo public comment with respect to the rules in this notice in order to reduce burden on eligible rural LEAs to the extent possible.

For Further Information Contact: Ms. Milagros Lanauze. Telephone: (202) 401–0039 or via Internet: *http://reap@ed.gov.*

If you use a telecommunications device for the deaf (TDD), you may call the Federal Information Relay Service (FIRS) at 1–800–877–8339.

Individuals with disabilities may obtain this notice in an alternative format (*e.g.*, Braille, large print, audiotape, or computer diskette) on request to the contact person listed above.

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Note: The official version of this document is the document published in the **Federal Register**. Free Internet access to the official version of the **Federal Register** and the Code of Federal Regulations is available on GPO access at: *http://www.access.gpo.gov/nara/index.html.*

Program Authority: Section 6212 of the ESEA, as amended by the No Child Left Behind Act of 2001 (Pub. L. 107–110).

Dated: July 7, 2003.

Eugene W. Hickok,

Under Secretary of Education.

[FR Doc. 03–17533 Filed 7–10–03; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

[CFDA No: 84.184D]

Office of Safe and Drug-Free Schools—Demonstration Grants for Student Drug Testing—Notice Inviting Applications for New Awards for Fiscal Year (FY) 2003

Purpose of Program: This program awards grants to local educational agencies (LEAs) and public and private entities, to develop or enhance, implement, and evaluate school-based drug testing programs for students.

For FY 2003 the competition for new awards focuses on projects designed to meet the priorities we describe in the PRIORITIES section of this application notice.

Eligible Applicants: LEAs and public and private entities.

Applications Available: July 11, 2003.

Deadline for Transmittal of Applications: August 20, 2003.

Deadline for Intergovernmental Review: September 19, 2003.

Estimated Available Funds: The Department expects to make available $2,000,000 for this program for FY 2003.

Estimated Range of Awards: $200,000–$400,000.

Estimated Average Size of Awards: $300,000.

Estimated Number of Awards: 7.

Note: The Department is not bound by any estimates in this notice.

Project Period: Up to 36 months.

Applicable Regulations: The Education Department General Administrative Regulations (EDGAR) in 34 CFR parts 74, 75, 77, 79, 80, 81, 82, 85, 86, 97, 98, and 99.

Other Requirements

Participation by Private School Children and Teachers

Entities receiving a grant under the Demonstration Grants for Student Drug Testing Program are required to provide for the equitable participation of private school children and their teachers or other educational personnel. In order to ensure that grant program activities address the needs of private school children, timely and meaningful consultation with appropriate private school officials must occur during the design and development of the program. Administrative direction and control over grant funds must remain with the grantee.

Maintenance of Effort

An LEA may receive a grant under the Demonstration Grants for Student Drug Testing Program only if the State educational agency finds that the combined fiscal efforts per student or the aggregate expenditures of the agency and the State with respect to the provisions of free public education by the agency for the preceding fiscal year was not less than 90 percent of the combined fiscal effort or aggregate expenditures for the second preceding fiscal year.

School-Based Programs

Applicants other than LEAs must demonstrate that they have established a partnership with one or more LEAs to carry out the program. This partnership must be demonstrated by submitting a partnership agreement signed by the superintendent or an authorized representative of the participating LEA. Letters of support for the proposed project are not sufficient to demonstrate the required partnership.

Assurance

Applicants must provide an assurance that legal counsel has reviewed the proposed program and advised that the program activities do not appear to violate established constitutional principles or State and Federal requirements related to implementing a student drug testing program.

SUPPLEMENTARY INFORMATION:

Additional Awards

Contingent upon the availability of funds, we may make additional awards in FY 2004 from the rank-ordered list of unfunded applications from this competition.

Participation of Faith-based Organizations

Faith-based organizations are eligible to apply for grants under this competition provided they meet all statutory and regulatory requirements.

Definition

Drug. The term drug includes controlled substances; the illegal use of alcohol and tobacco; and the harmful, abusive, or addictive use of substances, including inhalants and anabolic steroids.

Absolute Priority

We will award grants to LEAs and public and private entities to develop or enhance, implement, and evaluate school-based drug testing programs for students. Any random drug testing program conducted with funds awarded under this competition must be limited to one or more of the following: (1) Students who participate in the school's athletic program; (2) students who are engaged in competitive, extracurricular school-sponsored activities; and (3) students who, along with their parents or guardian, have consented or volunteered to participate in a random drug testing program.

In order to be eligible for an award, applicants must:

(1) Identify a target population and demonstrate a significant need for drug testing within the target population;

(2) Explain how the proposed drug testing program will be part of a comprehensive drug prevention program in the schools to be served;

(3) Provide a comprehensive plan for referral to treatment or counseling of students identified as drug users through the testing program; and

(4) Provide a plan to ensure the confidentiality of drug testing results.

For FY 2003, this priority is an absolute priority. Under 34 CFR 75.105(c)(3), we will consider only applications that meet this priority.

Competitive Preference Priority

In order to determine whether the drug testing projects supported under this program produce meaningful effects on student drug use, we have established a competitive preference priority within the absolute priority for this competition. We will award up to 10 additional points to applicants that propose experimental or quasi-experimental evaluation of projects. These points are in addition to any points the application earns under the selection criteria. The total number of points available for this competition is 110.

Evaluations using an experimental design are the strongest for determining program effectiveness. Thus, the project preferably uses an experimental design. An evaluation using an experimental design is one where subjects (students, teachers, classrooms, or schools) are randomly assigned to receive the program being evaluated or to be in a control group that does not receive the program.

If random assignment is not feasible, the project may employ a quasi-experimental design with carefully matched comparison conditions. This alternative design attempts to approximate a randomly assigned control group by matching subjects (students, teachers, classrooms, or schools) with non-participants possessing similar pre-program characteristics.

Data from reliable and valid measures of the intervention that the program intends to implement and of the outcomes that the program intends to affect, should be collected before and after participation in the program or the comparison condition.

Points awarded under this priority will be determined by the quality of the proposed evaluation. In determining the quality of the evaluation, we will consider the extent to which the applicant presents a feasible, credible plan that includes:

(1) The type of design to be used (random assignment or matched comparison);

(2) Outcomes to be measured;

(3) A discussion of how students, teachers, classrooms, or schools will be assigned to the program or matched for comparison with other students, teachers, classrooms, or schools; and

(4) A proposed evaluator, preferably independent, with the necessary background and technical expertise to carry out the proposed evaluation.

Applicants who apply for the competitive preference will have their applications reviewed separately by a panel of non-federal experts that includes at least one evaluation expert.

Performance Measures

The Secretary has established the following key performance measure for assessing the effectiveness of the Demonstration Grants for Student Drug Testing Program: The reduction of the incidence of drug use in the past month and past year. The Secretary has set an overall performance target that calls for the incidence of drug use by students in the target population to decline by five percent annually.

In applying the selection criteria that follow for ''Quality of project design'' and ''Quality of the project evaluation,'' the Secretary will take into consideration the extent to which the applicant demonstrates a strong capacity (1) To help achieve this target, and (2) to provide reliable data on this indicator.

Selection Criteria

The following selection criteria are used to evaluate applications for new grants under this competition. Together with the competitive preference priority, the maximum number of points that may be awarded is 110. The maximum score for each criterion or factor under that criterion is indicated in parentheses.

(1) *Need for project.* (20 points)

In determining the need for the proposed project, the following factor is considered:

The magnitude or severity of the problem to be addressed by the proposed project. (20 points)

Note: Under this criterion we will look for evidence that the applicant has conducted a student drug use survey or other needs assessment that demonstrates a significant need for drug testing in the target population.

(2) *Significance.* (20 points)

In determining the significance of the proposed project, the following factors are considered:

(a) The potential contribution of the proposed project to the development and advancement of theory, knowledge, and practices in the field of study. (10 points)

(b) The extent to which the proposed project involves the development or demonstration of promising new strategies that build on, or are alternatives to, existing strategies. (5 points)

(c) The potential for generalizing from the findings or results of the proposed project. (5 points)

(3) *Quality of the project design.* (30 points)

In determining the quality of the design of the proposed project, the following factors are considered:

(a) The extent to which the design of the proposed project reflects up-to-date knowledge from research and effective practice. (10 points)

(b) The extent to which the proposed project will establish linkages with other appropriate agencies and organizations providing services to the target population. (5 points)

(c) The quality of the proposed demonstration design and procedures for documenting project activities and results. (10 points)

(d) The extent to which the project demonstrates an exceptional approach to the priority established for the competition. (5 points)

(Note: Under this criterion we will look at the likelihood that the applicant's plan will lead to reductions in the incidence of drug use by students in the target population.)

(4) *Management plan.* (10 points)

In determining the quality of the management plan, the following factor is considered:

How the applicant will ensure that a diversity of perspectives are brought to bear in the operation of the proposed project, including those of parents, teachers, the business community, a variety of disciplinary and professional fields, recipients or beneficiaries of services, or others, as appropriate. (10 points)

(5) *Quality of the project evaluation.* (20 points)

In determining the quality of the evaluation, the following factors are considered:

(a) The extent to which the methods of evaluation provide for examining the effectiveness of project implementation strategies. (10 points)

(b) The extent to which the methods of evaluation include the use of objective performance measures that are clearly related to the intended outcomes of the project and will produce quantitative and qualitative data to the extent possible. (10 points)

(Note: Under this criterion, we will look for the applicant's plan to provide reliable data that measures declines in the incidence of drug use by students in the target population in the past month and in the past year.)

FOR APPLICATIONS AND FURTHER INFORMATION CONTACT: Heather Carkuff, U.S. Department of Education, Office of Safe and Drug-Free Schools, 400 Maryland Avenue, SW., Room 3E250, Washington, DC 20202–6450. E-mail: *heather.carkuff@ed.gov.* To download a copy of the application, visit the Web site for the Office of Safe and Drug-Free Schools at *http://www.ed.gov/offices/OSDFS.*

If you use a telecommunications device for the deaf (TDD), you may call the Federal Information Relay Service (FIRS) at 800/877–8339.

Individuals with disabilities may obtain this document in an alternative format (*e.g.*, Braille, large print, audiotape, or computer diskette) on request to the program contact person listed under **FOR APPLICATIONS AND FURTHER INFORMATION CONTACT.**

Individuals with disabilities also may obtain a copy of the application package in an alternative format by contacting that person. However, the Department is not able to reproduce in an alternative

format the standard forms included in the application package.

Waiver of Proposed Rulemaking

Under the Administrative Procedure Act (5 U.S.C. 553) the Department generally offers interested parties the opportunity to comment proposed regulations. Section 437(d)(2) of the General Education Provisions Act (GEPA), however, exempts from this rulemaking requirement those rules where the Secretary determines it would cause extreme hardship to the beneficiaries of the program that would be affected by those rules. The Secretary, in accordance with section 437(d)(2) of GEPA, has decided to issue these rules without first publishing them for public comment in order to ensure timely and high quality grant awards. These rules will apply only to grant applications submitted in FY 2003.

Pilot Project for Electronic Submission of Applications

In FY 2003, the U.S. Department of Education is continuing to expand its pilot project for electronic submission of applications to include additional formula grant programs and additional discretionary grant competitions. The Demonstration Grants for Student Drug Testing Program is one the programs included in the pilot project. If you are an applicant under this competition, you may submit your application to us in either electronic or paper format.

The pilot project involves the use of the Electronic Grant Application System (e-Application) portion of the Grants Administration and Payment System (GAPS). Users of e-Application will be entering data on-line while completing their applications. You may not e-mail a soft copy of a grant application to us. If you participate in this voluntary pilot project by submitting an application electronically, the data you enter on-line will be saved into a database. We request your participation in e-Application. We shall continue to evaluate its success and solicit suggestions for improvement.

If you participate in e-Application, please note the following:

- Your participation is voluntary.
- You will not receive any additional point value because you submit a grant application in electronic format, nor will we penalize you if you submit an application in paper format. When you enter the e-Application system, you will find information about its hours of operation.
- You may submit all documents electronically, including the Application for Federal Education Assistance (ED 424), Budget Information—Non-Construction Programs (ED 524), and all necessary assurances and certifications.
- After you electronically submit your application, you will receive an automatic acknowledgement, which will include a PR/Award Number (an identifying number unique to your application).
- Within three working days after submitting your electronic application, fax a signed copy of the Application for Federal Education Assistance (ED 424) to the Application Control Center after following these steps:

(1) Print ED 424 from the e-Application system.

(2) The institution's Authorizing Representative must sign this form.

(3) Place the PR/Award number in the upper right hand corner of the hard copy signature page of the ED 424.

(4) Fax the signed ED 424 to the Application Control Center at 202/260–1349.

- We may request that you give us original signatures on all other forms at a later date.
- *Closing Date Extension in Case of System Unavailability:* If you elect to participate in the e-Application pilot for the Demonstration Grants for Student Drug Testing Program and you are prevented from submitting your application on the closing date because the e-Application system is unavailable, we will grant you an extension of one business day in order to transmit your application electronically, by mail, or by hand delivery. For us to grant this extension—

(1) You must be a registered user of e-Application, and have initiated an e-Application for this competition; and

(2)(a) The e-Application system must be unavailable for 60 minutes or more between the hours of 8:30 a.m. and 3:30 p.m. (ET), on the deadline date; or (b) The e-Application system must be unavailable for any period of time during the last hour of operation (that is, for any period of time between 3:30 p.m. and 4:30 p.m. (ET)) on the deadline date. The Department must acknowledge and confirm these periods of unavailability before granting you an extension. To request this extension you must contact either (1) The person listed elsewhere in this notice under **FOR FURTHER INFORMATION CONTACT** or (2) the e-GRANTS help desk at 888/336–8930.

You may access the electronic grant application for the Demonstration Grants for Student Drug Testing Program: *http://e-grants.ed.gov.* We have included additional information about the e-Application pilot project (*see* Parity Guidelines Between Paper and Electronic Applications) in the application package.

Electronic Access to This Document

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To use PDF you must have Adobe Acrobat Reader, which is available free at this site. If you have questions about using PDF, call the U.S. Government Printing Office (GPO), toll free, at 888/293–6498; or in the Washington, DC, area at 202/512–1530.

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Program Authority: 20 U.S.C. 7131.

Dated: July 7, 2003.

Eric G. Andell,

Deputy Under Secretary for Safe and Drug-Free Schools.

[FR Doc. 03–17536 Filed 7–10–03; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

[Docket Nos. EA–282]

Application To Export Electric Energy; Xcel Energy Inc., d/b/a Northern States Power Company

AGENCY: Office of Fossil Energy, DOE.

ACTION: Notice of application.

SUMMARY: Excel Energy Inc., doing business as Northern States Power Company (NSP), has applied to export electric energy from the United States to Canada, pursuant to section 202(e) of the Federal Power Act.

DATES: Comments, protests or requests to intervene must be submitted on or before August 11, 2003.

ADDRESSES: Comments, protests or requests to intervene should be addressed as follows: Office of Coal & Power Import/Export (FE–27), Office of Fossil Energy, U.S. Department of Energy, 1000 Independence Avenue, SW., Washington, DC 20585–0350 (FAX 202–287–5736).

FOR FURTHER INFORMATION CONTACT: Rosalind Carter (Program Office) 202–586–7983 or Michael Skinker (Program Attorney) 202–586–2793.

SUPPLEMENTARY INFORMATION: Exports of electricity from the United States to a foreign country are regulated and

require authorization under section 202(e) of the Federal Power Act (FPA) (16 U.S.C. 824a(e)).

On June 23, 2003 Excel Energy Inc., doing business as NSP, applied to the Office of Fossil Energy, of the Department of Energy (DOE) for authority to export electric energy from the United States to Canada. NSP is a Minnesota corporation with its principal place of business in Minneapolis, Minnesota. NSP is an investor-owned utility and a wholly-owned subsidiary of Xcel Energy, Inc., and is engaged in the generation, distribution and sale of electric energy. NSP controls electric power generations and transmission facilities in the States of North Dakota, South Dakota, Minnesota, Wisconsin and Michigan. As a Regulated Utility, NSP produces and distributes electric power and conducts wholesale purchases and sales of capacity and energy.

In FE Docket No. EA–282, NSP proposes to export electric energy that is in excess of the amounts required to meet its native load obligations or that is purchased from generators, power marketers or federal power marketing agencies. NSP will arrange for the delivery of those exports to Canada over the international transmission facilities owned by Basin Electric Power Cooperative, Bonneville Power Administration, Citizens Utilities, Eastern Maine Electric Cooperative, International Transmission Co., Joint Owners of the Highgate Project, Long Sault, Inc., Maine Electric Power Company, Maine Public Service Company, Minnesota Power, Inc., Minnkota Power Cooperative, Inc., New York Power Authority, Niagara Mohawk Power Corp., Northern States Power Company and Vermont Electric Transmission Company. NSP will purchase the power to be exported from electric utilities and federal power marketing agencies as defined in the FPA.

The construction of each of the international transmission facilities to be utilized by NSP has previously been authorized by a Presidential permit issued pursuant to Executive Order 10485, as amended.

Procedural Matters: Any person desiring to become a party to this proceeding or to be heard by filing comments or protests to this application should file a petition to intervene, comment or protest at the address provided above in accordance with §§ 385.211 or 385.214 of the FERC's Rules of Practice and Procedures (18 CFR 385.211, 385.214). Fifteen copies of each petition and protest should be filed with the DOE on or before the date listed above.

Comments on the NSP application to export electric energy to Canada should be clearly marked with Docket EA–282. Additional copies are to be filed directly with Xcel Energy, Inc. for Northern States Power Company, 1099 18th Street, Suite 3000, Denver, CO 80202, ATTN: Director, Contract Administration.

A final decision will be made on this application after the environmental impact has been evaluated pursuant to the National Environmental Policy Act of 1969, and a determination is made by the DOE that the proposed action will not adversely impact on the reliability of the U.S. electric power supply system.

Copies of this application will be made available, upon request, for public inspection and copying at the address provided above or by accessing the Fossil Energy Home Page at *http://www.fe.doe.gov.* Upon reaching the Fossil Energy Home page, select ''Electricity Regulation,'' and then ''Pending Proceedings'' from the options menus.

Issued in Washington, DC, on July 7, 2003.

Anthony Como,

Deputy Director, Electric Power Regulation, Office of Coal & Power Import/Export, Office of Coal & Power Systems, Office of Fossil Energy.

[FR Doc. 03–17593 Filed 7–10–03; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

[Docket Nos. EA–283]

Application To Export Electric Energy; Xcel Energy Inc., d/b/a Public Service Company of Colorado

AGENCY: Office of Fossil Energy, DOE.

ACTION: Notice of application.

SUMMARY: Xcel Energy Inc., doing business as Public Service Company of Colorado (PSCO), has applied to export electric energy from the United States to Canada, pursuant to section 202(e) of the Federal Power Act.

DATES: Comments, protests or requests to intervene must be submitted on or before August 11, 2003.

ADDRESSES: Comments, protests or requests to intervene should be addressed as follows: Office of Coal & Power Import/Export (FE–27), Office of Fossil Energy, U.S. Department of Energy, 1000 Independence Avenue, SW., Washington, DC 20585–0350 (FAX 202–287–5736).

FOR FURTHER INFORMATION CONTACT: Rosalind Carter (Program Office) 202–586–7983 or Michael Skinker (Program Attorney) 202–586–2793.

SUPPLEMENTARY INFORMATION: Exports of electricity from the United States to a foreign country are regulated and require authorization under section 202(e) of the Federal Power Act (FPA) (16 U.S.C. 824a(e)).

On June 23, 2003, Xcel Energy Inc., doing business as PSCO, applied to the Office of Fossil Energy, of the Department of Energy (DOE) for authority to export electric energy from the United States to Canada. PSCO is a Colorado corporation with its principal place of business in Denver, Colorado. PSCO is an investor-owned utility and a wholly-owned subsidiary of Xcel Energy, Inc., and is engaged in the generation, distribution and sale of electric energy. PSCO controls electric power generation and transmission facilities in the States of Arizona, Colorado, Kansas, New Mexico, Oklahoma, Texas, and Wyoming. As a regulated utility, PSCO produces and distributes electric power and conducts wholesale purchases and sales of capacity and energy.

In FE Docket No. EA–283, PSCO proposes to export electric energy that is in excess of the amounts required to meet its native load obligations or that is purchased from generators, power marketers or federal power marketing agencies. PSCO will arrange for the delivery of those exports to Canada over the international transmission facilities owned by Basin Electric Power Cooperative, Bonneville Power Administration, Citizens Utilities, Eastern Maine Electric Cooperative, International Transmission Co., Joint Owners of the Highgate Project, Long Sault, Inc., Maine Electric Power Company, Maine Public Service Company, Minnesota Power, Inc., Minnkota Power Cooperative, Inc., New York Power Authority, Niagara Mohawk Power Corp., Northern States Power Company and Vermont Electric Transmission Company. PSCO will purchase the power to be exported from electric utilities and federal power marketing agencies as defined in the FPA.

The construction of each of the international transmission facilities to be utilized by PSCO has previously been authorized by a Presidential permit issued pursuant to Executive Order 10485, as amended.

Procedural Matters: Any person desiring to become a party to this proceeding or to be heard by filing comments or protests to this application

should file a petition to intervene, comment or protest at the address provided above in accordance with §§ 385.211 or 385.214 of the FERC's Rules of Practice and Procedures (18 CFR 385.211, 385.214). Fifteen copies of each petition and protest should be filed with the DOE on or before the date listed above.

Comments on the PSCO application to export electric energy to Canada should be clearly marked with Docket EA–283. Additional copies are to be filed directly with Xcel Energy, Inc., for Public Service Company of Colorado, 1099 18th Street, Suite 3000, Denver, CO 80202, Attn: Director, Contract Administration.

A final decision will be made on this application after the environmental impact has been evaluated pursuant to the National Environmental Policy Act of 1969, and a determination is made by the DOE that the proposed action will not adversely impact on the reliability of the U.S. electric power supply system.

Copies of this application will be made available, upon request, for public inspection and copying at the address provided above or by accessing the Fossil Energy Home Page at *http://www.fe.doe.gov.* Upon reaching the Fossil Energy Home page, select ''Electricity Regulation,'' and then ''Pending Proceedings'' from the options menus.

Issued in Washington, DC, on July 7, 2003.

Anthony Como,

Deputy Director, Electric Power Regulation, Office of Coal & Power Import/Export, Office of Coal & Power Systems, Office of Fossil Energy.

[FR Doc. 03–17592 Filed 7–10–03; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. EC03–18–002, et al.]

Athens Generating Company, L.P., et al.; Electric Rate and Corporate Filings

July 3, 2003.

The following filings have been made with the Commission. The filings are listed in ascending order within each docket classification.

1. Athens Generating Company, L.P., Covert Generating Company, LLC, Harquahala Generating Company, LLC, Millennium Power Partners, L.P., and MACH Gen, LLC

[Docket No. EC03–18–002]

Take notice that on June 25, 2003, Athens Generating Company, L.P., Covert Generating Company, LLC, Harquahala Generating Company, LLC, and Millennium Power Partners, L.P. (together, the NEG Companies), each of which is an indirect, wholly-owned subsidiary of PG&E National Energy Group, Inc., and MACH Gen, LLC (together with the NEG Companies, the Applicants) tendered for filing with the Federal Energy Regulatory Commission (Commission) pursuant to Section 203 of the Federal Power Act and part 33 of the Commission's regulations, 18 CFR part 33, a request for additional flexibility in implementing the proposed transfer of jurisdictional facilities (the Transfer) authorized by the Commission's June 5, 2003 order. *See* Athens Generating Company, L.P., 103 FERC ¶ 61,290 (2003).

Comment Date: July 16, 2003.

2. Francis Street Energy, LLC

[Docket No. EC03–99–000]

Take notice that on June 27, 2003, Francis Street Energy LLC (Applicant), filed with the Federal Energy Regulatory Commission (Commission) an application pursuant to Section 203 of the Federal Power Act seeking authorization for the Applicant to acquire 100% of the upstream membership interests in Capital Center Generating Company, LLC (CCGC). In addition, Applicant gave notice of the change in status that will result from the transaction described in the application.

Comment Date: July 18, 2003.

3. D. E. Shaw Plasma Power, L.L.C.

[Docket No. EL03–128–000]

Take notice that on July 1, 2003, D. E. Shaw Plasma Power, L.L.C. supplemented its Petition for A Declaratory Order Disclaiming Jurisdiction; and Request for Expedition (the Petition) by filing, confidentially, the form of License Agreement referenced in the Petition.

Comment Date: July 14, 2003.

4. Athens Generating Company, L.P., Covert Generating Company, LLC, Harquahala Generating Company, LLC, and Millennium Power Partners, L.P.

[Docket Nos. ER99–4282–004, ER01–520–004, ER01–748–004, and ER98–830–008]

Take notice that on June 30, 2003, Athens Generating Company, L.P., Covert Generating Company, LLC, Harquahala Generating Company, LLC, Millennium Power Partners, L.P., (together the NEG Companies), each of which is an indirect, wholly-owned subsidiary of PG&E National Energy Group, Inc., and MACH Gen, LLC, tendered for filing information that reflects a potential change in upstream ownership that is different from the characteristics relied upon by the Commission in approving market-based pricing for the NEG Companies.

Comment Date: July 14, 2003.

5. Entergy Services, Inc.

[Docket No. ER02–2014–011]

Take notice that on June 30, 2003, Entergy Services, Inc., (Entergy) submitted for filing in compliance with the Commission's order issued March 13, 2003, 102 FERC ¶ 61,28, a status report regarding two issues: (1) Entergy's evaluation of alternative methods of designating short-term network resources under the Network Integration Transmission Service provisions of the Entergy Open Access Transmission Tariff, and

(2) Energy's evaluation of an Available Flowgate Capacity methodology as an alternative to evaluating transmission service requests with Available Transfer Capability and Generator Operating Limits calculations.

Comment Date: July 21, 2003.

6. New York Independent System Operator, Inc.

[Docket No. ER03–690–001]

Take notice that on June 24, 2003, New York Independent System Operator, Inc. (NYISO) submitted for filing information relating to the proposed revisions to its Market Administration and Control Area Services Tariff and its Open Access Transmission Tariff to implement new pricing rules for the Hydro-Quebec.

Comment Date: July 15, 2003.

7. Dynegy Power Services, Inc.

[Docket No. ER03–999–000]

Take notice that on June 27, 2003, Dynegy Power Services, Inc. (DPS) pursuant to sections 35.15 and 131.53, 18 CFR 35.15 and 131.53, of the Commission's Regulations, filed with the Federal Energy Regulatory Commission a Notice of Cancellation of DPS's Market-Based FERC Electric Rate Tariff and all rate schedules and/or service agreements thereunder effective June 30, 2003.

Comment Date: July 18, 2003.

8. Illinova Energy Partners, Inc.

[Docket No. ER03–1000–000]

Take notice that on June 27, 2003, Illinova Energy Partners, Inc. (IEP)

pursuant to sections 35.15 and 131.53, 18 CFR 35.15 and 131.53, of the Commission's Regulations, filed with the Federal Energy Regulatory Commission a Notice of Cancellation of IEP's Market-Based FERC Electric Rate Tariff and all rate schedules and/or service agreements thereunder effective June 30, 2003.

Comment Date: July 18, 2003.

9. Galt Power, Inc.

[Docket No. ER03–1001–000]

Take notice that on June 30, 2003, Galt Power, Inc. (Galt Power) petitioned the Commission for acceptance of Galt Power Rate Schedule FERC No. 1; the granting of certain blanket approvals, including the authority to sell electricity at market-based rates; and the waiver of certain Commission Regulations.

Galt Power states that it intends to engage in wholesale electric power and energy purchases and sales as a marketer. Galt Power also states it is not in the business of generating or transmitting electric power.

Comment Date: July 21, 2003.

10. Michigan Electric Transmission Company, LLC

[Docket No. ER03–1003–000]

Take notice that on June 30, 2003, Michigan Electric Transmission Company, LLC (METC) submitted proposed amendments to the following agreements: (1) Project I Transmission Ownership and Operating Agreement Between Consumers Power Company and Michigan South Central Power Agency dated November 20, 1980; (2) Campbell Unit No. 3 Transmission Ownership and Operating Agreement Between Consumers Power Company and Northern Michigan Electric Cooperative, Inc. and Wolverine Electric Cooperative, Inc., dated August 15, 1980; (3) Campbell Unit No. 3 Transmission Ownership and Operating Agreement Between Consumers Power Company and Michigan Public Power Agency dated October 1, 1979; (4) Belle River Transmission Ownership and Operating Agreement Between Consumers Power Company and Michigan Public Power Agency dated December 1, 1982; and (5) Wolverine Transmission Ownership and Operating Agreement Between Consumers Power Company and Wolverine Power Supply Cooperative, Inc., dated July 27, 1992.

METC states that the proposed amendments are intended to allow for the reimbursement to METC for certain Midwest Independent Transmission System Operator, Inc. costs and annual charges associated with the load of the Customers. METC requests an effective date of July 1, 2003 for the proposed amendments.

Comment Date: July 21, 2003.

11. PJM Interconnection, L.L.C.

[Docket No. ER03–1004–000]

Take notice that on June 30, 2003, PJM Interconnection, L.L.C. (PJM), submitted for filing five interim interconnection service agreements (Interim ISAs) between PJM and PSEG Fossil, L.L.C., Exelon Corporation, Constellation Power Source Generation, Inc., and PSEG Power, L.L.C. and five notices of cancellation of certain Interim ISAs that have been superseded. PJM requests a waiver of the Commission's 60-day notice requirement to permit effective dates agreed to by the parties to the agreements.

PJM states that copies of this filing were served upon the parties to the agreements and the state regulatory commissions within the PJM region.

Comment Date: July 21, 2003.

12. PJM Interconnection, L.L.C.

[Docket No. ER03–1013–000]

Take notice that on July 2, 2003, PJM Interconnection, L.L.C. (PJM) tendered for filing with the Federal Energy Regulatory Commission (Commission) an emergency request for expedited approval of revisions to the PMJ Tariff and PJM Operating Agreement to establish an interim ceiling on the permitted number of bids and offers submitted in the monthly PJM financial transmission rights (FTR) auctions, to be effective during the period of suspension of the changes previously filed in this proceeding. PJM states that expedited approval is required because PJM is concerned that, absent such a ceiling, it may be unable to conduct the next monthly FTR auction, which is scheduled to commence on July 16, 2003.

PJM proposes an effective date of July 15, 2003 for the proposed revisions, and requests waiver of the Commission's 60-day notice requirement to permit such effective date. PJM states that copies of this filing were served upon all PJM members and each state electric utility regulatory commission in the PJM region. PJM states that it also served a copy of its filing by overnight delivery on all persons on the Commission's service list for this proceeding and posted a copy of the entire filing on its Internet site, *http://www.pjm.com*.

Comment Date: July 11, 2003.

Standard Paragraph

Any person desiring to intervene or to protest this filing should file with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). 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. All such motions or protests should be filed on or before the comment date, and, to the extent applicable, must be served on the applicant and on any other person designated on the official service list. This filing is available for review at the Commission or may be viewed on the Commission's Web site at *http://www.ferc.gov*, using the ''FERRIS'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov* or toll-free at (866) 208–3676, or for TTY, contact (202) 502–8659. Protests and interventions may be filed electronically via the Internet in lieu of paper; *see* 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site under the ''e-Filing'' link. The Commission strongly encourages electronic filings.

Magalie R. Salas,

Secretary.

[FR Doc. 03–17542 Filed 7–10–03; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER97–2353–012, et al.]

New York Electric & Gas Corporation, et al.; Electric Rate and Corporate Filings

July 2, 2003.

The following filings have been made with the Commission. The filings are listed in ascending order within each docket classification.

1. New York State Electric & Gas Corporation

[Docket Nos. ER97–2353–012]

Take notice that on June 30, 2003, New York State Electric & Gas Corporation (NYSEG) tendered for filing its compliance filing and refund report pursuant to the Federal Energy Regulatory Commission's (Commission) Opinion No. 447–C issued June 10, 2003. NYSEG requests that its revised transmission revenue requirement

calculated pursuant to this compliance filing be deemed to be effective as of November 18, 1999 pursuant to the Commission's Order issued on June 10, 2003 in Opinion No. 447–C.

NYSEG states that all refunds pursuant to Opinion No. 447–C have been made. NYSEG also states that copies of the compliance filing and refund report have been served on all the parties affected by Opinion No. 447–C and the New York State Public Service Commission.

Comment Date: July 21, 2003.

2. New England Power Pool

[Docket No. ER03–345–001]

Take notice that on June 30, 2003, ISO New England Inc. submitted a compliance report on the status of its Load Response programs pursuant to the Commission's Order issued February 25, 2003 in Docket No. ER03–345–000, 102 FERC ¶ 61,202.

Comment Date: July 21, 2003.

3. New York Independent System Operator, Inc.

[Docket No. ER03–560–001]

Take notice that on June 24, 2003, New York Independent System Operator, Inc. (NYISO) submitted for filing information relating to the proposed revisions to its Market Administration and Control Area Services Tariff and its Open Access Transmission Tariff to implement new pricing rules for the Hydro-Quebec.

Comment Date: July 15, 2003.

4. Devon Power LLC

[Docket Nos. ER03–563–012 and ER03–998–000]

Take notice that on June 27, 2003, Mirant Kendall, LLC (Mirant Kendall) submitted the fixed cost information supporting the fixed cost portion of the PUSH Reference Level for its two jet turbine units (the Kendall Jets) developed by ISO New England Inc. (ISO–NE) and placed into effect by ISO–NE as of June 30, 2003 in accordance with the New England Power Pool Market Rules.

Mirant Kendall states that copies of this filing are being served upon all parties to this proceeding.

Comment Date: July 18, 2003.

5. California Independent System Operator Corporation

[Docket No. ER03–683–002]

Take notice that on June 30, 2003, the California Independent System Operator Corporation (ISO) submitted a filing in compliance with the Commission's May 30, 2003 Order issued in Docket No. ER03–683–000, 103 FERC ¶ 61,265. The ISO states that it has also served copies of this filing upon all entities that are on the official service list for the docket.

Comment Date: July 21, 2003.

6. Niagara Mohawk Power Corporation

[Docket No. ER03–989–000]

Take notice that on June 30, 2003, Niagara Mohawk Power Corporation, a National Grid Company, submitted an Amended and Restated Rate Schedule FERC No. 159 for the Retail Transmission of Expansion Power for the Power Authority of the State of New York pursuant to sections 205 and 206 of the Federal Power Act.

Comment Date: July 21, 2003.

7. Niagara Mohawk Power Corporation

[Docket No. ER03–990–000]

Take notice that on June 30, 2003, Niagara Mohawk Power Corporation, a National Grid Company, submitted First Amended and Restated Service Agreement Nos. 224, 225 and 226 (the Service Agreements) under the grandfathered Open Access Transmission Tariff (OATT). Niagara Mohawk submits these proposed changes for filing pursuant to sections 205 and 206 of the Federal Power Act 16 U.S.C. 824d and 824e, and Rules 205 and 206 of the Commission's Rules of Practice and Procedure, 18 CFR 385.205 and 385.206.

Comment Date: July 21, 2003.

8. Niagara Mohawk Power Corporation

[Docket No. ER03–991–000]

Take notice that on June 30, 2003, Niagara Mohawk Power Corporation, a National Grid Company, submitted amendments to its Rate Schedule FERC No. 19 for the Retail Transmission of Replacement Power for The Power Authority of the State of New York pursuant to sections 205 and 206 of the Federal Power Act, 16 U.S.C. 824d and 824e, and Rules 205 and 206 of the Commission's Rules of Practice and Procedure, 18 CFR 385.205 and 385.206.

Comment Date: July 21, 2003.

9. Niagara Mohawk Power Corporation

[Docket No. ER03–992–000]

Take notice that on June 30, 2003, Niagara Mohawk Power Corporation, a National Grid Company (Niagara Mohawk) submitted a First Amended and Restated Rate Schedule FERC No. 249 for the Retail Transmission of Economic Development Power for the Power Authority of the State of New York pursuant to sections 205 and 206 of the Federal Power Act.

Comment Date: July 21, 2003.

10. Pacific Gas and Electric Company

[Docket No. ER03–993–000]

Take notice that on June 30, 2003, Pacific Gas and Electric Company (PG&E) tendered for filing a proposed executed Must-Run Service Agreement (Agreement) for the 336.6 MW hydroelectric system located at the Kings River Watershed in Auberry, California. PG&E states that it proposes to provide services under the Agreement to the California Independent System Operator Corporation.

PG&E state that copies of this filing have been served upon the California Independent System Operator Corporation, the California Public Utilities Commission and the California Electricity Oversight Board.

Comment Date: July 21, 2003.

11. Central Maine Power Company

[Docket No. ER03–994–000]

Please take notice that on June 30, 2003, Central Maine Power Company (CMP) tendered for filing, in accordance with Section 1.18 of the Settlement Agreement approved in Docket Nos. ER00–26–000, *et al.*, an informational filing containing the data used to update the formula rates in CMP's Open Access Transmission Tariff. The charges associated with the updated data took effect June 1, 2003.

CMP states that copies of this filing were served on Commission Staff and the Maine Public Utilities Commission.

Comment Date: July 21, 2003.

12. Midwest Independent Transmission System Operator, Inc.

[Docket No. ER03–995–000]

Take notice that on June 30, 2003, the Midwest Independent Transmission System Operator, Inc. (Midwest ISO) pursuant to Section 205 of the Federal Power Act and section 35.13 of the Commission's regulations, 18 CFR 35.13, submitted for filing an unexecuted Interconnection and Operating Agreement among American Transmission Company, the Midwest ISO and Wisconsin Public Service Company.

Midwest ISO states that a copy of this filing was provided to the American Transmission Company and Wisconsin Public Service Company.

Comment Date: July 21, 2003.

13. Midwest Independent Transmission System Operator, Inc.

[Docket No. ER03–996–000]

Take notice that on June 30, 2003, the Midwest Independent Transmission System Operator, Inc. (Midwest ISO) pursuant to Section 205 of the Federal Power Act and Section 35.12 of the

Commission's Regulations, 18 CFR 35.12, submitted for filing an Interconnection and Operating Agreement among Interstate Power and Light Company, a wholly owned subsidiary of Alliant Energy Corporation, Midwest ISO, and Interstate Power and Light Company, a wholly owned subsidiary of Alliant Energy Corporation.

Midwest ISO states that a copy of this filing was sent to Interstate Power and Light Company and Interstate Power and Light Company.

Comment Date: July 21, 2003.

Standard Paragraph

Any person desiring to intervene or to protest this filing should file with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). 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. All such motions or protests should be filed on or before the comment date, and, to the extent applicable, must be served on the applicant and on any other person designated on the official service list. This filing is available for review at the Commission or may be viewed on the Commission's Web site at *http://www.ferc.gov* , using the ''FERRIS'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. For assistance, contact FERC Online Support at *FERCOnlineSupport@ferc.gov* or toll-free at (866) 208–3676, or for TTY, contact (202) 502–8659. Protests and interventions may be filed electronically via the Internet in lieu of paper; *see* 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site under the ''e-Filing'' link. The Commission strongly encourages electronic filings.

Magalie R. Salas,

Secretary.

[FR Doc. 03–17543 Filed 7–10–03; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[OAR–2003–0081, FRL–7527–2]

Agency Information Collection Activities: Proposed Collection; Comment Request; Emission Reporting Requirements for Ozone SIP Revision Relating to Statewide Budgets for NO_X Emissions To Reduce the Regional Transport of Ozone, EPA ICR Number 1857.03, OMB Control Number 2060–0445

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*), this document announces that EPA is planning to submit a continuing Information Collection Request (ICR) to the Office of Management and Budget (OMB). This is a request to renew an existing approved collection. This ICR is scheduled to expire on 10/31/2003. Before submitting the ICR to OMB for review and approval, EPA is soliciting comments on specific aspects of the proposed information collection as described below.

DATES: Comments must be submitted on or before September 9, 2003.

ADDRESSES: Submit your comments, referencing docket ID number OAR–2003–0081, to EPA online using EDOCKET (our preferred method), by e-mail to *A-and-R-Docket@epa.gov,* or by mail to: EPA Docket Center, Environmental Protection Agency, Air Docket, Mail Code 6102T, Room B108, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

FOR FURTHER INFORMATION CONTACT: William L. Johnson, Air Quality Strategies and Standards Division, Ozone Policy Strategies Group, C539–02, Environmental Protection Agency, Research Triangle Park, North Carolina 27711; telephone number: (919) 541–5245; fax number: (919) 541–0824; e-mail address: *Johnson.WilliamL@epa.gov.*

SUPPLEMENTARY INFORMATION: The EPA has established a public docket for this ICR under Docket ID number OAR–2003–0081, which is available for public viewing at the Air Docket in the EPA Docket Center (EPA/DC), EPA West, Room B102, 1301 Constitution Ave., NW., Washington, DC 20460. The EPA Docket Center Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Reading Room is (202) 566–1744, and the telephone number for the Air Docket is (202) 566–1742. An electronic version of the public docket is available through EPA Dockets (EDOCKET) at *http://www.epa.gov/edocket.* Use EDOCKET to obtain a copy of the draft collection of information, submit or view public comments, access the index listing of the contents of the public docket, and to access those documents in the public docket that are available electronically. Once in the system, select ''search,'' then key in the docket ID number identified above.

Any comments related to this ICR should be submitted to EPA within 60 days of this notice. The EPA's policy is that public comments, whether submitted electronically or in paper, will be made available for public viewing in EDOCKET as EPA receives them and without change, unless the comment contains copyrighted material, CBI, or other information whose public disclosure is restricted by statute. When EPA identifies a comment containing copyrighted material, EPA will provide a reference to that material in the version of the comment that is placed in EDOCKET. The entire printed comment, including the coyrighted material, will be available in the public docket. Although identified as an item in the official docket, information claimed as CBI, or whose disclosure is otherwise restricted by statute, is not included in the official public docket, and will not be available for public viewing in EDOCKET. For further information about the electronic docket, *see* EPA's **Federal Register** notice describing the electronic docket at 67 FR 38102 (May 31, 2002), or go to *http://www.epa.gov/edocket.*

Affected entities: Entities potentially affected by this action are States covered by the NO_X SIP call and industries in those States which are large emitters of NO_X. This includes large electrical generating units or power plants and large boilers as well as possibly cement kilns.

Title: Emission Reporting Requirements for Ozone SIP Revision Relating to Statewide Budgets for NO_X Emissions to Reduce the Regional Transport of Ozone.

Abstract: States which are subject to the NO_X SIP call are required to collect data on NO_X emissions and submit this data to EPA. Data from large NO_X sources which States are requiring to be controlled to meet the State NO_X budget must be reported annually for the ozone season. States must report NO_X emissions from all sources triennially. In order to report this data, States must require large sources of NO_X emissions

to monitor emissions and report emissions to the State or to EPA. Resources must be expended by sources to install and calibrate emission monitors and to collect and report emissions data. This data is necessary to allow EPA to assess the ability of States to meet their NO_X budgets allocated under the NO_X SIP call. The data submission is not voluntary. It is required under 40 CFR 51.122. All emissions data received by EPA will be treated as public information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations are listed in 40 CFR part 9.

The EPA would like to solicit comments to:

(i) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(ii) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

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

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

Burden Statement: The total average annual reporting burden of this information collection is $54,097,149 and 492,192 hours. The annualized capital cost is $16,136,170. The annualized operating and maintenance cost is $12,606,505. These costs are mostly for installing and maintaining continuous emission monitors at industrial facilities including large electrical generating power plants. The average burden hour per response is estimated to be 142 hours. The frequency of response is annually or quarterly for large NO_X sources participating in a Federally approved NO_X trading program. The number of respondents is estimated to be 2,467 including States and industrial sources. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources, complete and review the collection of information; and transmit or otherwise disclose the information.

Dated: June 25, 2003.

Henry C. Thomas, Jr.,

Acting Director, Office of Air Quality Planning and Standards.

[FR Doc. 03–17612 Filed 7–10–03; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[ER–FRL–6641–9]

Environmental Impact Statements and Regulations; Availability of EPA Comments

Availability of EPA comments prepared pursuant to the Environmental Review Process (ERP), under section 309 of the Clean Air Act and section 102(2)(c) of the National Environmental Policy Act as amended. Requests for copies of EPA comments can be directed to the Office of Federal Activities at (202) 564–7167. An explanation of the ratings assigned to draft environmental impact statements (EISs) was published in FR dated April 04, 2003 (68 FR 16511).

Draft EISs

ERP No. D–AFS–J36053–UT Rating EC2, Monticello and Blanding Municipal Watershed Improvement Projects, Implementation, Manti-La Sal National Forest, Monticello Ranger District, San Juan County, UT.

Summary: EPA expressed environmental concerns with the loss of wetlands and impacts from logging. EPA supports replacing the failing water collection system in this watershed and will be providing grant funding for this project.

ERP No. D–AFS–L65420–AK Rating EC2, Greens Creek Tailings Disposal Project, Additional Dry Tailings Disposal Storage Facilities Construction, Authorization, Admiralty National Park Monument, Tongass National Forest, AK.

Summary: EPA expressed environmental concerns about the preferred alternative given uncertainty with achieving water quality standards for sulfate and selenium, lack of water quality data for 8 parameters, inconsistent use of standards and NPDES effluent limits, and use and effectiveness of carbon to effectively immobilize dissolved metals. The final EIS should disclose more commitments to using the existing treatment plant, and describe the methodology for meeting water quality standards.

ERP No. D–AFS–L65421–WA Rating EC2, 49 Degrees North Mountain Resort Revised Master Development Plan, Implementation, Colville National Forest, Newport Ranger District, Stevens County, WA.

Summary: EPA has environmental concerns regarding the Purpose and Need of the project and recommended an additional alternative that does not require additional ski terrain and the need for alternatives with Comfortable Carrying Capacities that exceed the proposed parking capacity should be provided. The final EIS should disclose information on consultation with Native American Tribes.

ERP No. D–BLM–J65376–CO Rating LO, Gunnison Gorge National Conservation Area Resource Management Plan, Implementation, Montrose and Delta Counties, CO.

Summary: EPA expressed lack of objections.

ERP No. D–BLM–K65251–CA Rating EC2, Santa Rosa and San Jacinto Mountains National Monument Management Plan, Implementation, Public Lands Management, Riverside County, CA.

Summary: EPA expressed environmental concerns with the following issues and requested clarification regarding the preferred alternative, tribal consultation, mitigation for impacts to recreation, implementation schedule and funding, land exchanges, acquisition strategy, existing conditions, Section 7 Endangered Species Act consultation and water resources.

ERP No. D–BLM–L67043–ID Rating EC2, North Rasmussen Ridge Mine, Agrium Conda Phosphate Operations, Proposal to Extend the Existing Mining Operations, Federal Phosphate Leases I–04375 and I–07619 within the Caribou-Targhee National Forest, and State Lease I–9313, Soda Springs, Caribou County, ID.

Summary: EPA expressed environmental concerns with habitat loss from mining activities, sedimentation and selenium contamination of water resources and uptake by wildlife. The draft EIS used extensive modeling to predict possible pathways of contaminants and size of

plume but analysis relied heavily on lab experimentation given lack of actual field data. Field verification of modeled results should be included in the final EIS as well as more detail on the placement of monitoring wells.

ERP No. D–COE–E39061–MS Rating LO, Royal D'Iberville Hotel and Casino Development Project, Construction and Operation, U.S. Army COE Section 10 and 404 and NPDES Permits Issuance, City of D'Iberville on the Back Bay, Mississippi, Gulf Coast, Harrison County, MS.

Summary: EPA has no significant environmental concerns regarding construction of this casino/hotel complex.

ERP No. D–COE–G35022–TX Rating LO, Gulf Intracoastal Waterway in the Laguna Madre, Maintenance Dredging from the JFK Causeway to the Old Queen Isabella Causeway, Nueces, Kleberg, Kennedy, Willacy and Cameron County, TX.

Summary: EPA has no objections to the selection of the preferred alternative with implementation of the mitigation measures as described in the DEIS.

ERP No. D–COE–K39078–CA Rating LO, Napa River Salt Marsh Restoration Project, Salinity Reduction and Habitat Restoration in the Napa River Unit, San Pablo Bay, Napa and Solano Counties, CA.

Summary: EPA supports the objectives of the proposed project to restore salt marsh and managed pond habitat analyzed in the Napa River Salt Marsh Restoration DEIS. EPA has no objections to the proposed project, but requested clarification on the need for a National Pollutant Discharge Elimination System permit.

ERP No. D–FHW J40160 UT Rating EC2, Southern Corridor Construction, I–15 at Reference Post 2 in St. George to UT–9 near Hurricane, Funding, Right-of-Way Grant and U.S. Army COE Section 404 Permit Issuance, St. George, Washington and Hurricane, Washington County, UT.

Summary: EPA has environmental concerns about the lack of appropriate analysis for a BLM right-of-way, mitigation for habitat fragmentation, the lack of a comparative analysis for potential interchanges on the highway, and no indirect and cumulative impacts they may have. EPA also recommends additional mitigation for air quality impacts from construction activities and additional mitigation for water quality impacts.

ERP No. D–FHW–L40218–WA Rating EC2, I–90 Two-Way Transit and HOV Operation Project, Provision of Reliable Transportation between Seattle and Bellevue, Sound Transit Regional Express, U.S. Coast Guard and U.S. Army COE Nationwide Permits Issuance, King County, WA.

Summary: While supporting the goals of the project, EPA has environmental concerns about the potential risk of cumulative impacts and induced growth in eastern King County, resulting from the proposed project. EPA also has concerns about user safety, and recommends more of an emphasis on transportation demand and safety management measures.

ERP No. D–NPS–D61056–DC Rating LO, Rock Creek Park and the Rock Creek and Potomac Parkway Project, General Management Plan, Implementation, Washington, DC.

Summary: EPA expressed no objection to the proposed action.

However, we requested clarifying information on motorist and visitor safety related to road improvements, including Beach Drive weekday closing and mid-afternoon reopening to motorists and more detail on the implementation plans to protect federally protected species and historic resources in the final EIS.

ERP No. D–NPS–K65253–CA Rating LO, Whiskeytown Fire Management Plan, Implementation, Whiskeytown National Recreation Area, Klamath Mountains, Shasta County, CA.

Summary: EPA believes that the mitigation measures proposed for smoke impacts are adequate, therefore EPA has no objection to the action as proposed.

ERP No. D–NPS–L61225–AK Rating EC2, Denali National Park and Preserve Backcountry Management Plan and General Management Plan Amendment, Implementation, AK.

Summary: EPA expressed environmental concerns about potential impacts of expanded snowmobile use under the revised plan to aquatic resources, streams, wetlands, soil, vegetation and wildlife. The final EIS should address concerns with recreational snowmobile use and Plan consistency with the Alaska National Interest Lands Conservation Act and the Wilderness Act.

ERP No. D–NRS–E36181–TN Rating LO, Cane Creek Watershed Remedial Plan, Widening and Degradation of the Cane Creek Channel, Lauderdale County, TN.

Summary: EPA has no significant environmental concerns regarding construction of the remedial structural and non-structural features as documented.

ERP No. D–NSA–G81012–NM Rating LO, Chemistry and Metallurgy Research Building Replacement Project, Consolidation and Relocation, Los Alamos National Laboratory, Los Alamos County, NM.

Summary: EPA has no objection to the selection of the preferred alternative and mitigation measures as proposed in the DEIS.

ERP No. DS–AFS–L65357–ID Rating EC2, East Beaver and Miner's Creek Timber Sale and Prescribed Burning Project, Timber Harvesting to Provide Forest Products, Implementation, Dubois Ranger District, Caribou-Targee National Forest, Clark County, ID.

Summary: EPA expressed environmental concerns related to cumulative impacts from grazing on water quality and adverse impacts to fish and their habitat. The final EIS should further address how the purpose and need and management direction is tied to achieving the desired future condition, the status of road decommissioning in the project area and impacts to tribes, as well as information on tribal consultation.

ERP No. DS–BLM–J65325–WY Rating EC2, Jack Morrow Hills Coordinated Activity Plan/Draft Green River Resource Management Plan Amendment, Updated Information, Rock Springs, Portion of Sweetwater, Fremont and Subelette Counties, WY.

Summary: EPA continued to express environmental concerns that the preferred alternative may cause adverse impacts to wildlife and their habitat for the Greater Sage-Grouse, and deer and elk herds. More detail is needed in the adaptive management plan.

ERP No. D1–FHW–L40184–WA Rating EO2, WA–167 Freeway Project, WA–161 (Meridian Street North) in the City of Puyallup to the WA–509 Freeway in the City of Tacoma, Funding, U.S. Coast Guard, NPDES and U.S. Army COE Section 10 and 404 Permits Issuance, Cities of Puyallup, Fife, Edgewood, Milton, and Tacoma, Pierce County, WA.

Summary: EPA has environmental objections to the proposed project's potential direct, secondary, and cumulative impacts to aquatic resources (wetlands, groundwater, surface water, and overall hydrological function and connectivity). The quality, quantity and overall effectiveness of mitigative actions should be improved with more analysis and application of the information to target actions. EPA has further objections regarding effects to threatened fish species, the Puyallup Tribe, air toxins, prime farmland, noise impacts, and lack of transportation demand management measures and facilities.

Final EISs

ERP No. F–AFS–F65030–IL Natural Area Trails Project, Construction, Reconstruction, Maintenance and Designation of Trails for Hikers and Equestrian Use, Approval of Site-Specific Mitigation and/or Monitoring Standards, Shawnee National Forest, Jackson, Pope, Johnson, Union, Hardin and Saline Counties, IL.

Summary: EPA has no objections to the proposed repair, relocation and establishment of trails in the Shawnee National Forest which are intended to reduce erosion and exotic plant introductions while providing a quality recreational experience for equestrian users and hikers.

ERP No. F–AFS–L65406–ID North Kennedy-Cottonwood Stewardship Project, Existing Transportation System Modifications and Forest Health Improvements through Vegetation Management both Commercial and Non-Commercial Methods, Boise National Forest, Emmett Ranger District, Gem and Valley Counties, ID.

Summary: EPA expressed environmental concerns with the level of restoration of degraded riparian areas, lack of differentiation between action alternatives and analysis of impacts. More details should be included in the final EIS on the selection of the preferred alternative.

ERP No. F–AFS–L67044–ID Golden Hand No. 3 and No. 4 Lode Mining Claims Plan of Operations Approval, Implementation, Frank Church-River of No Return (FC–RONR) Wilderness, Payette National Forest, Krassel Ranger District, Valley County, ID.

Summary: No formal comment letter was sent to the preparing agency.

ERP No. F–BLM–K81027–NV Nevada Test and Training Range Resource Management Plan, (formerly known as the Nellis Air Force Range (NAFR)), Implementation, Clark, Nye and Lincoln Counties, NV.

Summary: No formal comment letter was sent to the preparing agency.

ERP No. F–COE–G01015–TX Three Oaks Mine Project, Construction and Operation of a Surface Lignite Mine, U.S. Army COE Section 404 Permit Issuance, Lee and Bastrop Counties, TX.

Summary: EPA has no objections to the selection of the preferred alternative.

ERP No. F–FHW–C40144–NY US 219 between Springville to Salamanca Improvements from NY–39 to NY–17, Funding and US Army COE Section 404 Permit Issuance, Erie and Cattaraugus Counties, NY.

Summary: EPA has environmental objections to the selection of the freeway alternative as the preferred alternative. This alternative has greater impacts to wetlands and farmlands, as well as impacts from induced development, when compared to the upgrade alternative.

ERP No. F–FHW–L53003–WA Vancouver Rail Project, Rail Improvements at the Burlington Northern and Santa Fe Rail Yard and Possible Elimination of the West 39th Street At-Grade Crossing, Funding and NPDES Permit Issuance, Clark County, WA.

Summary: The final EIS adequately discloses the impacts and satisfactorily responded to most of EPA's previous comments on the draft EIS. In addition, EPA is pleased that the final EIS positively addressed issues of safety and accessibility. Therefore, EPA has no objection to the action as proposed.

ERP No. F–GSA–F11037–WI Badger Army Ammunition Plant, Property Disposal, Implementation, Townships of Sumpter and Merrimac, Sauk County, WI.

Summary: EPA has environmental concerns and requested that open burning, as a means of demolition of structures, be addressed before the property is transferred.

ERP No. F–TVA–E29001–TN Rarity Pointe Commercial Recreation and Residential Development on Tellico Reservoir Project, Request for TVA's Land and Approval of Water Use Facilities, Tellico Reservoir, Loudon County, TN.

Summary: EPA continues to express environmental concern regarding water quality impacts and requested specific commitments to mitigation measures in the ROD.

ERP No. FB–AFS–L65137–AK Tongass Land Management Plan Revision for Roadless Area Evaluation for Wilderness Recommendations, Implementation, Tongass National Forest, AK.

Summary: No formal comment letter was sent to the preparing agency.

ERP No. FS–COE–G36148–TX Dallas Floodway Extension, Flood Damage Reduction and Environmental Restoration, New Information concerning Additional Formulation, Trinity River Basin, Dallas County, TX.

Summary: EPA has no objection to the selection of the preferred alternative.

ERP No. FS–NPS–J61102–00 Yellowstone and Grand Teton National Parks and John D. Rockefeller, Jr., Memorial Parkway, Winter Use Plans, Updated and New Information on New Generation of Snowmobiles that Produce fewer Emissions and are Quieter, Fremont County, ID; Gallatin and Park Counties, MT and Park and Teton Counties, WY.

Summary: EPA continued to express environmental objections given the final supplemental EIS predicts the preferred alternative will result in localized visibility impairment and adverse human health effects in this Class 1 airshed. Additional mitigation to avoid these impacts should be considered along with an ongoing rule making process.

Dated: July 8, 2003.

Joseph C. Montgomery,

Director, NEPA Compliance Division, Office of Federal Activities.

[FR Doc. 03–17620 Filed 7–10–03; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[ER–FRL–6641–8]

Environmental Impact Statements; Notice of Availability

Responsible Agency: Office of Federal Activities, General Information (202) 564–7167 or *http://www.epa.gov/compliance/nepa/.* Weekly receipt of Environmental Impact Statements Filed June 30, 2003 Through July 3, 2003 Pursuant to 40 CFR 1506.9.

EIS No. 030304, Draft EIS, AFS, AL, Forest Health and Restoration Project, Proposal to Determine the Desired Future Conditions of all Existing Loblolly Pine Stands, National Forests in Alabama, Bankhead National Forest, Winston, Lawrence and Franklin Counties, AL, Comment Period Ends: August 25, 2003, Contact: John W. Creed (205) 489–5111.

EIS No. 030305, Draft EIS, AFS, ID, Twin Creek Timber Sale Project, Proposal to Cut and Remove Lodgepole Pine Sawtimber, Road Construction/Reconstruction, Montpelier Ranger District, Caribou National Forest, US Corps of Engineers Permit, Bear Lake County, ID, Comment Period Ends: August 25, 2003, Contact: Eric Mattson (208) 847–0375.

EIS No. 030306, Draft EIS, USA, Programmatic EIS—Army Transformation of the 172nd Infantry Brigade (Separate) to a Stryker Brigade Combat Team (SBCT), Forts Wainwright and Richardson, AK, Comment Period Ends: September 9, 2003, Contact: Kevin Gardner (907) 384–3003.

EIS No. 030307, Final Supplement, FHW, VA, U.S. Route 29 Bypass Improvement, between Route 250 Bypass in Charlottesville and the South Rivanna River in Albemarle,

Updated Information, To Consider the Effects of the Selected Alternative on the South Fork Rivanna River Reservoir and its Watershed, U.S. COE Section 404 Permit, Albemarle County, VA, Wait Period Ends: August 11, 2003, Contact: Edward S. Sundra (804) 775–3338.

EIS No. 030308, Final EIS, FHW, PA, NJ, Pennsylvania Turnpike/Interstate 95 Interchange Project, Pennsylvania Turnpike (I–276) and I–95 in Buck County, PA Connection with Proposed Interstate Improvements Extending east into Burlington County, NJ, Wait Period Ends: August 15, 2003, Contact: James A. Cheatham (717) 221–3461.

EIS No. 030309, Draft Supplement, FAA, CA, Los Angeles International Airport Proposed Master Plan Improvements, New Alternative, Enhanced Safety and Security Plan, Los Angeles County, CA, Comment Period Ends: August 25, 2003, Contact: David Kessler (310) 725–3615.

EIS No. 030310, Draft EIS, FHW, TX, TX–45 Highway Southeast Study, from Interstate Highway (IH) 35 south at Farm-to-Market (FM)1327 to TX–130/US 183, Proposal to Enhance the Local, Regional, and National Transportation Systems, Right-of-Way Permit, Travis County, TX, Comment Period Ends: August 25, 2003, Contact: Patrick Bauer (512) 536–5950.

EIS No. 030311, Final Supplement, AFS, MT, Threemile Stewardship Project, Additional Information concerning the Potential Effects on the Goshawk Habitat, Ashland Ranger District, Custer National Forest, Powder and Rosebud Counties, MT, Wait Period Ends: August 11, 2003, Contact: Elizabeth McFarland (406) 784–2344.

EIS No. 030312, Draft EIS, IBW, TX, Lower Rio Grande Flood Control Project, Addresses the Impacts of Alternative Vegetation Maintenance Practices, Located in the United States portions of the Rio Grande, Cameron, Hidalgo and Willacy Counties, TX, Comment Period Ends: August 29, 2003, Contact: Douglas Echlin (915) 832–4741.

EIS No. 030313, Draft EIS, NPS, NY, NJ, Ellis Island and Statue of Liberty National Monument Development Concept Plan, Long-Term Rehabilitation and Reuse for Historic Buildings, Implementation, New York Harbor, NY and NJ, Comment Period Ends: September 12, 2003, Contact: Gwen Wilder (202) 208–3891. This document is available on the Internet at: *http://www.nps.gov/elis.*

EIS No. 030314, Draft EIS, NPS, WI, Apostle Islands National Lakeshore Wilderness Study, Wilderness Designation or Nondesignation, Ashland and Bayfield Counties, WI, Comment Period Ends: October 9, 2003, Contact: Robert Krumenaker (715) 779–3397. This document is available on the Internet at: *http://www.nps.gov/apis/wstudy.htm.*

EIS No. 030315, Final EIS, COE, CO, Rueter-Hess Reservoir Project, Construction and Operation, Proposed Water Supply Reservoir and Off-Stream Dam, U.S. COE Section 404 Permit, Endangered Species Act (Section &) and Right-of-Way Use Permit, Located on Newlin Gulch along Cherry Creek, Town of Parker, Douglas County, CO, Wait Period Ends: August 11, 2003, Contact: Rodney J. Schwartz (402) 221–4143.

EIS No. 030316, Final EIS, DOD, CA, AS, AK, HI, WA, Ground-Based Midcourse Defense (GMD) Extended Test Range (ETR) Project, Proposal to Construct and Operate, Due: August 11, 2003, Contact: Julia Hudson-Elliott (256) 955–4822. This document is available on the Internet at: *http://www.acq.osd.mil/bmdo/bmdolink/html/bmdolink.html.*

Amended Notices

EIS No. 030301, Final EIS, UAF, CA, Los Angeles Air Force Base Land Conveyance, Construction and Development Project, Transfer Portions of Private Development in Exchange for Construction of New Seismically Stable Facilities, Cities of El Sequndo and Hawthorne, Los Angeles County, CA, Wait Period Ends: August 04, 2003, Contact: Jason Taylor (310) 363–0142. Revision of FR Notice Published on 7/3/2003:CEQ Comment Period Ending 8/18/2003 has been Corrected to CEQ Wait Period Ending 8/4/2003.

Dated: July 8, 2003.

Joseph C. Montgomery,

Director, NEPA Compliance Division, Office of Federal Activities.

[FR Doc. 03–17621 Filed 7–10–03; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–7525–7]

Good Neighbor Environmental Board Meeting

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of meeting.

SUMMARY: The next meeting of the Good Neighbor Environmental Board, a Federal advisory committee that reports to the President and Congress on environmental and infrastructure projects along the U.S. border with Mexico, will take place in Del Rio, Texas, on July 30 and 31, 2003. It is open to the public.

DATES: On July 30, the meeting will begin at 8:30 a.m. (registration at 8 a.m.) and end at 5:30 p.m. On July 31, the Board will hold a routine business meeting from 8 a.m. until 12 noon (registration at 7:30 a.m.).

ADDRESSES: The meeting site is the Kennedy Room of the City of Del Rio Civic Center, 1915 Veterans Boulevard, Del Rio, Texas.

FOR FURTHER INFORMATION CONTACT: Elaine M. Koerner, Designated Federal Officer for the Good Neighbor Environmental Board, U.S. Environmental Protection Agency Region 9 Office, 75 Hawthorne St., San Francisco, California, 94105. Tel: (415) 972–3437; E-mail: *koerner.elaine@epa.gov.*

SUPPLEMENTARY INFORMATION:

Meeting Access: Individuals requiring special accommodation at this meeting, including wheelchair access to the conference room, should contact the Designated Federal Officer at least five business days prior to the meeting so that appropriate arrangements can be made.

Agenda: On the morning of July 30, the first day of the meeting, guest speakers will discuss the meeting theme of ''Economy and Environment'' as it relates to different sectors and local issues. The morning session will begin at 8:30 a.m. and conclude with a public comment session from 12–12:30 p.m. For this session, the Board invites comments on a wide range of issues, including the topic for its upcoming Seventh Report: Links between children's health in the border region and the region's environmental infrastructure.

During the afternoon of July 30, beginning at 2 p.m., guest speakers will continue to address the meeting theme until 4:30 p.m. From 4:30–5:30 p.m., Board members will report out on recent activities within their organizations. The first day of the meeting will conclude at 5:30 p.m.

The second day of the meeting, July 31, will begin at 8 a.m. and conclude at noon. The format will be a routine business meeting, with agenda items including approval of minutes, planning for upcoming meetings, and status of reports.

Public Attendance: The public is welcome to attend all portions of the meeting. Members of the public who plan to file written statements and/or make brief (suggested 5-minute limit) oral statements at the public comment session are encouraged to contact the Designated Federal Officer for the Board prior to the meeting.

Background: The Good Neighbor Environmental Board meets three times each calendar year at different locations along the U.S.-Mexico border and also holds an annual strategic planning session. It was created by the Enterprise for the Americans Initiative Act of 1992. An Executive Order delegates implementing authority to the Administrator of EPA. The Board is responsible for providing advice to the President and the Congress on environmental and infrastructure issues and needs within the States contiguous to Mexico in order to improve the quality of life of persons residing on the United States side of the border. The statute calls for the Board to have representatives from U.S. Government agencies; the governments of the States of Arizona, California, New Mexico and Texas; and private organizations with expertise on environmental and infrastructure problems along the southwest border. The U.S. Environmental Protection Agency gives notice of this meeting of the Good Neighbor Environmental Board pursuant to the Federal Advisory Committee Act (Pub. L. 92–463).

Dated: June 25, 2003.

Oscar Carrillo,

Acting Designated Federal Officer.

[FR Doc. 03–17613 Filed 7–10–03; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[OPP–2003–0158; FRL–7312–3]

Certain Pesticides; Completion of Comment Period for Reregistration Eligibility Decision and Tolerance Reassessment Decision Documents

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces the closure of benomyl, butylate, chlorothalonil, oxadixyl, primisulfuron-methyl, and vinclozolin reregistration elegibility decisions (REDs) and tolerance reassessment decisions (TREDs). EPA developed these reregistration decisions pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and tolerance reassessments under the Federal Food, Drug, and Cosmetic Act (FFDCA).

FOR FURTHER INFORMATION CONTACT: Technical questions on the RED and TRED documents should be directed to the appropriate Chemical Review Managers listed in Unit II.A.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

This notice is directed to the public in general. As such, 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 information in this notice, contact the appropriate chemical review manager listed in the table inUnit II.A.

B. How Can I Get Copies of this Document and Other Related Information?

1. *Docket.* EPA has established an official public docket for this action under docket identification (ID) number OPP–2003–0158. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

2. *Electronic access.* The appropriate RED and TRED documents can be reviewed by utilizing the www.epa.gov/pesticides site. The site will provide background information for the chemicals listed in the table. Technical questions can be directed to the chemical review manager. An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at http://www.epa.gov/edocket/ to view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B.1. Once in the system, select ''search,'' then key in the appropriate docket ID number.

II. Background

A. What Action is the Agency Taking?

During fiscal years 1998–2002, EPA published Notices in the **Federal Register** announcing the availability of RED and TRED documents for a number of pesticides concluding reregistration and tolerance reassessments. This notice constitutes and announces the closing of the comment periods for the pesticides listed below. Thirty and 60–day comment periods have closed for each chemical. Because EPA did not receive any significant adverse comments, the Agency considers the RED and TRED for the pesticides as final decisions and hereby closed.

Chemical Name	Chemical Review Manager	Case Number	RED/TRED Date
Benomyl	Demson Fuller (703) 308–8062	0119	July 2002 Voluntary Cancellation August 2001
Butylate	Gary Mullins (703) 308–8044	0071	September 2001
Chlorothalonil	Jill Bloom (703) 308–8019	0097	September 1998

Chemical Name	Chemical Review Manager	Case Number	RED/TRED Date
Oxadixyl	John Pates (703) 308–8195	AI126701	September 2001
Primisulfuron-methyl	Christina Scheltema (703) 308–2201	AI128973	July 2002
Vinclozolin	Demson Fuller (703) 308–8062	2740	October 2000

B. What is the Agency's Authority for Taking this Action?

The legal authority for this decision falls under FIFRA, as amended in 1988 and 1996. Section 4(g)(2) of FIFRA directs that, after submission of all data concerning a pesticide active ingredient, ''the Administrator shall determine whether pesticides containing such active ingredient are eligible for reregistration'' before calling in product-specific data on individual end-use products, and either registering products or taking other ''appropriate regulatory action.''

List of Subjects

Environmental protection

Dated: July 1, 2003.

Richard P. Keigwin Jr.,

Acting Director, Special Review and Reregistration Division, Office of Pesticide Programs.

[FR Doc. 03–17616 Filed 7–10–03; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[OPP–2003–0189; FRL–7310–2]

Diazinon; Notice of Requests to Voluntarily Cancel Certain Pesticide Products

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: In accordance with section 6(f)(1) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, EPA is issuing a notice of requests by Drexel Chemical Company and Makhteshim Chemical Works, Ltd. to voluntarily cancel the registrations for all of their outdoor non-agricultural manufacturing-use products containing diazinon and a request by Walla Walla Environmental, Inc. to cancel one of its outdoor non-agricultural end-use products containing diazinon [O,O-Diethyl O-(2-isopropyl-6-methyl-4-pyrimidinyl) phosphorothioate]. The EPA intends to grant these requests by issuing a cancellation order at the close of the comment period for this announcement, unless the Agency receives substantive comments within the comment period that would merit its further review of these requests. It is EPA's intent that the cancellation of the outdoor non-agricultural manufacturing-use products will be effective upon issuance of the cancellation order, after the comment period, and that the cancellation of the outdoor non-agricultural end-use product will be effective August 31, 2003. The Agency requests public comment on these voluntary cancellation requests, and is providing a 30–day comment period.

DATES: Comments on the requested registration cancellations must be submitted to the address provided below and identified by docket ID number OPP–2003–0189. Comments must be received on or before August 11, 2003.

FOR FURTHER INFORMATION CONTACT: Stephanie Plummer, Special Review and Reregistration Division (7508C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–0076; e-mail address: *plummer.stephanie@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

This action is directed to the public in general. Although this action may be of particular interest to persons who produce or use pesticides, 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 information in this notice, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Get Copies of this Document and Other Related Information?

1. *Docket*. EPA has established an official public docket for this action under docket identification (ID) number OPP–2003–0189. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The EPA also established two dockets containing documents in support of the diazinon IRED. They are dockets OPP–34225 and OPP–2002–0251. The official public docket is the collection of materials that is available for public viewing at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

2. *Electronic access*. You may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr/*.

An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at *http://www.epa.gov/edocket/* to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B.1. Once in the system, select ''search,'' then key in the appropriate docket ID number.

II. What Action is the Agency Taking?

This notice announces requests made by Drexel Chemical Co. and Makhteshim Chemical Works, Ltd. to voluntarily cancel registrations for all of their outdoor non-agricultural manufacturing-use products containing diazinon and a request by Walla Walla Environmental, Inc. to cancel one of its outdoor non-agricultural end-use products containing diazinon. These registrations are listed in sequence by

registration number in Table 1 of this unit.

A. Background Information

Diazinon is an organophosphorous insecticide and is one of the most widely used insecticides in the U.S. It is used for outdoor non-agricultural, as well as agricultural, pest control.

Under the December 5, 2000 MOA between the technical registrants of diazinon and the EPA, as well as a February 14, 2001 letter from Drexel Chemical Co., both Makhteshim Chemical Works, Ltd. and Drexel Chemical Co. requested, under FIFRA section 6(f), that EPA cancel, effective as of June 30, 2003, the registrations of all diazinon manufacturing-use products permitting formulation for outdoor non-agricultural use. In a June 5, 2003 letter, Walla Walla Environmental, Inc. requested, under FIFRA section 6(f), that EPA cancel, effective August 31, 2003, the registration of one outdoor non-agricultural end-use product. EPA intends to grant these requests by issuing a cancellation order at the close of the comment period for this announcement, unless the Agency receives substantive comments within the comment period that would merit its further review of these requests.

The Reregistration Eligibilty Decision (RED) document summarizes the findings of EPA's reregistration process for individual chemical cases, and reflects the Agency's decision on risk assessment and risk management for uses of individual pesticides. Diazinon belongs to a group of pesticides known as organophosphates (OPs). EPA has issued the Interim RED assessing the risks of exposure from diazinon.

B. Requests for Voluntary Cancellation

Under section 6(f)(1)(A) of FIFRA, registrants may request, at any time, that their pesticide registrations be canceled or amended to terminate one or more pesticide uses. Section 6(f)(1)(B) of FIFRA requires that before acting on a request for voluntary cancellation, EPA must provide a 30–day public comment period on the request for voluntary cancellation. 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. Makhteshim Chemical Works, Ltd., Drexel Chemical Co., and Walla Walla Environmental, Inc. have requested a waiver of the comment period. The EPA will therefore apply a 30–day comment period.

TABLE 1.—REGISTRATIONS WITH PENDING REQUESTS FOR CANCELLATION

Registration No.	Product name	Chemical name
11678–62	Diazol Diazinon Technical Stabilized HG	Diazinon
11678–64	Diazol Diazinon Stabilized Oil Concentrate HG	Diazinon
19713–524	Drexel Diazinon Technical HG	Diazinon
47332–4	CPF-2D Insecticide	Diazinon

Unless the Agency determines that there are substantive comments that warrant further review of these requests, an order will be issued canceling all of these registrations.

Table 2 of this unit includes the names and addresses of record for all registrants of the products in Table 1 of this unit, in sequence by EPA company number:

TABLE 2.—REGISTRANTS REQUESTING VOLUNTARY CANCELLATION

EPA Company No.	Company name and address
11678	Makhteshim Chemical Works, Ltd. 551 Fifth Avenue, Suite 1100 New York, NY 10176
19713	Drexel Chemical Co., 1700 Channel Avenue P.O. Box 13327 Memphis, TN 38113
47332	Walla Walla Environmental, Inc., P.O. Box 1298, Walla Walla, WA 99362

III. What is the Agency's Authority for Taking this Action?

Section 6(f)(1) of FIFRA provides that a registrant of a pesticide product may at any time request that any of its pesticide registrations be canceled. FIFRA further provides that, before acting on the request, EPA must publish a notice of receipt of any such request in the **Federal Register**. Thereafter, the Administrator may approve such a request.

IV. Provisions for Disposition of Existing Stocks

The Agency intends to issue a cancellation order following consideration of all comments received during the comment period, unless the comments warrant further review of this request.

Existing stocks are those stocks of registered pesticide products which are currently in the United States and which have been packaged, labeled, and released for shipment prior to the effective date of the cancellation action. In a 2000 MOA between the EPA and the technical registrants of diazinon, the involved parties agreed to the following existing stocks provisions for outdoor non-agricultural manufacturing-use and end-use products:

A. Outdoor Non-Agricultural Manufacturing-Use Products

1. *Distribution or sale.* The distribution or sale of existing stocks of any outdoor non-agricultural manufacturing-use product referenced in this Notice (EPA Reg. No. 11678–62, 11678–64, and 19713–524) will not be lawful after the effective cancellation date, except for the purposes of export consistent with FIFRA section 17 and proper disposal in accordance with applicable law.

2. *Use for producing other products.* The use of existing stocks of any manufacturing- use product referenced in this Notice for formulation into any other product labeled for outdoor non-agricultural use will not be lawful under FIFRA after the effective date of the cancellation order.

The effective date of the cancellation order is intended to be immediate for the products listed in Table 1; however, EPA will consider any comments received within 30 days of publication of this Notice in the **Federal Register** prior to canceling the affected registrations.

B. Outdoor Non-Agricultural End-Use Products

1. *Distribution or sale by Registrant.* The distribution, sale, or use of existing stocks by Walla Walla Environmental, Inc. of the end-use product referenced in this Notice (EPA Reg. No. 47332–4)will not be lawful under FIFRA after August 31, 2003, except for purposes of shipping such stocks for export consistent with the requirements of FIFRA section 17 or proper disposal in accordance with applicable law.

2. *Retail and other distribution or sale.* The distribution or sale of existing stocks by persons other than Walla Walla Environmental, Inc. will be

prohibited after December 31, 2004, except for purposes of product recovery pursuant to the 2000 MOA, shipping such stocks for export consistent with the requirements of FIFRA section 17, or proper disposal in accordance with applicable law.

3. *Use of existing stocks*. Use of existing stocks may continue until stocks are exhausted. Any such use must be in accordance with the label.

List of Subjects

Environmental protection, Pesticides and pests.

Dated: June 25, 2003.

Richard P. Keigwin, Jr.,

Director, Special Review and Reregistration Division, Office of Pesticide Programs.

[FR Doc. 03–17512 Filed 7–10–03; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[OPP–2003–0183; FRL–7315–5]

Notice of Receipt of Requests to Voluntarily Cancel Certain Pesticide Registrations

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: In accordance with section 6(f)(1) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, EPA is issuing a notice of receipt of requests by Sumitomo Chemical Company, Limited and Bayer Environmental Science to voluntarily cancel the registrations for all of their products containing 4-chloro-alpha-(1-methylethyl)benzeneacetic acid, cyano(3-phenoxyphenyl)methyl ester (fenvalerate). At the close of the comment period, EPA intends to issue an order granting these cancellation requests, unless the Agency receives substantive comments within the comment period that would merit its further review of these requests, or the requests have been withdrawn.

DATES: Comments must be received by August 11, 2003. Unless the Agency receives any substantive comments within the comment period that would merit its further review of these requests, or the requests have been withdrawn by August 11, 2003, EPA intends to issue orders canceling these registrations at the close of the comment period.

ADDRESSES: Comments may be submitted electronically, by mail, or through hand delivery/courier. 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 ID number OPP–2003–0183 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: Wilhelmena Livingston, Special Review and Reregistration Division (7508C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–8025, e-mail address: *livingston.wilhelmena@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

This action is directed to the public in general. Although this action may be of particular interest to persons who produce or use pesticides, 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 information in this notice, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Get Copies of this Document and Other Related Information?

1. *Docket*. EPA has established an official public docket for this action under docket identification (ID) number OPP–2003–0183. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

2. *Electronic access*. You may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr/*.

An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at *http://www.epa.gov/edocket/* . You may use EPA docket to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B.1. Once in the system, select ''search,'' then key in the appropriate docket ID number.

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 ID number OPP–2003–0183 in the subject line on the first page of your response.

1. *By mail*. Submit your comments to: Public Information and Records Integrity Branch (PIRIB), Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.

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 Hwy., 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 describe 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 ID number OPP–2003–0183. Electronic comments also may 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 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 **FOR FURTHER INFORMATION CONTACT**.

II. What Action is the Agency Taking?

This notice announces receipt by the Agency of requests from Sumitomo Chemical Company, Limited and Bayer Environmental Science to cancel the registrations of three pesticide products registered under section 3 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). These three registrations constitute all registrations held by Sumitomo Chemical Company, Limited and Bayer Environmental Science of products containing 4-chloro-alpha-(1-methylethyl)benzeneacetic acid, cyano(3-phenoxyphenyl)methyl ester (fenvalerate). These requests are submitted pursuant to section 6(f) of FIFRA.

Fenvalerate is a synthetic pyrethroid insecticide which is used to control insects and related organisms, molluscs, fouling organisms and miscellaneous invertebrates on agricultural, pet care, domestic home and garden (domestic), and commercial/industrial/food and non-food/mosquito abatement (commercial) sites. On April 10, 2003, Sumitomo Chemical Company, Limited and on April 22, 2003, Bayer Environmental Science requested that EPA waive the 180–day period that typically has been allowed before requests for voluntary cancellation are approved or denied.

These registrations are listed in sequence by registration number in Table 1 of this unit:

TABLE 1.—REGISTRATIONS WITH PENDING REQUESTS FOR CANCELLATION

Registration No.	Product Name	Chemical Name
432–766	Technical Fenvalerate Insecticide	Fenvalerate
432–767	Gold Crest TributeTermiticide/Insecticide	Fenvalerate
10308–13	Technical Sumicidin Insecticide	Fenvalerate

At the close of the comment period, EPA intends to issue an order granting these cancellation requests, unless the Agency receives any substantive comments within the comment period that would merit its further review of these requests, or the requests have been withdrawn. Users of these pesticides or anyone else desiring the retention of a registration should send in their comments to EPA. In addition, they may wish to contact the applicable registrant directly.

Table 2 of this unit includes the names and addresses of record for all registrants of the products in Table 1 of this unit, in sequence by EPA company number:

TABLE 2.— REGISTRANTS REQUESTING VOLUNTARY CANCELLATION

EPA Company No.	Company Name and Address
432	Bayer Environmental Science, 95 Chestnut Ridge Road, Montvale, NJ 07645
10308	Sumitomo Chemical Company, Limited, 5-33 Kitahama 4-Chome, Chuo-ku Osaka, 541, Japan

III. What is the Agency's Authority for Taking this Action?

Section 6(f)(1) of FIFRA provides that a registrant of a pesticide product may at any time request that any of its pesticide registrations be canceled. FIFRA further provides that, before acting on the request, EPA must publish a notice of receipt of any such request in the **Federal Register** and provide a 30–day period in which the public may comment before the Agency may act on the request for voluntary cancellation. In the case of minor agricultural uses, section 6(f)(1)(c) of FIFRA provides for a 180–day comment period under certain circumstances. In this case, Bayer Environmental Science, and Sumitomo Chemical Company, Limited have requested that EPA waive the 180–day comment period. Accordingly, pursuant to section 6(f)(1)(c)(ii) of FIFRA. EPA is waiving the 180–day comment period and will provide interested parties 30 days to comment on the action.

IV. Procedures for Withdrawal of Request

Registrants who choose to withdraw a request for cancellation must submit such withdrawal in writing to the person listed under **FOR FURTHER INFORMATION CONTACT**, postmarked before August 11, 2003. This written withdrawal of the request for cancellation will apply only to the applicable FIFRA section 6(f)(1) request listed in this notice. If the product(s) have been subject to a previous cancellation action, the effective date of cancellation and all other provisions of any earlier cancellation action are controlling. The withdrawal request must also include a commitment to pay any reregistration fees due, and to fulfill any applicable unsatisfied data requirements. Any person, including the registrant, who wishes to support the continued registration of fenvalerate, must fulfil all outstanding data gaps. In addition, EPA must find that fenvalerate is eligible for reregistration.

V. Provisions for Disposition of Existing Stocks

The effective date of cancellation will be the date of the cancellation order. The orders effecting these requested cancellations will generally permit a registrant to sell or distribute existing stocks for 1 year after the date the cancellation is requested. This policy is in accordance with the Agency's statement of policy as prescribed in the **Federal Register** of June 26, 1991 (56 FR 29362) (FRL–3846–4). Exceptions to this general rule will be made if a product poses a risk concern, or is in noncompliance with reregistration requirements, or is subject to a Data Call-In. In all cases, product-specific disposition dates will be given in the cancellation orders. In this case, the Agency does not see a need to deviate from the Existing Stocks Policy. Unless the Agency receives substantive comments during the comment period that would merit its further review of this matter, the Agency intends to permit the registrants to sell and distribute the existing stocks for 1 year

after the effective date of the cancellation. Although in its original voluntary cancellation letter, Bayer requested 18 months to address any remaining stocks, in subsequent communication with the Agency, Bayer accepted a 12–month period for sale and distribution of the existing stocks.

Existing stocks are those stocks of registered pesticide products which are currently in the United States and which have been packaged, labeled, and released for shipment prior to the effective date of the cancellation action. Unless the provisions of an earlier order apply, existing stocks already in the hands of dealers or users can be distributed, sold, or used legally until they are exhausted, provided that such further sale and use comply with the EPA-approved label and labeling of the affected product. Exception to these general rules will be made in specific cases when more stringent restrictions on sale, distribution, or use of the products or their ingredients have already been imposed, as in a Special Review action, or where the Agency has identified significant potential risk concerns associated with a particular chemical. In this case, the Agency does not see a need to deviate from these general rules. Unless the Agency receives substantive comments during the comment period that would merit further review of this matter, the Agency intends to permit existing stocks already in the hands of dealers or users to be distributed, sold, or used until they are exhausted, provided that such further sale and use comply with the EPA-approved label and labeling of the affected product.

List of Subjects

Environmental protection, Pesticides and pests.

Dated: June 30, 2003.

Richard P. Keigwin, Jr.,

Acting Director, Special Review and Reregistration Division, Office of Pesticide Programs.

[FR Doc. 03–17509 Filed 7–10–03; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[OPP–2003–0145; FRL–7314–8]

Fenpyroximate; Notice of Filing a Pesticide Petition to Establish a Tolerance for a Certain Pesticide Chemical in or on Food

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces the initial filing of a pesticide petition proposing the establishment of regulations for residues of a certain pesticide chemical in or on various food commodities.

DATES: Comments, identified by docket ID number OPP–2003–0145, must be received on or before August 11, 2003.

ADDRESSES: Comments may be submitted electronically, by mail, or through hand delivery/courier. Follow the detailed instructions as provided in Unit I. of the **SUPPLEMENTARY INFORMATION.**

FOR FURTHER INFORMATION CONTACT: Shaja R. Brothers, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–3194; e-mail address: *brothers.shaja@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to:

- Crop production (NAICS 111)
- Animal production (NAICS 112)
- Food manufacturing (NAICS 311)
- Pesticide manufacturing (NAICS 32532)

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT.**

B. How Can I Get Copies of this Document and Other Related Information?

1. *Docket.* EPA has established an official public docket for this action under docket identification ID number OPP–2003–0145. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

2. *Electronic access.* You may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr/*.

An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at *http://www.epa.gov/edocket/* to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B.1. Once in the system, select ''search,'' then key in the appropriate docket ID number.

Certain types of information will not be placed in the EPA Dockets. Information claimed as CBI and other information whose disclosure is restricted by statute, which is not included in the official public docket, will not be available for public viewing in EPA's electronic public docket. EPA's policy is that copyrighted material will not be placed in EPA's electronic public docket but will be available only in printed, paper form in the official public docket. To the extent feasible, publicly available docket materials will be made available in EPA's electronic public docket. When a document is selected from the index list in EPA Dockets, the system will identify whether the document is available for viewing in EPA's electronic public docket. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B. EPA intends to work towards providing electronic access to all of the publicly available docket materials through EPA's electronic public docket.

For public commenters, it is important to note that EPA's policy is that public comments, whether submitted electronically or in paper, will be made available for public

viewing in EPA's electronic public docket as EPA receives them and without change, unless the comment contains copyrighted material, CBI, or other information whose disclosure is restricted by statute. When EPA identifies a comment containing copyrighted material, EPA will provide a reference to that material in the version of the comment that is placed in EPA's electronic public docket. The entire printed comment, including the copyrighted material, will be available in the public docket.

Public comments submitted on computer disks that are mailed or delivered to the docket will be transferred to EPA's electronic public docket. Public comments that are mailed or delivered to the docket will be scanned and placed in EPA's electronic public docket. Where practical, physical objects will be photographed, and the photograph will be placed in EPA's electronic public docket along with a brief description written by the docket staff.

C. How and to Whom Do I Submit Comments?

You may submit comments electronically, by mail, or through hand delivery/courier. To ensure proper receipt by EPA, identify the appropriate docket ID number in the subject line on the first page of your comment. Please ensure that your comments are submitted within the specified comment period. Comments received after the close of the comment period will be marked ''late.'' EPA is not required to consider these late comments. If you wish to submit CBI or information that is otherwise protected by statute, please follow the instructions in Unit I.D. Do not use EPA Dockets or e-mail to submit CBI or information protected by statute.

1. *Electronically*. If you submit an electronic comment as prescribed in this unit, EPA recommends that you include your name, mailing address, and an e-mail address or other contact information in the body of your comment. Also include this contact information on the outside of any disk or CD ROM you submit, and in any cover letter accompanying the disk or CD ROM. This ensures that you can be identified as the submitter of the comment and allows EPA to contact you in case EPA cannot read your comment due to technical difficulties or needs further information on the substance of your comment. EPA's policy is that EPA will not edit your comment, and any identifying or contact information provided in the body of a comment will be included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment.

i. *EPA Dockets*. Your use of EPA's electronic public docket to submit comments to EPA electronically is EPA's preferred method for receiving comments. Go directly to EPA Dockets at *http://www.epa.gov/edocket*, and follow the online instructions for submitting comments. Once in the system, select ''search,'' and then key in docket ID number OPP–2003–0145. The system is an ''anonymous access'' system, which means EPA will not know your identity, e-mail address, or other contact information unless you provide it in the body of your comment.

ii. *E-mail*. Comments may be sent by e-mail to *opp-docket@epa.gov*, Attention: Docket ID number OPP–2003–0145. In contrast to EPA's electronic public docket, EPA's e-mail system is not an ''anonymous access'' system. If you send an e-mail comment directly to the docket without going through EPA's electronic public docket, EPA's e-mail system automatically captures your e-mail address. E-mail addresses that are automatically captured by EPA's e-mail system are included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket.

iii. *Disk or CD ROM*. You may submit comments on a disk or CD ROM that you mail to the mailing address identified in Unit I.C.2. These electronic submissions will be accepted in WordPerfect or ASCII file format. Avoid the use of special characters and any form of encryption.

2. *By mail*. Send your comments to: Public Information and Records Integrity Branch (PIRIB) (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001, Attention: Docket ID number OPP–2003–0145.

3. *By hand delivery or courier*. Deliver your comments to: Public Information and Records Integrity Branch (PIRIB), Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, Attention: Docket ID number OPP–2003–0145. Such deliveries are only accepted during the docket's normal hours of operation as identified in Unit I.B.1.

D. How Should I Submit CBI to the Agency?

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E. What Should I Consider as I Prepare My Comments for EPA?

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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 ID number assigned to this action in the subject line on the first page of your response. You may also provide the name, date, and **Federal Register** citation.

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 a certain pesticide chemical 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 this petition contains data or information regarding the elements set forth in FFDCA section 408(d)(2); however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data support granting of the petition. Additional data may be needed before EPA rules on the petition.

List of Subjects

Environmental protection, Agricultural commodities, Feed additives, Food additives, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: June 30, 2003.

Debra Edwards,

Director, Registration Division, Office of Pesticide Programs.

Summaries of Petitions

The petitioner summaries of the pesticide petitions are printed below as required by FFDCA section 408(d)(3). The summaries of the petitions were prepared by the petitioner and represent the views of the petitioner. 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.

Interregional Research Project Number 4 (IR-4)

PP 3E6519

EPA has received a pesticide petition (3E6519) from IR-4, 681 U.S. Highway #1 South, North Brunswick, NJ 08902–3390 proposing, pursuant to 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 a tolerance for residues of combined residues of fenpyroximate benzoic acid, 4-[[[(E)-(1,3-dimethyl-5-phenoxy-1H-pyrazol-4-yl) methylene]amino] oxy]methyl]-, 1,1-dimethylethyl ester] and its z-isomer benzoic acid, 4-[[[[(Z)-(1,3-dimethyl-5-phenoxy-1H-pyrazol-4-yl) methylene]amino]oxy]methyl]-,1,1-dimethylethyl ester)]] in or on the raw agricultural commodity fruit, pome, group 11 at 0.3 parts per million (ppm). Nichino America, Incorporated.

PP 2F6437

EPA has also received a pesticide petition (2F6437) from Nichino America, Inc., 4550 New Linden Hill Road, Wilmington, DE 19808 proposing, pursuant to section 408(d) of the FFDCA, 21 U.S.C. 346a(d), to amend 40 CFR part 180 by establishing tolerances for residues of combined residues of fenpyroximate benzoic acid, 4-[[[(E)-(1,3-dimethyl-5-phenoxy-1H-pyrazol-4-yl) methylene]amino] oxy]methyl]-, 1,1-dimethylethyl ester] and its z-isomer benzoic acid, 4-[[[[(Z)-(1,3-dimethyl- 5-phenoxy-1H-pyrazol-4-yl) methylene]amino]oxy]methyl]-,1,1-dimethylethyl ester)]] in or on the following raw agricultural commodities: Cotton, undelinted seed at 0.1 ppm, cotton, gin byproducts at 9.0 ppm, apple, fruit at 0.08 ppm, and grape at 0.3 ppm. Additionally, EPA has received request for tolerances for the combined residues of fenpyroximate benzoic acid, 4-[[[(E)-(1,3-dimethyl-5-phenoxy-1H-pyrazol-4-yl) methylene]amino] oxy]methyl]-, 1,1-dimethylethyl ester] and its z-isomer benzoic acid, 4-[[[[(Z)-(1,3-dimethyl-5-phenoxy-1H-pyrazol-4-yl) methylene]amino]oxy]methyl]-,1,1-dimethylethyl ester)] and the acid metabolite ((E)-4-[(1,3-dimethyl-5-phenoxypyrazol-4-yl)-methyleneamino oxymethyl benzoic acid (M-3)], all expressed as fenpyroximate in or on milk at 0.01 ppm; meat at 0.02 ppm; fat at 0.8 ppm; kidney at 0.5 ppm; liver at 0.5 ppm; and meat byproducts at 0.01 ppm of cattle, goats, hogs, horses and sheep. 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 summary has been prepared by the Nichino American, Inc., Wilmington, DE 19808, the registrant.

A. Residue Chemistry

1. *Plant metabolism*. The metabolism of fenpyroximate and z- isomer has been studied in cotton, apples, grapes, and citrus and is adequately understood.

2. *Analytical method*. As a result an enforcement method has been developed which involves extraction of fenpyroximate from crops with acetone, filtration, partitioning and cleanup, and analysis by gas chromatography using a nitrogen/phosphorous detector. This method allows detection of residues at or above the proposed tolerances. The method has undergone independent laboratory validation as required by PR Notices 88–5 and 96–1.

3. *Magnitude of residues*—i. *Magnitude of residues in crops field residue trials meeting*. EPA study requirements have been conducted at the maximum label rate for cotton, grapes, and pome fruit. Results from these trials demonstrate that the highest fenpyroximate and z-isomer residues found will not exceed the proposed tolerances when the product is applied following the proposed use directions.

ii. *Magnitude of the residue in animals*—a. *Ruminants*. Maximum residues of fenpyroximate, z-isomer, and acid metabolite in a cattle feeding study demonstrate that the highest fenpyroximate, z-isomer, and acid metabolite, combined as fenpyroximate, will not exceed the proposed tolerances in or on milk (0.01 ppm); meat (0.02 ppm), fat (0.8) ppm, kidneys and liver (0.5) ppm, and meat byproducts (0.01) ppm in cattle, goats, hogs, horses, sheep.

b. *Poultry*. The maximum poultry dietary burden results from a diet composed of cotton meal for a total dietary burden that is significantly lower than the levels that would require the proposal of tolerances in poultry. This conclusion is based on the exaggerated rate field crop studies carried out on fenpyroximate and the z-isomer. Therefore, an exemption from tolerances in poultry meat, poultry meat by-products, fat and eggs under 40 CFR 180.6(a)(3) and (b) is proposed as it is not possible to establish with certainty whether finite residues will be incurred, but there is no reasonable expectation of finite residues.

B. Toxicological Profile

A full description of the studies describing the toxicity of fenpyroximate can be found in the posting for the import tolerances on hops and wine grapes in the **Federal Register** of April 10, 2001 (66 FR 18561) (FRL–6773–2).

1. *Animal metabolism*. The qualitative nature of the residues of fenpyroximate and z-isomer and acid metabolite, in animals is adequately understood. Fenpyroximate was not metabolized to volatiles to any significant degree. The majority of either benzyl or pyrazole labels (approximately 70% to 92%) is excreted in the feces. Urinary excretion accounts for less (approximately 9% to 18%) of the label. Thus, feces and urine are the major routes of excretion for fenpyroximate. Tissue did not accumulate fenpyroximate or its metabolites to any great extent. The greatest levels of label were in liver, kidneys, adrenals, and fat (to a lesser degree). In blood, nearly all the label is in the plasma.

2. *Endocrine disruption*. Chronic, lifespan, and multigenerational bioassays in mammals and acute and subchronic studies on aquatic organisms and wildlife did not reveal any endocrine effects for fenpyroximate. Any endocrine-related effects would have been detected in this

comprehensive series of required tests. The probability of any such effect due to agricultural uses of fenpyroximate is negligible.

C. Aggregate Exposure

1. *Dietary exposure*. The potential dietary exposure to fenpyroximate has been calculated from the proposed tolerances for use on cotton, grapes, and pome fruit. These very conservative chronic dietary exposure estimates used the tolerance value for all the raw agricultural commodities. In addition, these estimates assume that 100% of the crops contain fenpyroximate residues.

i. *Food*. Chronic dietary exposure to fenpyroximate was estimated on the basis of 100% crop treatment for cotton, grapes, and pome fruit and assuming tolerance level residues on these crops. These estimated exposures were compared to the chronic dietary RfD for fenpyroximate, which has already been established by EPA at 0.010 milligrams/kilogram/day (mg/kg/day), in connection with the import tolerance on wine grapes and hops.

ii. *Drinking water*. Laboratory and field data have demonstrated that fenpyroximate is immobile in soil and will not leach into ground water. Other data show that fenpyroximate is virtually insoluble in water. As a result, NAI concludes that residues reaching surface waters from field runoff will quickly adsorb to sediment particles and be partitioned from the water column. Further, a screening evaluation of leaching potential for other miticides was conducted using EPA's Pesticide Root Zone Model (PRZM) and Screening Concentration in Ground Water (SCI-GROW). Based on this screening assessment, the potential concentrations of fenpyroximate and z-isomer in water at depths of 1 and 2 meters are essentially zero (<1 part per trillion (ppt)). Surface water concentrations using PRZM and EXAMS were predicted in the simulated pond of 0.0242 part per billion (ppb).

2. *Non-dietary exposure*. There are no registered or proposed residential uses of fenpyroximate. Thus, a residential exposure assessment is not required. Exposure to fenpyroximate for the mixer/loader/ground boom applicator was calculated using the Pesticides Handlers Exposure Data base (PHED). These PHED assessments were based on a 70 kg operator treating <50 acres per day using ground boom equipment on both apples and grapes and 80 acres per day on cotton by ground application with an operator treating at a maximum use rate of 0.1 lb active ingredient per acre. All mixer/loaders and workers/operators were assumed to be wearing gloves, long pants and long-sleeved shirts.

D. Cumulative Effects

In consideration of potential cumulative effects of fenpyroximate and other substances that may have a common mechanism of toxicity, to our knowledge there are no currently available data or other reliable information indicating that any toxic effects produced by fenpyroximate would be cumulative with those of other chemical compounds; thus only the potential risks of fenpyroximate have been considered in this assessment of its aggregate exposure.

E. Safety Determination

1. *U.S. population*—i. *Acute*. Using the 100% crop treatment scenario the acute population adjusted dose (aPAD) for the general population is 0.002309 mg/kg/day. Of the standard subgroups which are analyzed by the Dietary Exposure Evaluation Model (DEEM), the subgroup with the highest exposures is infants (<1 year) with an acute dietary exposure estimated at 0.006368 mg/kg/day (12.74% of the acute reference aRfD). For children in the age brackets 1–6 years and 7–12 years, the dietary exposures are approximately 0.004716 mg/kg/day (9.43% of the aRfD) and 0.002581 mg/kg/day (5.16% of the aRfD), respectively. Males and females aged 13 and older have an estimated acute dietary exposure of 0.001054 and 0.000911 mg/kg/day, respectively (2.11% and 1.82% of the aRfD, respectively). Even applying the Food Quality Protection Act (FQPA) factor of 10X to females aged 13 and older the percent aRfD utilization is only a modest 11.82%. All values for percentage utilization of the aRfD are well below 100% and no value exceeds 12.74%.

ii. *Chronic*. Of the standard subgroups which are analyzed by the DEEM, and using the conservative estimates, of 100% crop treatment scenario, the chronic population adjusted dose (cPAD) for the general population, is approximately 0.0002579 mg/kg/day (which is 2.58% of the RfD). This value is based on the no observed adverse effect level (NOAEL) of 0.97 mg/kg/day observed in the chronic rat feeding study, the worse case estimate of chronic dietary exposure of fenpyroximate from cotton, grape, and pome fruit and a safety (uncertainty) factor of 100.

2. *Non-dietary exposure*—i. *Acute*. The margins of exposure relative to the acute dietary endpoint (5 mg/kg/day) are all in excess of 1,000. Therefore, there is a reasonable certainty that no harm will occur from acute exposure to crops treated at the maximum labeled use rates and minimum preharvest intervals for fenpyroximate. Worker exposure (mixer/loader and applicator) estimates provide for margins of safety of >100 in all scenarios. Worker exposure is therefore expected, to a reasonable degree of scientific certainty, to be without harm. Based on the above, exposures of the U.S. population to fenpyroximate associated with the uses addressed in this reduced risk submission are expected, to a reasonable degree of scientific certainty, to be without harm.

ii. *Chronic*. The margins of exposure relative to the chronic dietary endpoint are all in excess of 1,700. Therefore, there is a reasonable certainty that no harm will occur from chronic exposure to crops treated at the maximum labeled use rates and minimum preharvest intervals for fenpyroximate.

3. *Infants and children*—i. *Acute*. Using the 100% crop treatment scenario, the subgroup with the highest exposures is infants (<1 year) with an acute dietary exposure estimated at 0.006368 mg/kg/day (12.74% of the aRfD). For children in the age brackets 1–6 years and 7–12 years, the acute dietary exposures are approximately 0.004716 mg/kg/day (9.43% of the aRfD) and 0.002581 mg/kg/day (5.16% of the aRfD), respectively. Acute dietary exposure of infants and children is therefore expected, to a reasonable degree of scientific certainty, to be without harm. Based on the above, exposures of infants and children to fenpyroximate associated with the uses addressed in this reduced risk submission are expected, to a reasonable degree of scientific certainty, to be without harm.

ii. *Chronic*. Using the 100% crop treatment scenario, infants (less than 1 year) have the highest chronic exposure (0.0009228 mg/kg/day, which is 9.23 % of the RfD). For children in the age brackets 1–6 years and 7–12 years, the dietary exposures are approximately 0.0005244 mg/kg/day (5.24% of the RfD) and 0.0002733 mg/kg/day (2.73% of the RfD), respectively. Chronic dietary exposure of the infants and children is therefore expected, to a reasonable degree of scientific certainty, to be without harm.

iii. *Conclusion*. There is a complete toxicity data base for fenpyroximate and exposure data are conservatively estimated based on data that reasonably account for potential exposures. Based on these risk assessments, Nichino America, Inc. concludes that, there is a reasonable certainty that no harm will result to infants and children from

aggregate exposure to combined residues of fenpyroximate.

F. International Tolerances

Codex Maximum Residue Levels (MRLs) have been established for residues of fenpyroximate and z-isomer on apples in Brazil at 0.1 ppm, France 0.2 ppm, Japan 1.0 ppm, Spain (pome fruits) 0.3 ppm, and Switzerland 0.2 ppm. Codex MRLs have been established on grapes in France at 0.2 ppm, Japan 2.0 ppm, Spain 0.3 ppm, and Switzerland 0.2 ppm.

[FR Doc. 03–17617 Filed 7–10–03; 8:45 am]
BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[OPP–2003–0230; FRL–7316–1]

2-Ethylhexyl-L-Lactate; Notice of Filing a Pesticide Petition to Establish a Tolerance for a Certain Pesticide Chemical in or on Food

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces the initial filing of a pesticide petition proposing the establishment of regulations for residues of a certain pesticide chemical in or on various food commodities.

DATES: Comments, identified by docket identification (ID) number OPP–2003–0230, must be received on or before August 11, 2003.

ADDRESSES: Comments may be submitted electronically, by mail, or through hand delivery/courier. Follow the detailed instructions as provided in Unit I. of the **SUPPLEMENTARY INFORMATION**.

FOR FURTHER INFORMATION CONTACT: Kathryn Boyle, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–6304; e-mail address: *boyle.kathryn@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to:

- Crop production (NAICS 111)
- Animal production (NAICS 112)
- Food manufacturing (NAICS 311)
- Pesticide manufacturing (NAICS 32532)

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Get Copies of this Document and Other Related Information?

1. *Docket*. EPA has established an official public docket for this action under docket ID number OPP–2003–0230. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

2. *Electronic access*. You may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr/*.

An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at *http://www.epa.gov/edocket/* to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B.1. Once in the system, select ''search,'' then key in the appropriate docket ID number.

Certain types of information will not be placed in the EPA Dockets. Information claimed as CBI and other information whose disclosure is restricted by statute, which is not included in the official public docket, will not be available for public viewing in EPA's electronic public docket. EPA's policy is that copyrighted material will not be placed in EPA's electronic public docket but will be available only in printed, paper form in the official public docket. To the extent feasible, publicly available docket materials will be made available in EPA's electronic public docket. When a document is selected from the index list in EPA Dockets, the system will identify whether the document is available for viewing in EPA's electronic public docket. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B.1. EPA intends to work towards providing electronic access to all of the publicly available docket materials through EPA's electronic public docket.

For public commenters, it is important to note that EPA's policy is that public comments, whether submitted electronically or in paper, will be made available for public viewing in EPA's electronic public docket as EPA receives them and without change, unless the comment contains copyrighted material, CBI, or other information whose disclosure is restricted by statute. When EPA identifies a comment containing copyrighted material, EPA will provide a reference to that material in the version of the comment that is placed in EPA's electronic public docket. The entire printed comment, including the copyrighted material, will be available in the public docket.

Public comments submitted on computer disks that are mailed or delivered to the docket will be transferred to EPA's electronic public docket. Public comments that are mailed or delivered to the docket will be scanned and placed in EPA's electronic public docket. Where practical, physical objects will be photographed, and the photograph will be placed in EPA's electronic public docket along with a brief description written by the docket staff.

C. How and to Whom Do I Submit Comments?

You may submit comments electronically, by mail, or through hand delivery/courier. To ensure proper receipt by EPA, identify the appropriate docket ID number in the subject line on the first page of your comment. Please ensure that your comments are

submitted within the specified comment period. Comments received after the close of the comment period will be marked ''late.'' EPA is not required to consider these late comments. If you wish to submit CBI or information that is otherwise protected by statute, please follow the instructions in Unit I.D. Do not use EPA dockets or e-mail to submit CBI or information protected by statute.

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iii. *Disk or CD ROM*. You may submit comments on a disk or CD ROM that you mail to the mailing address identified in Unit I.C.2. These electronic submissions will be accepted in WordPerfect or ASCII file format. Avoid the use of special characters and any form of encryption.

2. *By mail*. Send your comments to: Public Information and Records Integrity Branch (PIRIB) (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001, Attention: Docket ID Number OPP–2003–0230.

3. *By hand delivery or courier*. Deliver your comments to: Public Information and Records Integrity Branch (PIRIB), Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, Attention: Docket ID Number OPP–2003–0230. Such deliveries are only accepted during the docket's normal hours of operation as identified in Unit I.B.1.

D. How Should I Submit CBI to the Agency?

Do not submit information that you consider to be CBI electronically through EPA's electronic public docket or by e-mail. You may claim information that you submit to EPA as CBI by marking any part or all of that information as CBI (if you submit CBI on disk or CD ROM, mark the outside of the disk or CD ROM as CBI and then identify electronically within the disk or CD ROM the specific information that is 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 docket and EPA's electronic public docket. If you submit the copy that does not contain CBI on disk or CD ROM, mark the outside of the disk or CD ROM clearly that it does not contain CBI. Information not marked as CBI will be included in the public docket and EPA's electronic public docket 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?

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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 ID number assigned to this action in the subject line on the first page of your response. You may also provide the name, date, and **Federal Register** citation.

II. What Action is the Agency Taking?

EPA has received a pesticide petition as follows proposing the establishment and/or amendment of regulations for residues of a certain pesticide chemical in or on various food commodities under section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a. EPA has determined that this petition contains data or information regarding the elements set forth in FFDCA section 408(d)(2); however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data support granting of the petition. Additional data may be needed before EPA rules on the petition.

List of Subjects

Environmental protection, Agricultural commodities, Feed additives, Food additives, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: June 30, 2003.

Peter Caulkins,

Acting Director, Registration Division, Office of Pesticide Programs.

Summary of Petition

The petitioner's summary of the pesticide petition is printed below as required by FFDCA section 408(d)(3). The summary of the petition was prepared by the petitioner and represents the view of the petitioner. 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.

I. PURAC America, Inc.

PP OF6179

EPA has received a pesticide petition (PP OF6179) from PURAC America, Inc., 111 Barclay Boulevard, Lincolnshire Corporate Center, Lincolnshire, IL 60069 proposing, pursuant to section 408(d) of FFDCA, 21 U.S.C. 346a(d), to amend 40 CFR 180.950 to establish an exemption from the requirement of a tolerance for 2-ethylhexyl-L-lactate, when used in accordance with good agricultural or manufacturing practice. EPA has determined that the petition contains data or information regarding the elements set forth in section 408(d)(2) of the FFDCA; however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data support granting of the petition. Additional data may be needed before EPA rules on the petition.

A. Toxicological Profile

1. *Acute toxicity*. The oral LD_{50} of 2-ethylhexyl-L-lactate in rats is greater than 2,000 mg/kg (per Organization for Economic Cooperation and Development (OECD) Guideline No. 401). In the acute oral study, 5 rats per sex, per group were used. The test substance was diluted with water (20% (w/v) and given by gavage at a dose of 10 milligrams/kilogram (mg/kg). Clinical observations, mortality, body weights and gross pathological changes were recorded during a 14–day observation period. Piloerection was seen for up to 4 hours after treatment, but no gross necropsy changes were noted.

2. *Genotoxicity*. Ames testing of a similar lactate, ethyl-L-lactate did not show any activity.

3. *Reproductive and developmental toxicity*. The embryotoxicity and teratogenicity of aerosolized 2-ethylhexyl lactate at 200 and 600 mg/m^3 was studied. Only minor developmental effects, most attributable to the stress conditions, and no teratogenic effects were observed.

4. *Subchronic toxicity*. Subacute inhalation studies have been conducted at concentrations up to 600 mg/m^3. For aerosol exposure, 2-ethylhexyl-L-lactate was noted to cause minimal damage, the vapor being slightly less toxic than the aerosol. Lactates do not appear to cause systemic toxicity, except at very high concentration (1,800 mg/m^3 or higher). These systemic effects may be secondary to severe irritation seen at high doses.

5. *Animal metabolism*. The *in vitro* hydrolysis of lactate esters (methyl, ethyl, butyl, pentyl, isoamyl, isopropyl, isobutyl, 2-ethylhexyl) in rat olfactory epithelium homogenate has been evaluated. In general, of the eight lactates evaluated, the rat nasal epithelium showed increased capacity to hydrolyze the lactates and increased affinity with increasing molecular weight (increase in alcohol chain length). Based on the similarity of effects and kinetic parameters, it appears that lactic acid is most likely the cause of the lactate toxicity. The *in vitro* hydrolysis of 2-ethylhexyl lactate and di-(2-ethylhexyl)-phthalate by homogenates of rat liver, small intestinal mucosa, blood, skin and caecum content was investigated. The study concluded that 2-ethylhexyl-lactate will be effectively hydrolysed before, during or rapidly after absorption. Results showed the most rapid hydrolysis was in the intestinal mucosa, followed in decreasing order by the liver, caecum, blood, and skin.

6. *Metabolite toxicology*. 2-Ethylhexyl-L-lactate is rapidly hydrolyzed in the body and environment to lactic acid and 2-ethylhexanol (both are listed as exempt from requirements for a tolerance under 40 CFR 180.1001). Lactic acid is a metabolic break down product of all lactates. It is a normal metabolite in humans and is found in or added to foods (21 CFR 172.515). Endogenous production of L(+) lactate in a resting human is 100–124 grams per day. Lactic acid oral LD_{50} in rats is 3,730 mg/kg. It is not active in mutagenic tests. It will produce skin and eye irritation at high concentrations. The 2-ethylhexanol has an exemption from tolerance under 40 CFR 180.1001 with no limit on use as a cosolvent, defoamer or solvent for all pesticides used before crop emerges from soil and in herbicides before or after crop emergence.

B. Aggregate Exposure

Non-dietary exposure. 2-Ethylhexyl-L-lactate will be used at an application rate of between 0.4 and 1.7 lb/acre as part of the emulsion concentrate or as a solvent for herbicides, fungicides, insecticides, and, other pesticide formulations. The low vapor pressure would tend to keep airborne exposure low.

[FR Doc. 03–17618 Filed 7–10–03; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[OPP–2003–0227; FRL–7315–8]

Lactic Acid, n-Butyl Ester and Lactic Acid, Ethyl Ester; Notice of Filing a Pesticide Petition to Establish a Tolerance for a Certain Pesticide Chemical in or on Food

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces the initial filing of a pesticide petition proposing the establishment of regulations for residues of a certain pesticide chemical in or on various food commodities.

DATES: Comments, identified by docket ID number OPP–2003–0227, must be received on or before August 11, 2003.

ADDRESSES: Comments may be submitted electronically, by mail, or through hand delivery/courier. Follow the detailed instructions as provided in Unit I. of the **SUPPLEMENTARY INFORMATION**.

FOR FURTHER INFORMATION CONTACT: Kathryn Boyle, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: 703–305–6304; e-mail address: *boyle.kathryn@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to:

- Crop production (NAICS code 111)
- Animal production (NAICS code 112)
- Food manufacturing (NAICS code 311)
- Pesticide manufacturing (NAICS code 32532)

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult

the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Get Copies of this Document and Other Related Information?

1. *Docket*. EPA has established an official public docket for this action under docket identification (ID) number OPP–2003–0227. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

2. *Electronic access*. You may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr/*.

An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at *http://www.epa.gov/edocket/* to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B.1. Once in the system, select ''search,'' then key in the appropriate docket ID number.

Certain types of information will not be placed in the EPA Dockets. Information claimed as CBI and other information whose disclosure is restricted by statute, which is not included in the official public docket, will not be available for public viewing in EPA's electronic public docket. EPA's policy is that copyrighted material will not be placed in EPA's electronic public docket but will be available only in printed, paper form in the official public docket. To the extent feasible, publicly available docket materials will be made available in EPA's electronic public docket. When a document is selected from the index list in EPA Dockets, the system will identify whether the document is available for viewing in EPA's electronic public docket. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B. EPA intends to work towards providing electronic access to all of the publicly available docket materials through EPA's electronic public docket.

For public commenters, it is important to note that EPA's policy is that public comments, whether submitted electronically or in paper, will be made available for public viewing in EPA's electronic public docket as EPA receives them and without change, unless the comment contains copyrighted material, CBI, or other information whose disclosure is restricted by statute. When EPA identifies a comment containing copyrighted material, EPA will provide a reference to that material in the version of the comment that is placed in EPA's electronic public docket. The entire printed comment, including the copyrighted material, will be available in the public docket.

Public comments submitted on computer disks that are mailed or delivered to the docket will be transferred to EPA's electronic public docket. Public comments that are mailed or delivered to the docket will be scanned and placed in EPA's electronic public docket. Where practical, physical objects will be photographed, and the photograph will be placed in EPA's electronic public docket along with a brief description written by the docket staff.

C. How and to Whom Do I Submit Comments?

You may submit comments electronically, by mail, or through hand delivery/courier. To ensure proper receipt by EPA, identify the appropriate docket ID number in the subject line on the first page of your comment. Please ensure that your comments are submitted within the specified comment period. Comments received after the close of the comment period will be marked ''late.'' EPA is not required to consider these late comments. If you wish to submit CBI or information that is otherwise protected by statute, please follow the instructions in Unit I.D. Do not use EPA Dockets or e-mail to submit CBI or information protected by statute.

1. *Electronically*. If you submit an electronic comment as prescribed in this unit, EPA recommends that you include your name, mailing address, and an e-mail address or other contact information in the body of your comment. Also include this contact information on the outside of any disk or CD ROM you submit, and in any cover letter accompanying the disk or CD ROM. This ensures that you can be identified as the submitter of the comment and allows EPA to contact you in case EPA cannot read your comment due to technical difficulties or needs further information on the substance of your comment. EPA's policy is that EPA will not edit your comment, and any identifying or contact information provided in the body of a comment will be included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment.

i. *EPA Dockets*. Your use of EPA's electronic public docket to submit comments to EPA electronically is EPA's preferred method for receiving comments. Go directly to EPA Dockets at *http://www.epa.gov/edocket*, and follow the online instructions for submitting comments. Once in the system, select ''search,'' and then key in docket ID number OPP–2003–0227. The system is an ''anonymous access'' system, which means EPA will not know your identity, e-mail address, or other contact information unless you provide it in the body of your comment.

ii. *E-mail*. Comments may be sent by e-mail to *opp-docket@epa.gov*, Attention: Docket ID Number OPP–2003–0227. In contrast to EPA's electronic public docket, EPA's e-mail system is not an ''anonymous access'' system. If you send an e-mail comment directly to the docket without going through EPA's electronic public docket, EPA's e-mail system automatically captures your e-mail address. E-mail addresses that are automatically captured by EPA's e-mail system are included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket.

iii. *Disk or CD ROM*. You may submit comments on a disk or CD ROM that you mail to the mailing address identified in Unit I.C.2. These electronic submissions will be accepted in WordPerfect or ASCII file format. Avoid the use of special characters and any form of encryption.

2. *By mail*. Send your comments to: Public Information and Records Integrity Branch (PIRIB) (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington,

DC 20460–0001, Attention: Docket ID Number OPP–2003–0227.

3. *By hand delivery or courier*. Deliver your comments to: Public Information and Records Integrity Branch (PIRIB), Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, Attention: Docket ID Number OPP–2003–0227. Such deliveries are only accepted during the docket's normal hours of operation as identified in Unit I.B.1.

D. How Should I Submit CBI to the Agency?

Do not submit information that you consider to be CBI electronically through EPA's electronic public docket or by e-mail. You may claim information that you submit to EPA as CBI by marking any part or all of that information as CBI (if you submit CBI on disk or CD ROM, mark the outside of the disk or CD ROM as CBI and then identify electronically within the disk or CD ROM the specific information that is 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 docket and EPA's electronic public docket. If you submit the copy that does not contain CBI on disk or CD ROM, mark the outside of the disk or CD ROM clearly that it does not contain CBI. Information not marked as CBI will be included in the public docket and EPA's electronic public docket 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. 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 ID number assigned to this action in the subject line on the first page of your response. You may also provide the name, date, and **Federal Register** citation.

II. What Action is the Agency Taking?

EPA has received a pesticide petition as follows proposing the establishment and/or amendment of regulations for residues of a certain pesticide chemical in or on various food commodities under section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a. EPA has determined that this petition contains data or information regarding the elements set forth in FFDCA section 408(d)(2); however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data support granting of the petition. Additional data may be needed before EPA rules on the petition.

List of Subjects

Environmental protection, Agricultural commodities, Feed additives, Food additives, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: June 30, 2003.

Peter Caulkins,

Acting Director, Registration Division, Office of Pesticide Programs.

Summary of Petition

The petitioner summary of the pesticide petition is printed below as required by FFDCA section 408(d)(3). The summary of the petition was prepared by the petitioner and represents the view of the petitioner.

PURAC America, Inc.

PP 5E4510 and 5E4515

EPA has received an amendment to pesticide petitions PP 5E4510 and 5E4515 from PURAC America, Inc., 111 Barclay Boulevard, Lincolnshire Corporate Center, Lincolnshire, IL 60069 proposing, pursuant to section 408(d) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(d), to amend 40 CFR part 180 to amend the existing exemption from the requirement of a tolerance for lactic acid, n-butyl ester (CAS No. 138–22–7) and lactic acid, ethyl ester (CAS No. 97–64–3), to also include lactic acid, n-butyl ester, (S) (CAS No. 34451–19–9) and lactic acid, ethyl ester, (S) (CAS No. 687–47–8) as also exempt from the requirement for a tolerance under 40 CFR 180.950, when used in accordance with good agricultural or manufacturing practice.

The existing exemptions for lactic acid, ethyl ester and lactic acid, butyl ester were established using the general CAS Registry Numbers. These CAS numbers are correct and do adequately identify the chemical substance. However, the actual test substance for many of the studies submitted by PURAC were performed using an isomeric form of the lactate ester. The form of the lactate ester produced by fermentation from sugar can be referred to as the L (+) or the (S) isomer. The basic chemical and physical properties for these stereochemical isomers are identical to that of the general substances. Use of both the general CAS number and the (S) isomer CAS number better identify the product produced and sold by PURAC.

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.

A. Toxicological Profile

All data currently on file for the general CAS substances were generated using the (L) stereoisomer.

B. Aggregate Exposure

All data currently on file for the general CAS substances were generated using the (L) stereoisomer.

[FR Doc. 03–17619 Filed 7–10–03; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[FRL–7525–8]

Federal Agency Hazardous Waste Compliance Docket

AGENCY: Environmental Protection Agency.

ACTION: Notice of seventeenth update of the Federal Agency Hazardous Waste Compliance Docket, pursuant to CERCLA section 120(c).

SUMMARY: Section 120(c) of the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA), as amended by the Superfund Amendments and Reauthorization Act of 1986 (SARA), requires the Environmental Protection Agency (EPA) to establish a Federal Agency Hazardous Waste Compliance Docket. The docket is to contain certain

information about Federal facilities that manage hazardous waste or from which hazardous substances have been or may be released. (As defined by CERCLA section 101(22), a release is any spilling, leaking, pumping, pouring, emitting, emptying, discharging, injecting, escaping, leaching, dumping, or disposing into the environment.) CERCLA requires that the docket be updated every six months, as new facilities are reported to EPA by Federal agencies. The following list identifies the Federal facilities to be included in this seventeenth update of the docket and includes facilities not previously listed on the docket and reported to EPA since the last update of the docket, 68 FR 107, January 2, 2003, which was current as of February 4, 2003. SARA, as amended by the Defense Authorization Act of 1997, specifies that, for each Federal facility that is included on the docket during an update, evaluation shall be completed in accordance with a reasonable schedule. Such site evaluation activities will help determine whether the facility should be included on the National Priorities List (NPL) and will provide EPA and the public with valuable information about the facility. In addition to the list of additions to the docket, this notice includes a section that comprises revisions (that is, corrections and deletions) of the previous docket list. This update contains 34 additions and 8 deletions since the previous update, as well as numerous other corrections to the docket list. At the time of publication of this notice, the new total number of Federal facilities listed on the docket is 2,254.

DATES: This list is current as of February 4, 2003.

FOR FURTHER INFORMATION CONTACT: Electronic versions of the docket may be obtained at *http://www.epa.gov/compliance/cleanup/federal/index.html*.

SUPPLEMENTARY INFORMATION:

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1.0 Introduction
2.0 Revisions of the Previous Docket
3.0 Process for Compiling the Updated Docket
4.0 Facilities Not Included
5.0 Facility Status Reporting
6.0 Information Contained on Docket Listing

1.0 Introduction

Section 120(c) of the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA), 42 United States Code (U.S.C.) 9620(c), as amended by the Superfund Amendments and Reauthorization Act of 1986 (SARA), required the establishment of the Federal Agency Hazardous Waste Compliance Docket. The docket contains information on Federal facilities that is submitted by Federal agencies to the U.S. Environmental Protection Agency (EPA) under sections 3005, 3010, and 3016 of the Resource Conservation and Recovery Act (RCRA), 42 U.S.C. 6925, 6930, and 6937, and under section 103 of CERCLA, 42 U.S.C. 9603. Specifically, RCRA section 3005 establishes a permitting system for certain hazardous waste treatment, storage, and disposal (TSD) facilities; RCRA section 3010 requires waste generators and transporters and TSD facilities to notify EPA of their hazardous waste activities; and RCRA section 3016 requires Federal agencies to submit biennially to EPA an inventory of hazardous waste sites that the Federal agencies own or operate. CERCLA section 103(a) requires that the National Response Center (NRC) be notified of a release. CERCLA section 103(c) requires reporting to EPA the existence of a facility at which hazardous substances are or have been stored, treated, or disposed of and the existence of known or suspected releases of hazardous substances at such facilities.

The docket serves three major purposes: (1) To identify all Federal facilities that must be evaluated to determine whether they pose a risk to human health and the environment sufficient to warrant inclusion on the National Priorities List (NPL); (2) to compile and maintain the information submitted to EPA on such facilities under the provisions listed in section 120(c) of CERCLA; and (3) to provide a mechanism to make the information available to the public.

The initial list of Federal facilities to be included on the docket was published on February 12, 1988 (53 FR 4280). Updates of the docket have been published on November 16, 1988 (54 FR 46364); December 15, 1989 (54 FR 51472); August 22, 1990 (55 FR 34492); September 27, 1991 (56 FR 49328); December 12, 1991 (56 FR 64898); July 17, 1992 (57 FR 31758); February 5, 1993 (58 FR 7298); November 10, 1993 (58 FR 59790); April 11, 1995 (60 FR 18474); June 27, 1997 (62 FR 34779); November 23, 1998 (63 FR 64806); June 12, 2000 (65 FR 36994); December 29, 2000 (65 FR 83222), October 2, 2001 (66 FR 50185), July 1, 2002 (67 FR 44200), and January 2, 2003 (68 FR 107). This notice constitutes the seventeenth update of the docket.

Today's notice is divided into three sections: (1) Additions, (2) deletions, and (3) corrections. The additions section lists newly identified facilities that have been reported to EPA since the last update and that now are being included on the docket. The deletions section lists facilities that EPA is deleting from the docket. The corrections section lists changes in information about facilities already listed on the docket.

The information submitted to EPA on each Federal facility is maintained in the docket repository located in the EPA Regional office of the Region in which the facility is located (see 53 FR 4280 (February 12, 1988) for a description of the information required under those provisions). Each repository contains the documents submitted to EPA under the reporting provisions and correspondence relevant to the reporting provisions for each facility. Contact the following docket coordinators for information on Regional docket repositories:

Gerardo Millán-Ramos (HBS), US EPA Region 1, #1 Congress St., Suite 1100, Boston, MA 02114–2023, (617) 918–1377.

Helen Shannon (ERRD), US EPA Region 2, 290 Broadway, 18th Floor, New York, NY 10007–1866, (212) 637–4260.

Philip Ofosu (6SF–RA), US EPA Region 6, 1445 Ross Avenue, Dallas, TX 75202–2733, (214) 665–3178.

D. Karla Asberry (FFSC), US EPA Region 7, 901 N. Fifth Street, Kansas City, KS 66101, (913) 551–7595.

Alida Karas (ERRD), US EPA Region 2, 290 Broadway, New York, NY 10007–1866, (212) 637–4276.

Cesar Lee (3HS50), US EPA Region 3, 1650 Arch Street, Philadelphia, PA 19107, (215) 814–3205.

Gena Townsend (4WD–FFB), US EPA Region 4, 61 Forsyth St., SW, Atlanta, GA 30303, (404) 562–8538.

Laura Ripley (SE–5J), US EPA Region 5, 77 W. Jackson Blvd., Chicago, IL 60604, (312) 886–6040.

Stan Zawistowski (EPR–F), US EPA Region 8, 999 18th Street, Suite 500, Denver, CO 80202–2466, (303) 312–6255.

Philip Armstrong (SFD–9–1), US EPA Region 9, 75 Hawthorne Street, San Francisco, CA 94105, (415) 972–3098.

Ken Marcy (ECL–115), US EPA Region 10, 1200 Sixth Avenue, Seattle, WA 98101, (206) 553–2782.

Monica Lindeman (ECL, SACU2), US EPA Region 10, 1200 Sixth Avenue, Seattle, WA 98101, (206) 553–5113.

2.0 Revisions of the Previous Docket

Following is a discussion of the revisions of the previous docket, including additions, deletions, and corrections.

2.1 Additions

Today, 34 facilities are being added to the docket, primarily because of new information obtained by EPA (for example, recent reporting of a facility pursuant to RCRA sections 3005, 3010, or 3016 or CERCLA section 103). SARA, as amended by the Defense Authorization Act of 1997, specifies that, for each Federal facility that is included on the docket during an update, evaluation shall be completed in accordance with a reasonable schedule.

Of the 34 facilities being added to the docket, none are facilities that have reported to the NRC the release of a reportable quantity (RQ) of a hazardous substance. Under section 103(a) of CERCLA, a facility is required to report to the NRC the release of a hazardous substance in a quantity that equals or exceeds the established RQ. Reports of releases received by the NRC, the U.S. Coast Guard (USCG), and EPA are transmitted electronically to the Transportation Systems Center at the U.S. Department of Transportation (DOT), where they become part of the Emergency Response Notification System (ERNS) database. ERNS is a national computer database and retrieval system that stores information on releases of oil and hazardous substances. Facilities being added to the docket and facilities already listed on the docket for which an ERNS report has been filed are identified by the notation ''103(a)'' in the ''Reporting Mechanism'' column.

It is EPA's policy generally not to list on the docket facilities that are small-quantity generators (SQG) and that have never generated more than 1,000 kilograms (kg) of hazardous waste in any single month. If a facility has generated more than 1,000 kg of hazardous waste in any single month (that is, if the facility is an episodic generator), it will be added to the docket. In addition, facilities that are SQGs and have reported releases under CERCLA section 103 or hazardous waste activities pursuant to RCRA section 3016 will be listed on the docket and will undergo site evaluation activities, such as a PA and, when appropriate, an SI. All such facilities will be listed on the docket, whether or not they are SQGs pursuant to RCRA. As a result, some of the facilities that EPA is adding to the docket today are SQGs that had not been listed on the docket but that have reported releases or hazardous waste activities to EPA under another reporting provision.

In the process of compiling the documents for the Regional repositories, EPA identified a number of facilities that had previously submitted PA reports, SI reports, Department of Defense (DoD) Installation Restoration Program (IRP) reports, or reports under another Federal agency environmental restoration program, but do not appear to have notified EPA under CERCLA section 103. Section 120(c)(3) of CERCLA requires that EPA include on the docket, among other things, information submitted under section 103. In general, section 103 requires persons in charge of a facility to provide notice of certain releases of hazardous substances. The reports under various Federal agency environmental restoration programs may contain information regarding releases of hazardous substances similar to that provided pursuant to section 103. EPA believes that CERCLA section 120(c) authorizes the agency to include on the docket a facility that has provided information to EPA through documents such as a report under a Federal agency environmental restoration program, regardless of the absence of section 103 reporting. Therefore, some of the facilities that EPA is adding today are being placed on the docket because they have submitted the documents described above that contain reports of releases of hazardous substances.

EPA also includes privately owned, government-operated (POGO) facilities on the docket. CERCLA section 120(c) requires that the docket contain information submitted under RCRA sections 3005, 3010, and 3016 and CERCLA section 103, all of which impose duties on operators as well as owners of facilities. In addition, other subsections of CERCLA section 120 refer to facilities ''owned or operated'' by an agency or other instrumentality of the Federal government. That terminology clearly includes facilities that are operated by the Federal government, even if they are not owned by it. Specifically, CERCLA section 120(e), which sets forth the duties of the Federal agencies after a facility has been listed on the NPL, refers to the Federal agency that ''owns or operates'' the facility. In addition, the primary basis for assigning responsibility for conducting PAs and SIs, as required when a facility is listed on the docket, is Executive Order 12580, which assigns that responsibility to the Federal agency having ''jurisdiction, custody, or control'' over a facility. An operator may be deemed to have jurisdiction, custody, or control over a facility.

2.2 Deletions

Today, 8 facilities are being deleted from the docket for various reasons, such as incorrect reporting of hazardous waste activity, change in ownership, and exemption as an SQG under RCRA (40 CFR 262.44). Facilities being deleted no longer will be subject to the requirements of CERCLA section 120(d).

2.3 Corrections

Changes necessary to correct the previous docket were identified by both EPA and Federal agencies. The changes needed varied from simple changes in addresses or spelling to corrections of the recorded name and ownership of a facility. In addition, some changes in the names of facilities were made to establish consistency in the docket. Many new entries are simply corrections of typographical errors. For each facility for which a correction has been entered, the original entry (designated by an ''O''), as it appeared in the February 12, 1988 notice or subsequent updates, is shown directly below the corrected entry (designated by a ''C'') for easy comparison.

3.0 Process for Compiling the Updated Docket

In compiling the newly reported facilities for the update being published today, EPA extracted the names, addresses, and identification numbers of facilities from four EPA databases—ERNS, the Biennial Inventory of Federal Agency Hazardous Waste Activities, the Resource Conservation and Recovery Information System (RCRIS), and the Comprehensive Environmental Response, Compensation, and Liability Information System (CERCLIS)—that contain information about Federal facilities submitted under the four provisions listed in CERCLA section 120(c).

Extensive computer checks compared the current docket list with the information obtained from the databases identified above to determine which facilities were, in fact, newly reported and qualified for inclusion on the update. In spite of the quality assurance efforts EPA has undertaken, state-owned or privately owned facilities that are not operated by the Federal government may have been included. Such problems are caused by procedures historically used to report and track data on Federal facilities; EPA is working to resolve them. Representatives of Federal agencies are asked to write to EPA's docket coordinator at the following address if revisions of this update

information are necessary: Augusta K. Wills, Federal Agency Hazardous Waste Compliance Docket Coordinator, Federal Facilities Enforcement Office (Mail Code 2261A), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue NW., Washington, DC 20004.

4.0 Facilities Not Included

As explained in the preamble to the original docket (53 FR 4280), the docket does not include the following categories of facilities (note, however, that any of these types of facilities may, when appropriate, be listed on the NPL):

- Facilities formerly owned by a Federal agency and now privately owned will not be listed on the docket. However, facilities that are now owned by another Federal agency will remain on the docket and the responsibility for conducting PAs and SIs will rest with the current owner.
- SQGs that have never produced more than 1,000 kg of hazardous waste in any single month and that have not reported releases under CERCLA section 103 or hazardous waste activities under RCRA section 3016 will not be listed on the docket.
- Facilities that are solely transporters, as reported under RCRA section 3010, will not be listed on the docket.

5.0 Facility Status Reporting

EPA has expanded the docket database to include information on the NFRAP status of listed facilities. Indicating NFRAP status allows easy identification of facilities that, after submitting all necessary site assessment information, were found to warrant no further involvement on the part of EPA at the time of the status change. Accordingly, the docket database includes the following facility status codes:

U=Undetermined
N=No further remedial action planned (NFRAP)

NFRAP is a term used in the Superfund site assessment program to identify facilities for which EPA has found that currently available information indicates that listing on the NPL is not likely and further assessment is not appropriate at the time. NFRAP status does not represent an EPA determination that no environmental threats are present at the facility or that no further environmental response action of any kind is necessary. NFRAP status means only that the facility does not appear, from the information available to EPA at this time, to warrant listing on the NPL and that, therefore, EPA anticipates no further involvement by EPA in site assessment or cleanup at the facility. However, additional CERCLA response actions by the Federal agency that owns or operates the facility, whether remedial or removal actions, may be necessary at a facility that has NFRAP status. The status information contained in the docket database is the result of Regional evaluation of information taken directly from CERCLIS. (CERCLIS is a database that helps EPA Headquarters and Regional personnel manage sites, programs, and projects. It contains the official inventory of all CERCLA (NPL and non-NPL) sites and supports all site planning and tracking functions. It also integrates financial data from preremedial, remedial, removal and enforcement programs.) The status information was taken from CERCLIS and sent to the Regional docket coordinators for review. The results of those reviews were incorporated into the status field in the docket database. Subsequently, an updated list of facilities having NFRAP status (those for which an ''N'' appears in the status field) was generated; the list of updates since the previous publication of the docket is being published today.

Important limitations apply to the list of facilities that have NFRAP status. First, the information is accurate only as of February 4, 2003. Second, a facility's status may change at any time because of any number of factors, including new site information or changing EPA policies. Finally, the list of facilities that have NFRAP status is based on Regional review of CERCLIS data, is provided for information purposes only, and should not be considered binding upon either the Federal agency responsible for the facility or EPA.

The status information in the docket database will be reviewed and a new list of facilities classified as NFRAP will be published at each docket update.

6.0 Information Contained on Docket Listing

As discussed above, the update information below is divided into three separate sections. The first section is a list of new facilities that are being added to the docket. The second section is a list of facilities that are being deleted from the docket. The third section comprises corrections of information included on the docket. Each facility listed for the update has been assigned a code(s) that indicates a more specific reason(s) for the addition, deletion, or correction. The code key precedes the lists.

SARA, as amended by the Defense Authorization Act of 1997, specifies that, for each Federal facility that is included on the docket during an update, evaluation shall be completed in accordance with a reasonable schedule. Therefore, all facilities on the additions list to this fifteenth docket update must submit a PA and, if warranted, an SI to EPA. The PA must include existing information about a site and its surrounding environment, including a thorough examination of human, food-chain, and environmental targets, potential waste sources, and migration pathways. From information in the PA or other information coming to EPA's attention, EPA will determine whether a follow-up SI is required. An SI augments the data collected in a PA. An SI may reflect sampling and other field data that are used to determine whether further action or investigation is appropriate. This policy includes any facility for which there is a change in the identity of the responsible Federal agency. The reports should be submitted to the Federal facilities coordinator in the appropriate EPA Regional office.

The facilities listed in each section are organized by state and then grouped alphabetically within each state by the Federal agency responsible for the facility. Under each state heading is listed the name and address of the facility, the Federal agency responsible for the facility, the statutory provision(s) under which the facility was reported to EPA, and the correction code(s).

The statutory provisions under which a facility reported are listed in a column titled ''Reporting Mechanism.'' Applicable mechanisms are listed for each facility: for example 3010, 3016, and 103(c).

The complete list of Federal facilities that now make up the docket and the complete list of facilities classified as no further remedial action planned (NFRAP) are not being published today. However, the lists are available to interested parties and can be obtained at *http://www.epa.gov/compliance/cleanup/federal/index.html* or by calling the HQ Docket Coordinator at (202) 564–2468. As of today, the total number of Federal facilities that appear on the docket is 2,254.

Dated: July 2, 2003.

David J. Kling,

Director, Federal Facilities Enforcement Office.

Docket Revisions

Categories of Revisions for Docket Update by Correction Code

Categories for Deletion of Facilities

(1) Small-Quantity Generator
(2) Not Federally Owned
(3) Formerly Federally Owned

(4) No Hazardous Waste Generated
(5) (This correction code is no longer used.)
(6) Redundant Listing/Site on Facility
(7) Combining Sites Into One Facility/ Entries Combined
(8) Does Not Fit Facility Definition
(9) (This correction code is no longer used.)
(10) (This correction code is no longer used.)
(11) (This correction code is no longer used.)
(12) (This correction code is no longer used.)
(13) (This correction code is no longer used.)
(14) (This correction code is no longer used.)

Categories for Addition of Facilities

(15) Small-Quantity Generator With Either a RCRA 3016 or CERCLA 103 Reporting Mechanism
(16) One Entry Being Split Into Two/ Federal Agency Responsibility Being Split
(17) New Information Obtained Showing That Facility Should Be Included
(18) Facility Was a Site on a Facility That Was Disbanded; Now a Separate Facility
(19) Sites Were Combined Into One Facility
(19A) New Facility

Categories for Corrections of Information About Facilities

(20) Reporting Provisions Change
(20A) Typo Correction/Name Change/ Address Change
(21) Changing Responsible Federal Agency (New Responsible Federal Agency Must Submit proof of previously performed PA, which is subject to approval by EPA)
(22) Changing Responsible Federal Agency and Facility Name (New Responsible Must Submit proof of previously performed PA, which is subject to approval by EPA)
(23) New Reporting Mechanism Added at Update
(24) Reporting Mechanism Determined to Be Not Applicable After Review of Regional Files

Note: Further information on definitions of categories can be obtained by calling Augusta K. Wills, the HQ Docket Coordinator at (202) 564–2468.

FEDERAL AGENCY HAZARDOUS WASTE COMPLIANCE DOCKET #17—ADDITIONS

Facility name	Address	City	State	Zip code	Agency	Reporting mechanism	Code
FWS—Stuttgart Army Airfield.	6 Miles N. of Stuttgart ...	Stuttgart	AR	72160	Interior	103c	19A
FWS—Arthur R. Marshall Loxahatchee National Wildlife Refuge—Boneyard Site.	10216 Lee Road	Boynton Beach ..	FL	33437–4796	Interior	3016	19A
FWS—Great White Heron National Wildlife Refuge–Navy Skeet Range.	Boca Chica Naval Air Station.	Key West	FL	33041	Interior	3016	19A
Cedar Rapids (EX) National Guard Target Range.	4 Miles N of Iowa City, 19 Miles S/SW of Cedar Rapids.	Cedar Rapids	LA	52401	Corps of Rapids Engineers, Civil.	103c	19A
Forbes (EX) Survival Training Annex.	5 Miles N/NW of Lyndon	Lyndon	KS	66451	Corps of Engineers, Civil.	103c	19A
Mcconnell Titan II–2	7 Mile N of El Dorado ...	El Dorado	KS	67042	Air Force	103c	19A
Mcconnell Titan II–8	9 Miles E of Winfield on U.S. Hwy 160.	Tesdale	KS	67156	Air Force	103c	19A
McConnell Titan II–12	2 Miles S of Conway Springs State Hwy 49.	Conway	KS	67031	Air Force	103c	19A
McConnell Titan II–15	2.5 Miles SE of Rago & 1/2 Mile E of Sta.	Rago	KS	67128	Air Force	103c	19A
McConnell Titan II–17	4 Miles NE of Kingman	Kingman	KS	67068	Air Force	103c	19A
McConnell Titan II–18	2 Miles W of St. Joe, E of Cheney Reserv.	St. Joe	KS	67543	Air Force	103c	19A
FWS—D'Arbonne National Wildlife Refuge.	11372 Hwy 143	Farmerville	LA	71241–0401	Interior	3016	19A
FWS—Upper Ouachita National Wildlife Refuge.	11372 Hwy 143	Farmerville	LA	71241–0401	Interior	3016	19A
FWS—Assabet River National Wildlife Refuge.	73 Weir Hill Road	Sudbury	MA	01776–1420	Interior	3016	19A
FWS—Nomans Land Island National Wildlife Refuge.	73 Weir Hill Road	Sudbury	MA	01776–1420	Interior	3016	19A
FWS—Oxbow National Wildlife Refuge.	73 Weir Hill Road	Sudbury	MA	01776–1420	Interior	3016	19A
Fork—Control	End of Hutschenreuter Rd.	Glen Arm	MD	21057	Defense	103c	19A
FWS—Aroostook National Wildlife Refuge.	97 Refuge Road	Limestone	ME	04750–9743	Interior	3016	19A
Jefferson Barracks (EX) Target Range.	90 Miles South of St. Louis 2 Miles SE of Arcadia.	Arcadia	MO	63621	Agriculture	103c	19A

FEDERAL AGENCY HAZARDOUS WASTE COMPLIANCE DOCKET #17—ADDITIONS—Continued

Facility name	Address	City	State	Zip code	Agency	Reporting mechanism	Code
Marquand (EX) Gap Filler Annex P–7OD.	NW 1/4 Section 18, T32N, R8E.	Marquand	MO	63655	Agriculture	103c	19A
Military Personnel Records Center (EX).	9700 Page Avenue	St Louis	MO	63132	General Services Administration.	103c	19A
FWS—Currituck National Wildlife Refuge.	P.O. Box 39	Knotts Island	NC	27950–0039	Interior	3016	19A
FWS—Great Bay National Wildlife Refuge.	100 Merrimac Drive	Newington	NH	03801–2903	Interior	3016	19A
FWS–Malheur NWR: Buena Vista Stn.	E of Hwy 205 at 35 Mi S of Burns, 25 Mi SE of Princeton T29S R31E, WM, Harney County.	Princeton	OR	97721	Interior	3016	19A
FWS—Culebra National Wildlife Refuge.	P.O. Box 190	Culebra	PR	00775	Interior	3016	19A
FWS—Desecheo National Wildlife Refuge.	P.O. Box 510	Boqueron	PR	00622–0510	Interior	3016	19A
FWS—Matagorda Island National Wildlife Refuge.	P.O. Box 100	Austwell	TX	77950–0100	Interior	3016	19A
Virginia Ordnance Works	Main Street	Glen Wilton	VA	24438	Agriculture	103c	19A
ANG—Four Lakes Station.	12414 Andrews Rd, T24N R42E S30.	Cheney	WA	99004	Air Force	103c	19A
FWS—Little Pend Oreille NWR: Landfill.	1310 Bear Creek Rd, 3.5 Mi S of Colville.	Colville	WA	99114	Interior	3016	19A
FWS—Turnbull NWR: Smith Road Site.	26010 S Smith Rd, 3.5 Mi S of Cheney.	Cheney	WA	99004	Interior	3016	19A
FWS—Umatilla NWR: Whitcomb Island Unit.	Whitcomb Isl, off Hwy 14, 2 Mi E of Whitcomb, 9 Mi W of Baterson, T5N R25E, WM, Benton County.	Paterson	WA	99345	Interior	3016	19A
FWS—Willapa NWR: SE Long Island Area Site.	SE Long Island, 8.5 Mi NE of Ilwaco +46 42 N, −123.933 W.	Ilwaco	WA	98624	Interior	3016	19A
FWS—Cokeville Meadows National Wildlife Refuge.	c/o Seedskadee National Wildlife Refuge, P.O. Box 700.	Green River	WY	82935–0700	Interior	3016	19A

FEDERAL AGENCY HAZARDOUS WASTE COMPLIANCE DOCKET UPDATE #17—DELETIONS

Facility name	Address	City	State	Zip code	Agency	Reporting mechanism	Code
Casmalia Resources	NTU Rd	Casmalia	CA	93429	EPA	103a 3010	2
San Gabriel Area 1 4 NPL Site.	San Gabriel Valley	Los Angeles	CA	90001		3010	2
New England Regional Laboratory.	60 Westview St	Lexington	MA	02173	EPA	3010 103a	2
Edward Hines Medical Center Hospital.	5th & Roosevelt Rd	Hines	IL	60141	Veterans Affairs	3010	1
Port Washington Post Office.	104 E Main	Port Washington	WI	53094	Postal Service	3010	4
DEA-Austin	3410 Far W Blvd #220	Austin	TX	78731	Justice	3010	4
DEA-Dallas	1880 Regal Row	Dallas	TX	75235	Justice	3010	4
Lackland Training Center	Ray Ellison Dr & Hwy 90	San Antonio	TX	78236	Air Force	3005 3010 3016	6

FEDERAL AGENCY HAZARDOUS WASTE COMPLIANCE DOCKET UPDATE #17—CORRECTIONS

Facility name	Address	City	State	Zip Code	Agency	Reporting mechanism	Code
FAA—Bettles Station	Bettles Airport 66°54′ N 151°41′ W.	Bettles	AK	99726	Transportation	103c 3016	20A
FAA—Bettles Station	Bettles Airport	Bettles	AK	99726	Transportation	103c 3016	
FAA—Farewell Station	T28N R25W S15&22 Seward Meridian.	Farewell	AK	99627	Transportation	3010 103c 3016	20A
FAA—Fairwell Station	62D30M24SN, 153D53M37SW.	McGrath	AK	99627	Transportation	3010 103c 3016	

FEDERAL AGENCY HAZARDOUS WASTE COMPLIANCE DOCKET UPDATE #17—CORRECTIONS—Continued

Facility name	Address	City	State	Zip Code	Agency	Reporting mechanism	Code
FAA—Sisters Island	T43S R62E S3 & T42S R62E S34, CRM.	Juneau	AK	99803	Transportation ...	103c	20A
FAA—Sisters Island	58d10M40SN, 135d15M24SW.	Juneau	AK	99803	Transportation ...	103c	
FAA—Strawberry Point ..	Point Bentinck Nav Aids, NE Hinchinbrook Isl, +60.3966° N, −146.0875° W.	Hinchinbrook Island.	AK	99574	Transportation ...	103c 3010	20A, 23
FAA—Strawberry Point ..	Point Bentinck Nav Aids	Cordova	AK	99574	Transportation ...	103c	
FWS—AK Maritime Nwr: Cape Yakak AWS Site.	Yakak Peninsula SW Adak Isl.	Adak	AK	99546	Interior	103c 3016	23
FWS—AK Maritime Nwr: Cape Yakak AWS Site.	Yakak Peninsula SW Adak Isl.	Adak	AK	99546	Interior	103c	
FWS—Alaska Maritime NWR: Agattu Island AWR/Nav Aid.	20 Mi SW of Shemya	Shemya	AK	99546	Interior	103c 3016	20A, 23
FWS—Alaska Maritime NWR: Agattu Island AWR/Nav Aid.	20 Mi SW of Eareckson AFB.	Shemya	AK	99546	Interior	103c	
FWS—Alaska Maritime NWR: Attu Island.	30 Mi NW of Eareckson AFB.	Shemya	AK	99546	Interior	103c 3016	23
FWS—Alaska Maritime NWR: Attu Island.	30 Mi NW of Eareckson AFB.	Shemya	AK	99546	Interior	103c	
FWS—Alaska Maritime NWR: Kiska Island.	300 Mi W of Atka	Atka	AK	99547	Interior	103c 3016	23
FWS—Alaska Maritime NWR: Kiska Island.	300 Mi W of Atka	Atka	AK	99547	Interior	103c	
FWS—Alaska Maritime NWR: Tanaga Island.	65 Mi W of Adak Naval Facility.	Adak	AK	99546	Interior	103c 3016	23
FWS—Alaska Maritime NWR: Tanaga Island.	65 Mi W of Adak Naval Facility.	Adak	AK	99546	Interior	103c	
FWS—Arctic NWR: Griffin Point Dewline Staging Site.	70d04M00SN, 142D54M00SW, 18 Mi E of City.	Kaktovik	AK	99747	Interior	103c 3016	23
FWS—Arctic NWR: Griffin Point Dewline Staging Site.	70d04M00SN, 142D54M00SW, 18 Mi E of City.	Kaktovik	AK	99747	Interior	103c	
FWS—Arctic NWR: Nuvagapak Dewline Site.	35 Mi E of Kaktovik	Kaktovik	AK	99747	Interior	103c 3016	23
FWS—Arctic NWR: Nuvagapak Dewline Site.	35 Mi E of Kaktovik	Kaktovik	AK	99747	Interior	103c	
Tongass NF: Bokan Mountain Mine AKA Ross Adams Mine.	Prince of Wales Is, 33 Mi SE of Cy.	Hydaburg	AK	99922	Agriculture	103c	20A
Tongass NF: Ross-Adams Mine.	Prince of Wales Island, 33 Mi SW of City.	Ketchikan	AK	99919	Agriculture	103c	
Coosa River Storage Annex.	4 Miles NE Hwy 202	Talladega	AL	35160	Army	103c	20A
Coosa River Storage Annex.	.....	Talladega	AL	35160	Army	103c	
FWS—Wheeler National Wildlife Refuge.	2700 Refuge Headquarters Road.	Decatur	AL	35603–5202	Interior	3016 103c	20A, 21
Wheeler National Wildlife Refuge.	PO Box 1643	Decatur	AL	35602	Army	3016 103c	
Gunter Annex	55 South Lemay Plaza ..	MAFB	AL	36112	Air Force	103c 3016 3010	20A
Gunter Air Force Station	U.S. 231 & Dalride Road	Montgomery	AL	36112	Air Force	103c 3016 3010	
Millwood Reservoir	Route 1	Ashdown	AR	71822	Corps of Engineers, Civil.	103c	20A
Millwood Resident Engineers Office.	Route 1	Ashdown	AR		Corps of Engineers, Civil.	103c	
BIA—Inspiration Cnsld. Copper-Oxhide Area.	Sec 22–28, 33–36, 2–4 T1N&S R14E.	Miami	AZ	85539	Interior	103c	20A
BLM—Inspiration Inspiration Con. Copper-Oxhide Area.	T1NR15ES2, 5, 13, 15, 18.	4 Mi W of	AZ	85501	Interior	103c	
BIA—Somerton Landfill	S of AZ 95 at 16th. St & Ave B.	Somerton	AZ	85350	Interior	103c	20A

FEDERAL AGENCY HAZARDOUS WASTE COMPLIANCE DOCKET UPDATE #17—CORRECTIONS—Continued

Facility name	Address	City	State	Zip Code	Agency	Reporting mechanism	Code
BIA—Somerton Landfill	S of AZ 95 at 16th St and Ave B.	Somerton	AZ		Interior	103c	
Luke Air Force Base	Litchfield & Glendale Roads.	Glendale	AZ	85309	Air Force	3005 3010 3016 103c	20A
Luke Air Force Base	Bounded by I–8 & Mexican Border.	Gila Bend	AZ	85337	Air Force	3005 3010 3016 103c	
WAPA—liberty Substation.	Tuthill Road And Broadway.	Buckeye	AZ	85326	Energy	3010 103a	20A
WAPA—liberty Substation.	Nr Buckeye	Buckeye	AZ	85326	Energy	3010 103a	
BLM—Rinconada Mine	T 30S, R 14E, Sec 21, S ½ Mt Diablo ME.	Paso Robles	CA	93446	Interior	103c 3016	20A
BLM—Rinconda Mine	S½, Sec 21, T30s, R14E, Mt Diablo.	San Luis Obispo County.	CA		Interior	103c 3016	
Energy Technology Engineering Center.	Santa Susana Mount—Top of Woolsey Canyon.	Simi Valley	CA	93064	Energy	3005 3016 3010 103c	20A
Energy Technology Engineering Center.	Santa Susana Mountain	Simi Hills	CA	93063	Energy	3005 3016 3010 103c	
Former ENGFLDACT West San Bruno.	900 Commodore Dr	San Bruno	CA	94066	Navy	103c	20A
Former NAVFAC Engineering Field Activity West.	900 Commodore Dr	San Bruno	CA	94066	Navy	103c	
Former MCAS El Toro	EEPB Fac Mgmt Dept	Santa Ana	CA	92709	Navy	3005 3010 3016 103c 103a	20A
El Toro Marine Corps Air Station.	EEPB Fac Mgmt Dept	Santa Ana	CA	92709	Navy	3005 3010 3016 103c 103a	
Former NAS Alameda	Atlantic Ave at Main St	Alameda	CA	94501	Navy	3005 3010 3016 103c 103a	20A
Alameda Naval Air Station.	W End of City	Alameda	CA	93550	Navy	3005 3010 3016 103c 103a	
Former NAS Moffett Field.	Hwy 101 at Stevens Creek.	Moffett Field	CA	94035	Navy	3005 3010 3016 103c 103a	20A
Moffett Field Naval Air Station.		Moffett Field	CA	94035	Navy	3005 3010 3016 103c 103a	
Former NAS Moffett Field—ANG 129th Cav.	129 ARRG/CC	Moffett Field	CA	94035	Navy	3010 103c 3016	20A
Moffett Field Air National Guard.	129 ARRG/CC	Sunnyvale	CA	94031	Navy	3010 103c 3016	
Former Naval Civil Engineering Laboratory.	NCBC	Port Hueneme	CA	93043	Navy	3010 103a 103c 3016	20A
Civil Engineering Laboratory.	NCBC	Port Hueneme	CA	93043	Navy	3010 103a 103c 3016	
Former Naval Housing Area—San Pedro.	25th St & El Anita Dr	San Pedro	CA	90732	Navy	103c	20A
Portsmouth Naval Housing Area.	25th St & El Anita Dr	San Pedro	CA		Navy	103c	
Former NAVFAC Centerville Beach.	Centerville Beach Rd	Ferndale	CA	95536	Navy	103c 3010 3016	20A
Centerville Beach Naval Facility.	Centerville Beach Rd	Ferndale	CA	95536	Navy	103c 3010 3016	
Former NOSC Azusa	Hwy 39	Azusa	CA	91702	Navy	3010 3016 103c	20A

FEDERAL AGENCY HAZARDOUS WASTE COMPLIANCE DOCKET UPDATE #17—CORRECTIONS—Continued

Facility name	Address	City	State	Zip Code	Agency	Reporting mechanism	Code
Azusa Naval Ocean Systems Center.	Hwy 39	Azusa	CA	91702	Navy	3010 3016 103c	
MCB Camp Pendleton	Bldg 2631	Camp Pendleton	CA	92055	Navy	3005 3010 3016 103c 103a	20A
Camp Pendleton Marine Corps Base.	Bldg 2631	Camp Pendleton	CA	92055	Navy	3005 3010 3016 103c 103a	
MCLB Barstow	3 Miles East of Barstow on I40.	Barstow	CA	92311	Navy	3005 3010 3016 103c 103a	20A
Barstow Marine Corps Logistics Base.	Barstow	Barstow	CA	92311	Navy	3005 3010 3016 103c 103a	
MCMWTC Bridgeport	Hwy 108 at Pickle Meadows.	Bridgeport	CA	93517	Navy	3010 103c 3016	20A
Bridgeport Marine Corps Mountain Warfare Training.	Pickle Meadows	Bridgeport	CA	93517	Navy	3010 103c 3016	
NAF El Centro	1605 3rd St-Bldg 214	El Centro	CA	92243	Navy	3005 3010 103c 3016 103a	20A
El Centro Naval Air Facility.	Rte 80	El Centro	CA	92234	Navy	3005 3010 103c 3016 103a	
Naval Postgraduate School-Annex.	1 Grace Hopper Ave	Monterey	CA	93943	Navy	3010	20A
Montery Naval Postgraduate School Annex.	1 Grace Hopper Ave	Monterey	CA	93940	Navy	3010	
NAVBASE Coronado-Amphibious Base.	Hwy 75 on Silver Strand	Coronado	CA	92118	Navy	3010 103c 3016 103a	20A
Coronado Naval Amphibious Base.	On Rte 75 on The Strand.	San Diego	CA	91255	Navy	3010 103c 3016 103a	
NAVCOMTELSTA San Diego-NRTF Dixon.	Radio Station Rd	Dixon	CA	95620	Navy	103c 3016	20A
Dixon Naval Radio Transmitting Facility.	Radio Station Rd	Dixon	CA	95620	Navy	130c 3016	
NAVWPNSTA Seal Beach-Concord Det.	10 Delta St	Concord	CA	94520	Navy	3005 3016 103c 3010	20A
Concord Naval Weapons Station.	10 Delta St	Concord	CA	94520	Navy	3005 3016 103c 3010	
NAVWPNSTA Seal Beach-Pomona Annex.	1675 Mission Blvd	Pomona	CA	91769	Navy	103c 3010	20A
Pomona Naval Industrial Reserve Ordnance Plant.	Pomona/Mission Boulevard.	Pomona	CA	91766	Navy	103c 3010	
Navy Gunnery Range Chocolate Mtn-Seal Camp.	3 Miles East of Niland	Niland	CA	92557	Navy	103c	20A
Chocolate Mtn Aerial Gunnery Range-Seal Camp Area.	Niland Nearest Town	Imperial County	CA	92557	Navy	103c	
Sandia National Laboratory.	7261 East Ave	Livermore	CA	94550	Energy	3005 3010 3016 103c	20A
Sandia National Laboratory.	7011 East Avenue	Livermore	CA	94550	Energy	3005 3010 3016 103c	
VA West Los Angeles Healthcare Center.	11296 Wilshire & Sawfelle Blvd.	Los Angeles	CA	90073	Veterans Affairs	103c 3010	20A

FEDERAL AGENCY HAZARDOUS WASTE COMPLIANCE DOCKET UPDATE #17—CORRECTIONS—Continued

Facility name	Address	City	State	Zip Code	Agency	Reporting mechanism	Code
Los Angeles Medical Center.	11296 Wilshire & Sawfelle Blvd.	Los Angeles	CA		Veterans Affairs	103c 3010	
White Point Former Nike Site.	Western & 25th Sts	San Pedro	CA	90732	Air Force	103c	20A
White Point Former Nike Site.	Western & 25th Sts	San Pedro	CA		Air Force	103c	
Hamilton Air Force Base	Hamilton Air Force Base	Novato	CA	94947	Air Force	103c	20A, 22
Hamilton Army Air Field	Hamilton Army Air Field	Novato	CA	94947	Army	103c	
BLM—South Fork Landfill.	T40nNR3E Sec 26	Monte Vista	CO	81144	Interior	103c	20A
BLM—South Fork Landfill.	T40NR3E Sec 26	Southfork	CO	81144	Interior	103c	
FWS—Bombay Hook National Wildlife Refuge.	2591 Whitehall Neck Road.	Smyrna	DE	19977–2912	Interior	103c 3016	20A, 23
FWS—Bombay Hook National Wildlife Refuge.	Route 1, Box 147	Smyrna	DE	19977	Interior	103c	
BLM—Olustee Dump	Hwy 90 & Olustee Battlefield R.	Olustee	FL	32072	Interior	103c	20A
BLM—Olustee Dump	Hwy 90 & Olustee Battlefield R.	Olustee	FL		Interior	103c	
Naval Complex Apra Harbor-Dental Center.	Apra Harbor Naval Complex.	Piti	GU	96925	Navy	3016 103c	20A, 23
Guam Naval Dental Clinic.	FPO	San Francisco	GU	96630–1670	Navy	3016	
Naval Housing S. Finegayan-Former CB Landfill.	Near Park Rd & Coral Tree Dr.	Dededo	GU	96929	Navy	103c	20A
Finegayan Housing Abandoned Dump.	Naval Communications Center.	S Finegayan	GU	96630	Navy	103c	
Navy PWC Guam-Former Piti Power Plant.	Piti Harbor	Piti	GU	96915	Navy	3005 3010 3016 103c	20A
Guam Naval Station	Navy Public Wks Ctr	Agana	GU	96630	Navy	3005 3010 3016 103c	
Marine Camp H.M. Smith.	Halawa Heights Headquarters-Aiea.	Aiea	HI	96701	Navy	3010 3016 103c	20A
Camp H.M. Smith	Halawa Heights Rd	Camp Smith	HI	96861	Navy	3010 3016 103c	
Naval Complex Pearl Harbor-Submarine Base.	Naval Submarine Base	Pearl Harbor	HI	96860	Navy	3010 103a 103c 3016	20A
Pearl Harbor Naval Submarine Base.		Pearl Harbor	HI	96860	Navy	3010 103a 103c 3016	
Saylorville Reservoir And Recreation Area.		Johnston	IA		Corps of Engineers, Civil.	103c	20A, 22
Polk County (EX) National Guard Target Range.			IA		Army	103c	
USA Fort Campbell	AFZB–FE–CE	Fort Campbell	KY	42223	Army	3005 3010 3016 103c	20A
HQ, 101st Airborne Div. (AASLT) Ft. Campbell.	HWY 41–A N at State Line.	Fort Campbell	KY	42223	Army	3005 3010 3016 103c	
VA Medical Center Alexandria.	Hwy 165 and HWY 71	Alexandria	LA	71306–9004	Veterans Affairs	3010 103c	20A, 23
Alexandria Medical Center.	Shreveport HWY 2.5m N	Alexandria	LA		Veterans Affairs	3010	
Hanscom Field/Hanscom Air Force Base.	66 ABW/CC, 120 Greenier Street.	Bedford	MA	01731	Air Force	3005 3010 3016 103c 103a	20A
Hanscom Field/Hanscom Air Force Base.	3245 ABG/CC Environmental Site 66CES4/CEVR 12th Grenier Street.	Bedford	MA	01731	Air Force	3005 3010 3016 103c 103a	

FEDERAL AGENCY HAZARDOUS WASTE COMPLIANCE DOCKET UPDATE #17—CORRECTIONS—Continued

Facility name	Address	City	State	Zip Code	Agency	Reporting mechanism	Code
FWS—Patuxent Research Refuge.	12100 Beech Forest Road.	Laurel	MD	20708–4036	Interior	3016 103c 3010	20A
FWS—Patuxent Wildlife Research Center.	Rt 197 & Powdermill Rd	Laurel	MD	20708	Interior	3016 103c 3010	
Naval Electronic Systems Eng Act St Inigoes.	Villa Road Off Rte 5	Saint Inigoes	MD	20684	Navy	3010 103c	20A
Saint Inigoes Naval Electronic System Eng Activity.	St Inigoes	Saint Inigoes	MD	20684	Navy	3010 103c	
FWS—Seal Island National Wildlife Refuge.	P.O. Box 1077	Calais	ME	04169	Interior	103c 3016	23
FWS—Seal Island National Wildlife Refuge.	P.O. Box 1077	Calais	ME	04169	Interior	103c	
Air Force (EX) Plant # 84.	Lambert Airport	St Louis	MO		Navy	103c	21
Air Force (EX) Plant # 84.	Lambert Airport	St Louis	MO	Air Force 84	103c.		
FWS—Bozeman Fish Technology Center.	4050 Bridger Canyon Road.	Bozeman	MT	59715–4050	Interior	3010 3016	20A, 23
FWS—Bozeman Fish Tech Center.	4050 Bridger Canyon Road.	Bozeman	MT	59715–8433	Interior	3010	
FWS—Red Rock Lakes National Wildlife Refuge.	27820 Southside Centennial Road.	Lima	MT	59739–9709	Interior	3010 3016	20A, 23
FWS—Red Rock Lakes National Wildlife Refuge.	Monida Star Rt, 28 Mi E	Lakeview	MT	59739	Interior	3016	
FWS—Clay County Waterfowl Production Area-McMurtrey Marsh.	P.O. Box 1686	Kearney	NE	68848–1686	Interior	103c 3016	20A, 23
FWS—Rainwater Basin Wetlands Management District.	P.O. Box 1686	Kearney	NE	68847	Interior	103c	
VA Asset Management Service.	152 Route 206 South	Hillsborough	NJ	08844	Veterans Affairs	103c 3010	20A
Hillsborough Supply Depot.	Route 206	Hillsborough Twp	NJ	08853	Veterans Affairs	103c 3010	
Utah Test & Training Range.	Immediately SW of Wendover.	Wendover	NV	89883	Air Force	103c	20A
Utah Test & Training Range.		Wendover	NV	89835	Air Force	103c	
FWS—Klamath Forest NWR: Toxaphene Cow Dip Pit.	T30S R10E S19 Willamette Meridian.	Chiloquin	OR	97624	Interior	103c 3016	23
FWS—Klamath Forest NWR: Toxaphene Cow Dip Pit.	T30S R10E S19 Willamette Meridian.	Chiloquin	OR	97624	Interior	103c	
Allegheny National Forest.	222 Liberty Street Box 847.	Warren	PA	16365	Agriculture	103c 3016	20A
Allegheny National Forest.	222 Liberty Street Box 847.	Warren	PA		Agriculture	103c 3016	
Former NAVAIRWARCEN Warminster—8 Waste Areas.	Jacksonville Road and Route 132.	Warminster	PA	18974	Navy	3005 3010 3016 103c	20A
Warminster Naval Air Warfare Center.	NAVFAC-NORTHDIV.code 114.	Warminster	PA	19112	Navy	3005 3010 3016 103c	
FWS—Erie National Wildlife Refuge.	11926 Wood Duck Lane	Guys Mills	PA	16327–9499	Interior	103c 3016	20A, 23
FWS—Erie National Wildlife Refuge.	Rd 1, Wood Duck Lane	Guys Mills	PA	16237	Interior	103c	
FWS—John Heinz National Wildlife Refuge at Tinicum.	2 International Plaza, Suite 104.	Philadelphia	PA	19113–1505	Interior	103c 3016	20A
FWS—John Heinz Natl Wildlife Refuge at Tinicum.	Scott Plaza 2, Suite 104	Philadelphia	PA	19113	Interior	103c 3016	

FEDERAL AGENCY HAZARDOUS WASTE COMPLIANCE DOCKET UPDATE #17—CORRECTIONS—Continued

Facility name	Address	City	State	Zip Code	Agency	Reporting mechanism	Code
Pittsburgh Naval Reactors Office.	P.O. Box 109	West Mifflin	PA	15122–0109	Energy	3005 3010 3016 103c	20A
Bettis Atomic Power Laboratory.	814 Pittsburgh McKeesport Blvd.	West Mifflin	PA	15122–0109	Energy	3005 3010 3016 103c	
FWS—Ninigret National Wildlife Refuge.	Shoreline Plaza, Route 1A, P.O. Box 307.	Charlestown	RI	02813–0307	Interior	3016 103c	20A
FWS—Ninigret National Wildlife Refuge.	P.O. Box 307	Charlestown	RI	02813	Interior	3016 103c	
FWS—Sachuest Point National Wildlife Refuge.	Shoreline Plaza, Route 1A, P.O. Box 307.	Charlestown	RI	02813–0307	Interior	103c 3016	20A, 23
FWS—Sachuest Point National Wildlife Refuge.	P.O. Box 307	Middletown	RI	02813	Interior	103c	
FWS—Trustom Pond National Wildlife Refuge.	Matunuck Road	Wakefield	RI	02879	Interior	103c 3016	20A, 23
FWS—Trustom Pond National Wildlife Refuge.	P.O. Box 307	Charlestown	RI	02813	Interior	103c	
Chattanooga Garage	412 East 10th St	Chattanooga	TN	37401	Tennessee Valley Authority.	103c	20A
Chattanooga Garage	412 East 10th St	Chattanooga	TN		Tennessee Valley Authority.	103c	
Anthony Federal Correctional Institution.	15 Mi W. of El Paso	Anthony	TX	79821	Justice	3010	20A
Anthony Federal Correctional Institution.	15 Mi W of El Paso	Anthony	TX	88021	Justice	3010	
Bureau of Engraving and Printing Western Currency Facility.	9000 Blue Mound Rd—1 Mile South FM.	Fort Worth	TX	76131	Treasury	3010 103c	20A, 23
Bureau of Engraving & Printing.	9000 Blue Mound Rd	Fort Worth	TX	76131	Treasury	3010	
Moore Air Base	Rte 3, Bld 6017, Box 1004.	Mission	TX	78539	Agriculture	103c 3016	20A
Moore Air Base	6 Miles North of Alton Texas, Route 6017.	Edinburg	TX	78539	Agriculture	103c 3016	
Midway Island Naval Air Station.	USNAVY NAS Midway	Midway Islands	UM	96614	Navy	3016 103a 103c	20A
Midway Island Naval Air Facility.	FPO	San Francisco	MQ	96614–1200	Navy	3016 103a 103c	
Green River Launch Complex.	1.2 Mi SE of Green River.	Green River	UT	84525	Army	103c	20A
Green River Launch Complex.	1 Mi SE of Town	Green River	UT	84523	Army	103c	
Tooele Army Depot (North Area).	3 Mi S of Tooele on Hwy 36.	Tooele	UT	84074	Army	103c 3010	23
Tooele Army Depot (North Area).	3 Mi S of Tooele on Hwy 36.	Tooele	UT	84074	Army	103c	
Central Intelligence Agency Headquarters.	Route 123	McLean	VA	22101	CIA	3010 103c	20A, 23
Central Intelligence Agency Headquarters.	Route 123	Washington	DC	20505	CIA	3010	
Defense Mapping Agency.	925 Springvale Road	Great Falls	VA	22066	Defense	103c	20A, 22
Herndon Site	925 Springvale Road	Herndon	VA	22070	Army	103c	
FWS—Eastern Shore of Virginia National Wildlife Refuge.	5003 Hallet Circle	Cape Charles	VA	23310–1128	Interior	3016 103c 3010	20A
FWS—Eastern Shore of Virginia Natl Wildlife Refuge.	RFD 1, Box 122b	Cape Charles	VA	23310	Interior	3016 103c 3010	
FWS—Fishermans Island National Wildlife Refuge.	Fisherman Island	Cape Charles	VA	23310–1128	Interior	103c 3016	20A, 23
FWS–Fishermans Island National Wildlife Refuge.	RFD 1, Box 122b	Cape Charles	VA	23310	Interior	103c	

FEDERAL AGENCY HAZARDOUS WASTE COMPLIANCE DOCKET UPDATE #17—CORRECTIONS—Continued

Facility name	Address	City	State	Zip Code	Agency	Reporting mechanism	Code
FWS—Plum Tree Island National Wildlife Refuge.	4005 Sandpiper Road ...	Virginia Beach ...	VA	23456–4347	Interior	103c 3016	20A, 23
FWS—Plum Tree Island National Wildlife Refuge.	P.O. Box 6286	Virginia Beach ...	VA	23456	Interior	103c	
FWS—Necedah Wildlife Refuge.	W7996 20th Street West	Necedah	WI	54646–7531	Interior	3010 3016	20A, 23
FWS—Necedah Wildlife Refuge.	W7996 20th W	Necedah	WI	54646	Interior	3010	
BLM—Cody Landfill	1 Mile West of Hwy 120—SO of Cody.	Cody	WY	82414	Interior	103c	20A
BLM—Cody Landfill	T52NR101WSEC20	Cody	WY		Interior	103c	
Hoe Creek Underground Coal Gasification Project.	W½ SW¼ T47N R72W Sec 7.	Gillette	WY	82716	Energy	103c 3016	20A
Hoe Creek Underground Coal Gasification Project.	531 Hoe Creek Road	Gillette	WY	82717	Energy	103c 3016	

FEDERAL AGENCY HAZARDOUS WASTE COMPLIANCE DOCKET UPDATE #17—NFRAP STATUS CHANGES

Facility name	Address	City	State	Zip Code	NFRAP status	Agency	Reporting mechanism
FS—Tongass NF: Tonka Log Transfer Facility.	7.75 Mi SW of Petersburg	Petersburg ...	AK	99833	NFRAP	Agriculture	3010
FWS—AK Maritime Nwr: Cape Yakak AWS Site.	Yakak Peninsula SW Adak Isl.	Adak	AK	99546	NFRAP	Interior	103c 3016
Gunter Annex	55 South Lemay Plaza	MAFB	AL	36112	NFRAP	Air Force	103c 3016 3010
Muscle Shoals Power Service Center.	AL Hwy 133	Muscle Shoals.	AL	35660	Undetermined	Tennessee Valley Authority	3005 3010 3016 103a 103c
Barry M. Goldwater Air Force Range.	.....	Phoenix	AZ	85309	NFRAP	Air Force	103c
Golden Falcon Company ..	23rd St./1M West of Ave B	Yuma	AZ	85364	NFRAP		103c
Luke Air Force Base	Litchfield & Glendale Roads.	Glendale	AZ	85309	NFRAP	Air Force	3005 3010 3016 103c
Beale Air Force Base	6451 B St	Beale	CA	95903	NFRAP	Air Force	3005 3010 103c 3016 103a
BLM—Adin Transfer Station.	1 Mi SE of Adin; T.39N, R9E, Sec 27.	Adin	CA	96006	NFRAP	Interior	103c 3016
BLM—Kern Valley Sanitary Landfill.	T25S, R33E, N½ SW¼ Sec 35, MDM.	Kernville	CA	93238	NFRAP	Interior	103c 3016
BLM—Needles Landfill	T89R25ESec18	Needles	CA	92363	NFRAP	Interior	103c
BLM-Nipton Unauthorized Landfill.	1 Mi NW of Nipton	Nipton	CA	92624	NFRAP	Interior	103c
Camp Parks Communication Annex.	6594 ABS/CC Onizuka Air Force Base.	Pleasanton ..	CA	94088	NFRAP	Air Force	3010 103c
Campbell Postal Service ...	1587 Dell Avenue	Campbell	CA	95008	NFRAP	Postal Service	103c
Former NAVFAC Centerville Beach.	Centerville Beach Road	Ferndale	CA	95536	NFRAP	Navy	103c 3010 3016
NAF El Centro	1605 3rd St-Bldg 214	El Centro	CA	92234	NFRAP	Navy	3005 3010 103c 3016 103a
Former NAS Moffett Field-ANG 129th Cav.	129 ARRG/CC	Moffett Field	CA	94035	NFRAP	Navy	3010 103c 3016
Former Naval Housing Area—San Pedro.	25th St & El Anita Dr	San Pedro ...	CA	90732	NFRAP	Navy	103c
Fort Hunter Liggett	Fort Hunter Liggett	Jolon	CA	93928	NFRAP	Army	3005 3010 3016 103c
FS-Golden Jubilee Mine	T37N R8W S4 NE¼	Trinity Center	CA	96091	NFRAP	Agriculture	103c

FEDERAL AGENCY HAZARDOUS WASTE COMPLIANCE DOCKET UPDATE #17—NFRAP STATUS CHANGES—Continued

Facility name	Address	City	State	Zip Code	NFRAP status	Agency	Reporting mechanism
Geological Survey	345 Middlefield Road	San Mateo	CA	94025	NFRAP	General Services Administration	103c 3010
Goldstone Tracking Facility	36 Mi N of Barstow @ Ft Irwin.	Barstow	CA	92311	NFRAP	Nasa	103c 3010 d
HL Dryden Flight Research Facility.	PO Box 273	Edwards	CA	93523	NFRAP	Air Force	3005 3010 3016 103c 103a
Lawrence Livermore National Laboratory—Camp Parks.	Camp Parks	Pleasanton	CA	94566	NFRAP	Army	3010 103c
Los Angeles Air Force Base Lawndale Annex.	6592 ABG/CC 14724 S Aviation Blvd.	Hawthorn	CA	90260	NFRAP	Air Force	103c
Menlo Park Medical Center	795 Willow Rd	Menlo Park	CA	94025	NFRAP	Veterans Affairs	3010 103c
Mt. Hebron Work Center	T46N R7E Sec 32	Macdoel	CA	96058	NFRAP	Agriculture	103c
Naval Postgraduate School	1 University Cir	Monterey	CA	93943	NFRAP	Navy	3010 3016 103a 103c
NAVWPNSTA Seal Beach—Pomona Annex.	1675 Mission Blvd	Pomona	CA	91769	NFRAP	Navy	103c 3010
Navy Gunnery Range Chocolate Mtn—Seal Camp.	3 Miles East of Niland	Niland	CA	92557	NFRAP	Navy	103c
Novato Housing Facility	Branch Hsg Office Bldg 1000.	Novato	CA	94939	NFRAP	Navy	3010 3016 103c
NPS—El Portal Barium Tailings.	Int of Forest & Barium Mine Rd.	El Portal	CA	95318	NFRAP	Interior	103c
NPS—Yosemite	Yosemite Natl Park	Yosemite	CA	95389	NFRAP	Interior	3010 103c
Ozol Defense Fuel supply Center.	700 Carquinez Scenic Drive.	Martinez	CA	94553	NFRAP	Defense	3010 3016 103c
Point Arena Air Force Station.	26 ADS/DE	Pt Arena AFS.	CA	95468	NFRAP	Air Force	3016 103c
Salton Sea Test Base	Hwy 86	Salton City	CA	92275	Undetermined	Navy	103c 3005 3010
San Diego Naval Station	Bldg 3275 PO Box 113	San Diego	CA	92136	NFRAP	Navy	3005 3010 3016 103c 103a
San Francisco Camspac	525 Mesa Road	Bolinas	CA	92956	NFRAP	Transportation	3010 103c
San Pedro Defense Fuel Support Point.	3171 N. Gaffey Street	San Pedro	CA	90731	NFRAP	Defense Logistics Agency	3010 3016 103c 103a
Sierra NF: Big Creek Pesticide Building.	T8S, R25E S28 SW1\4	Big Creek	CA	93605	NFRAP	Agriculture	103c
Singer Education Division	1325 Iris Ave Bldg 60	Imperial Beach.	CA	92032	NFRAP	Navy	3010 103c
Tupman Naval Petroleum Reserve #1.	Elk Hills, PO Box 11	Tupman	CA	93276	NFRAP	Energy	3016 103c 3010 3005
VA West Los Angeles Healthcare Center.	11296 Wilshire & Sawfelle Blvd.	Los Angeles	CA	90073	NFRAP	Veterans Affairs	103c 3010
Vandenberg Air Force Base.	1 STRAD/ET	Lompoc	CA	93436	NFRAP	Air Force	3005 3010 3016 103c 103a
WAPA—Tracy Pump & Substation.	Mountainhouse and Kelsa Roads.	Tracy	CA	95376	NFRAP	Energy	103c 3010 3016
White Point Former Nike Site.	Western & 25th Sts	San Pedro	CA	90732	NFRAP	Air Force	103c
BLM—South Fork Landfill	T40N R3E Sec 26	Monte Vista	CO	81144	NFRAP	Interior	103c
BR—Taylor Park Reservoir	T145 R93 W Gunnison NF Rd 742.	CO	81230	NFRAP	Interior	103a 103c	
Fort Morgan Substation	Intersection of I–76 & Co Hwy 52.	Fort Morgan	CO	80701	NFRAP	Energy	103c

FEDERAL AGENCY HAZARDOUS WASTE COMPLIANCE DOCKET UPDATE #17—NFRAP STATUS CHANGES—Continued

Facility name	Address	City	State	Zip Code	NFRAP status	Agency	Reporting mechanism
Water & Power Resources	Denver Federal Center Bldg 56.	Denver	CO	80225	NFRAP	General Services Administration	103c
BLM—Olustee Dump	Hwy 90 & Olustee Battlefield R.	Olustee	FL	32072	NFRAP	Interior	103c
Miami Coast Guard Air Station.	Opa Locka Airport	Opa Locka	FL	33054	NFRAP	Transportation	103c 3010
Osceola National Forest Site 2.	North of Highway 100	Lake City	FL	32055	NFRAP	Agriculture	3016 103c
Osceola National Forest Site 3.	Cortez Road, South of Highway 90.	Lake City	FL	32055	NFRAP	Agriculture	3016 103c
Osceola National Forest Site 4.	West of Dirt Road, Off Route 772.	Lake City	FL	32055	NFRAP	Agriculture	3016 103c
Osceola National Forest Site 5.	Hwy 90 to Osceola Forest Office.	Lake City	FL	32055	NFRAP	Agriculture	3016 103c
Osceola National Forest Site 6.	South of Hwy 90 on Possum Trot Road.	Lake City	FL	32055	NFRAP	Agriculture	3016 103c
Navy PWC Guam—Former Piti Power Plant.	Piti Harbor	Piti	GU	96915	NFRAP	Navy	3005 3010 3016 103c
Santa Rita Naval Magazine	Rte 5	Santa Rita	GU	96915	NFRAP	Navy	3005 3010 3016 103c
Sasa Valley Fuel Depot	Apra Hbr	Piti	GU	96630	NFRAP	Navy	103c
Tenjo Vista Oily Solid Waste Disposal.	Marine Dr	Piti	GU	96630	NFRAP	Navy	103c
Barbers Point Public Works Center.	Public Works Center	Barbers Point	HI	96862	NFRAP	Navy	3005 3010 103c
Kaena Point Satelite Tracking Station.	33 Mi NW of Honolulu on Rte 930.	Waianae	HI	96792	NFRAP	Air Force	103c 3016
Kapalama Military Reservation.	Sand Island Access Road	Oahu Island	HI	96898	NFRAP	Army	103c
Kilauea Military Reservation.	Highway 11, 28 M Marker	Hawaii National Park.	HI	96718	NFRAP	Army	103c
Kokee Air Force Station	Kokee State Park	Waimea	HI	96796	NFRAP	Air Force	103c 3016
Marine Camp H.M. Smith	Halawa Heights Headquarters—Aiea.	Aiea	HI	96701	NFRAP	Navy	3010 3016 103c
Pacific Missile Range Facility.	Pacific Missile Range Facility.	Kekaha	HI	96752	NFRAP	Navy	3005 3010 3016 103c
Pearl Harbor Fleet Training Group.	1430 South Ave	Pearl Harbor	HI	96860	NFRAP	Navy	3010 103c
Punamano Air Force Station.	28 Mi NNE Honolulu on Rte 83.	Kahuku	HI	96731	NFRAP	Air Force	103c 3016
Shore Intermediate Maintenance Activity.		Pearl Harbor	HI	96860	NFRAP	Navy	3005 3010 3016 103c
FS—Targhee NF: Chemical Warfare Service Test Site.	Fremont County	Island Park	ID	83429	NFRAP	Agriculture	103c
Louisiana Veterans Affairs Medical Center.	Hwy 165 And Hwy 71	Alexandria	LA	71306–9004	NFRAP	Veterans Affairs	3010 103c
Hanscom Field/Hanscom Air Force Base.	3245 ABG/CC Environmental Site 66CES4/ CEVR 12th Grenier Street.	Bedford	MA	01731	NFRAP	Air Force	3005 3010 3016 103c 103a
Naval Electronic Systems Eng Act St Inigoes.	Villa Road Off Rte 5	Saint Inigoes	MD	20684	NFRAP	Navy	3010 103c
Hiawatha NF: Bay Mills Landfill.	3 Mi NW of Brimley	Superior Township.	MI	49829	NFRAP	Agriculture	103c
Concrete Missile Early Warning Station.	Det 1 57 AD/DE	Concrete	ND	58221	NFRAP	Air Force	103c 3010 3005
Garrison Dam & Lake Sakakawea.	T146N R84W Sec 6	Riverdale	ND	58545	NFRAP	Corps of Engineers, Civil	103c
BLM—Monite Dynamite Site.	T20N R20E S28 SW¼ MDW.	Sparks	NV	89436	NFRAP	Interior	103c 3010

FEDERAL AGENCY HAZARDOUS WASTE COMPLIANCE DOCKET UPDATE #17—NFRAP STATUS CHANGES—Continued

Facility name	Address	City	State	Zip Code	NFRAP status	Agency	Reporting mechanism
Boulder Cy Engineering Lab (BR-Date Street Complex).	500 Date St	Boulder	NV	89005	NFRAP	Interior	3005 3010 103c
Hawthorne Army Ammunition Plant.	Hwy 95	Hawthorne	NV	89416	NFRAP	Army	3005 3010 3016 103c
Utah Test & Training Range.	Immediately SW of Wendover.	Wendover	NV	89883	NFRAP	Air Force	103c
Pittsburgh Naval Reactors Office.	P.O. Box 109	West Mifflin	PA	15122–0109	NFRAP	Energy	3005 3010 3016 103c
FWS—Trustom Pond National Wildlife Refuge.	Matunuck Road	Wakefield	RI	02879	NFRAP	Interior	103c 3016
Oahe Dam	Oahe Power Plant	Pierre	SD	57501	NFRAP	Corps of Engineers, Civil	103a 3010 103c
WAPA—Watertown Substation.	1 Mi. E. of I–29	Watertown	SD	57201	NFRAP	Energy	3010 103c 3016
Chattanooga Garage	412 East 10th St	Chattanooga	TN	37401	NFRAP	Tennessee Valley Authority	103c
Knoxville Garage	4216 Greenway	Knoxville	TN	37902	NFRAP	Tennessee Valley Authority	103c 3010 3005
Carswell Air Force Base	1510 Chenault Ave	Fort Worth	TX	76127	NFRAP	Navy	3005 3010 3016 103c 103a
Corpus Christi Coast Guard Depot.	1201 Navigation Blvd	Corpus Christi.	TX	78407	NFRAP	Transportation	3010 103c
Lake Lavon—St Paul—Site 2.	S End Rolling Meadows St	Wylie	TX	75098	Undetermined	Corps of Engineers, Civil	103c 3010
Fort Douglas (Fort Carson Subinstallation).	AFZC–D–DEH	Salt Lake City.	UT	84113	NFRAP	Army	103c
Central Intelligence Agency Headquarters.	Route 123	McLean	VA	22101	NFRAP	CIA	3010 103c
FWS—Fisherman Island National Wildlife Refuge.	Fisherman Island	Cape Charles.	VA	23310–1128	NFRAP	Interior	103c 3016

[FR Doc. 03–17614 Filed 7–10–03; 8:45 am]
BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–7527–3]

Public Water System Supervision Program Revision for the State of South Carolina

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: Notice is hereby given that the State of South Carolina is revising its approved Public Water System Supervision Program. South Carolina has adopted drinking water regulations for the Filter Backwash Recycling Rule. EPA has determined that the State Filter Backwash Recycling Rule meets all minimum federal requirements, and is no less stringent than the corresponding federal regulations. Therefore, EPA has tentatively decided to approve the State program revisions.

All interested parties may request a public hearing. A request for a public hearing must be submitted by August 11, 2003 to the Regional Administrator at the address shown below. Frivolous or insubstantial requests for a hearing may be denied by the Regional Administrator. However, if a substantial request for a public hearing is made by August 11, 2003, a public hearing will be held. If no timely and appropriate request for a hearing is received and the Regional Administrator does not elect to hold a hearing on his own motion, this determination shall become final and effective on August 11, 2003. Any request for a public hearing shall include the following information: (1) The name, address, and telephone number of the individual, organization, or other entity requesting a hearing. (2) A brief statement of the requesting person's interest in the Regional Administrator's determination and of information that the requesting person intends to submit at such hearing. (3) The signature of the individual making the request; or, if the request is made on behalf of an organization or other entity, the signature of a responsible official of the organization or other entity.

ADDRESSES: All documents relating to this determination are available for inspection between the hours of 8 a.m. and 4:30 p.m., Monday through Friday, at the following offices:

South Carolina Department of Health and Environmental Control, Bureau of Water, 2600 Bull Street, Columbia, South Carolina 29201.

Environmental Protection Agency, Region 4, Drinking Water Section, 61 Forsyth Street, SW., Atlanta, Georgia 30303.

FOR FURTHER INFORMATION CONTACT: Janine Morris, EPA Region 4, Drinking Water Section at the Atlanta address given above (telephone 404–562–9480).

Authority: (Section 1401 and section 1413 of the Safe Drinking Water Act, as amended (1996), and 40 CFR part 142).

Dated: July 2, 2003.

J.I. Palmer, Jr.,

Regional Administrator, EPA Region 4.

[FR Doc. 03–17615 Filed 7–10–03; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL RESERVE SYSTEM

Change in Bank Control Notices; Acquisition of Shares of Bank or Bank Holding Companies

The notificants listed below have applied under the Change in Bank Control Act (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire a bank or bank holding company. The factors that are considered in acting on the notices are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The notices are available for immediate inspection at the Federal Reserve Bank indicated. The notices also will be available for inspection at the office of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank indicated for that notice or to the offices of the Board of Governors. Comments must be received not later than July 25, 2003.

A. Federal Reserve Bank of St. Louis (Randall C. Sumner, Vice President) 411 Locust Street, St. Louis, Missouri 63166–2034:

1. Suzanne M. Rhea, Somerville, Tennessee; to retain voting shares, along with Reuben S. Rhea, Sr., Reuben S. Rhea, Jr., and the Whitney Burnette Rhea Husband's Trust, all of Somerville, Tennessee, of Moscow Bancshares, Inc., Moscow, Tennessee, and thereby indirectly retain voting shares of The Bank of Moscow, Moscow, Tennessee.

B. Federal Reserve Bank of Kansas City (James Hunter, Assistant Vice President) 925 Grand Avenue, Kansas City, Missouri 64198–0001:

1. Sandra Kathleen Morris, Tulsa, Oklahoma; to retain control of Green Country Bancorporation, Inc., Ketchum, Oklahoma, and thereby indirectly retain voting shares of The First State Bank, Ketchum, Oklahoma.

Board of Governors of the Federal Reserve System, July 7, 2003.

Robert deV. Frierson,

Deputy Secretary of the Board.

[FR Doc. 03–17540 Filed 7–10–03; 8:45 am]

BILLING CODE 6210–01–S

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR Part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The applications listed below, as well as other related filings required by the Board, are available for immediate inspection at the Federal Reserve Bank indicated. The application also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)). If the proposal also involves the acquisition of a nonbanking company, the review also includes whether the acquisition of the nonbanking company complies with the standards in section 4 of the BHC Act (12 U.S.C. 1843). Unless otherwise noted, nonbanking activities will be conducted throughout the United States. Additional information on all bank holding companies may be obtained from the National Information Center website at www.ffiec.gov/nic/.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than August 4, 2003.

A. Federal Reserve Bank of Richmond (A. Linwood Gill, III, Vice President) 701 East Byrd Street, Richmond, Virginia 23261–4528:

1. The South Financial Group, Inc., Greenville, South Carolina; to acquire 9.9 percent of the voting shares of Florida Banks, Inc., Jacksonville, Florida, and thereby indirectly acquire Florida Bank, National Association, Tampa, Florida.

2. The South Financial Group, Inc., Greenville, South Carolina; to acquire 100 percent of the voting shares of MountainBank Financial Corporation, Hendersonville, North Carolina, and thereby indirectly acquire MountainBank, Hendersonville, North Carolina, and Community National Bank, Pulaski, Virginia.

B. Federal Reserve Bank of Dallas (W. Arthur Tribble, Vice President) 2200 North Pearl Street, Dallas, Texas 75201–2272:

1. Tradition Bancshares, Inc., Houston, Texas, and Tradition Bancshares of Delaware, Inc., Wilmington, Delaware; to become bank holding companies by acquiring Tradition Bank, Houston, Texas, and First National Bank of Bellaire, Houston, Texas.

Board of Governors of the Federal Reserve System, July 7, 2003.

Robert deV. Frierson,

Deputy Secretary of the Board.

[FR Doc. 03–17541 Filed 7–10–03; 8:45 am]

BILLING CODE 6210–01–S

FEDERAL RETIREMENT THRIFT INVESTMENT BOARD

Sunshine Act Notice

TIME AND DATE: 9 a.m. (EDT),

PLACE: 4th Floor, Conference Room, 1250 H Street, NW., Washington, DC

STATUS: Parts will be open to the public and parts closed to the public.

MATTERS TO BE CONSIDERED:

Parts Open to the Public

1. Approval of minutes of June 16, 2003, Board member meeting.

2. Executive Director's report.

3. Status of new record keeping system.

Parts Closed to the Public

4. Discussion of personnel matters (closed portion of meeting).

5. Discussion of pending litigation (closed portion of meeting).

6. Discussion of draft request for proposals for audit services (closed portion of meeting).

FOR FURTHER INFORMATION CONTACT: Thomas J. Trabucco, Director, Office of External Affairs, (202) 942–1640.

Dated: July 9, 2003.

Elizabeth S. Woodruff,

Secretary to the Board, Federal Retirement Thrift Investment Board.

[FR Doc. 03–17749 Filed 7–9–03; 2:15 pm]

BILLING CODE 6760–01–M

GENERAL SERVICES ADMINISTRATION

[2003–N02]

E-Authentication Policy for Federal Agencies; Request for Comments

AGENCY: Office of Electronic Government and Technology, GSA.

ACTION: Notice of policy and request for comments.

SUMMARY: The General Services Administration, in coordination with the Office of Management and Budget (OMB) request comments on the attached draft policy on E-Authentication for Federal Agencies. GSA has coordinated this draft policy with OMB and will work closely with OMB in reviewing comments and issuing the final policy. In this draft policy, GSA is requiring that agencies implement this E-Authentication Policy, which establishes four assurance levels to create a Governmentwide standard framework for determining what is required to access a particular Government transaction online.

DATES: To ensure consideration of comments, comments must be in writing and received by GSA no later than August 11, 2003.

ADDRESSES: Comments on this notice should be addressed to Ms. Von Harrison, General Services Administration; Office of Electronic Government and Technology (MEI), Washington, DC 20405. You are encouraged to submit these comments by facsimile to (202) 501–6455, or by electronic mail to *egov.taskforce@gsa.gov.*

FOR FURTHER INFORMATION CONTACT: Ms. Von Harrison, General Services Administration, Office of Electronic Government and Technology (MEI), Washington, DC 20405; or by phone at (202) 273–0721.

SUPPLEMENTARY INFORMATION: As required by the Government Paperwork Elimination Act of 1998 (Public Law 105–277), most transactions currently accomplished by filing a Government paper form will be converted to an electronic format. These transactions will require some type of identity verification or authentication before taking place. It is also important that these electronic transactions incorporate the appropriate level of security. This attached GSA policy guidance provides agencies with a policy for the use of electronic authentication (or e-authentication) in electronic transactions. As the Federal Government works to expand the use of information technology and e-government, trust in electronic transactions is especially critical.

This memorandum establishes a four level approach for authentication to ensure trustworthy electronic transactions and to fulfill Federal privacy and information security requirements. These four levels reflect an increasing degree of confidence in the identity presented and represent a range of authentication technologies. This guidance will promote for the public—

- Use of a standard set of criteria for assessing e-government transactions authentication requirements;
- Consistent terminology when discussing authentication and levels of assurance;
- Secure, easy-to-use, and consistent method for managing identity in electronic transactions with the Government;
- Burden reduction in Government services and Government filings;
- Reuse of credentials for access to multiple Government services;
- Clearly understood criteria for access to particular Government services; and
- Protection against fraud in online transactions with the Government.

Having a consistent e-authentication process and policy guidance will enable Federal Agencies to—

- Reduce authentication system development and acquisition costs, and reallocate labor resources used to develop such systems;
- Reduce the burden on the public in complying with repeated, duplicate or inconsistent processes of identity proofing;
- Make consistent authentication decisions;
- Promote public trust in the use of online service delivery;
- Use existing and future e-authentication processes, within their organizations or those that are available Governmentwide; and
- Reduce the number and type of electronic credentials that Federal employees, citizens, and businesses need to conduct business electronically with the Government.

This guidance updates the Procedures and Guidance for Implementing the Government Paperwork Elimination Act (GPEA) issued by the Office of Management and Budget (OMB), which requires agencies to provide the option for electronic filing and electronic signature capabilities for Government activities and services unless it is not practicable to do so by October 2003. The GPEA implementation guidance (found at: *http://www.whitehouse.gov/omb/memoranda/m00–10.html,* April 25, 2000), provided agencies with guidance on the risk factors agencies should consider in planning and implementing electronic transactions. This e-authentication policy updates the GPEA guidance to take in account current e-authentication practices, including the impacts of the E-Authentication E-Government Initiative and recent National Institute of Standards and Technology (NIST) standards. NIST will be issuing companion technical guidance on this issue.

This guidance reflects substantial work of the E-Authentication Initiative and the Federal CIO Council in FY 2003. Accordingly, CIOs are responsible for assuring all agencies or cross agency teams that implemented electronic authentication solutions or are planning to use shared authentication services are applying this policy.

All existing transactions/systems which require authentication of their users must complete an e-authentication risk assessment and be categorized into one of the described assurance levels by September 15, 2005. Agencies should complete the e-authentication risk assessment process in the following order:

- The E-Government Initiatives (who have already started the process described in this guidance) must be completed by October 1, 2003.
- Systems classified as ''major'' should be completed by September 15, 2004.
- New authentication solutions should begin to be categorized within 90 days of the completion of the final E-Authentication Technical Guidance.

The results of the authentication risk assessment must be made publicly available through the agency Web site, the **Federal Register**, or other means (*e.g.*, upon request). As part of the E-Authentication Initiative, E-Authentication will post the results of the assessments at a central location to allow for public access. In addition, the Business Compliance One Stop Initiative will be working with agencies' applications that concern small businesses. Agencies will be asked to report on their process as part of the requirements of Section 203 of the E-Government Act in the annual E-Government Act report due annually on September 15th beginning in 2004. Your cooperation and comments are appreciated.

Dated: July 8, 2003.

G. Martin Wagner,

Associate Administrator for Governmentwide Policy.

Draft E—Authentication Policy for Federal Agencies

Section 1: Introduction
Section 2: Assurance Levels
Section 3: Determining Assurance for Credential Service Providers
Section 4: Implementing an Authentication Process
Section 5: Effective Dates of Guidance

1. Introduction

1.1. Summary

• This guidance should be applied to all Federal electronic transactions requiring authentication, except those that are national security systems as defined in 44 U.S.C. 3542(b)(2).

• This guidance does *not* stipulate which technology solutions should be implemented for each assurance level. The Department of Commerce's National Institute for Standards and Technology (NIST) is developing complementary e-authentication technical guidance that will be used by agencies to determine appropriate technology solutions, based on the process described in this guidance.

• Agencies are required to review existing and categorize new electronic transactions to ensure that these transactions comply with this guidance.

• As detailed in Section 9c of OMB's GPEA guidance, agencies should continue to minimize the likelihood of denial or repudiation of the information individuals transmit electronically. As an element of assessing the risks that are relevant to the required assurance level, agencies must consider how they plan to minimize the likelihood of repudiation by ensuring the user's approval of the information transmitted in electronic transactions. General guidance on minimizing the likelihood of repudiation is included in Section 8c of the OMB Procedures and Guidance on Implementing GPEA.

• This guidance does not directly apply to authorization. Authentication focuses on establishing a person's identity, based on the reliability of the credential he or she offers; while authorization focuses on what actions that identity, at that level of assurance, is permitted to do. Decisions concerning authorization are and should remain the purview of the electronic business process owner.

• Authentication is an inherent part of an electronic signature; however this guidance does not cover ''intent to sign,'' or when an agency uses authentication credentials as an electronic signature. For more information on electronic signatures, please consult OMB's guidance on implementing GPEA and the Electronic Signatures in Global and National Commerce Act (found at: *http://www.whitehouse.gov/omb/memoranda/m00–15.html,* September 25, 2000).

• Agencies should implement an e-authentication process using the following steps, described in Section 2.2: (1) Conduct a risk assessment as explained in Part II of the GPEA guidance and Section 2 of this guidance, (2) match identified risks with assurance levels, and (3) determine implementation technology based on the e-authentication technical guidance.

• Each step of the authentication process—from identity proofing, to issuance of a credential, to technical and administrative management and use of the credential by an application, and ultimately to record keeping and auditing—influences whether the process conforms to the desired assurance level. There are many layers of risk related to authentication. This guidance document is intended to assist agencies in identifying and analyzing risks associated specifically with the improper authentication of users of electronic transactions. These risks are highly dependent on the type of application and transactions offered.

• This document does not address risks that are associated with the improper management of authentication controls or processes, or risks to the underlying authentication technical architecture or infrastructure. This document does not confer, and may not be used to support, any right on behalf of any person or entity against the United States or its agencies or officials.

• This guidance does not refer to the authentication of systems or between services (for example, security socket layer (SSL) authentication). Instead, it is focusing on the attribute or identity authentication of individuals who are authenticated for Government services online.

1.2. Overview

This document provides agencies with guidance on electronic identity and attribute authentication (or e-authentication). E-authentication is the process of establishing confidence in both identities and attributes after being electronically presented to an information system. Individual authentication is the process of establishing an understood level of confidence that an identifier refers to a specific individual. Attribute authentication is the process of establishing an understood level of confidence that an attribute applies to a specific individual. The process of e-authenticating an individual may involve establishing the individual's unique identity (identity authentication) or establishing that the individual is a member of a group (such as a military veteran or U.S. citizen) (attribute authentication). For a complete list of definitions, refer to the Report of the National Research Council ''Who Goes There? Authentication Through the Lens of Privacy'' (found at: *http://www.nap.edu/books/0309088968/html/,* March 31, 2003).

E-authentication is the first step in the related process of deciding what an individual ought to be allowed to do, called ''authorization.'' Authentication focuses on establishing a person's identity, based on the reliability of the credential he or she offers; while authorization focuses on what actions that identity is permitted to do.

Agencies providing the e-government services need to determine how certain they need to be in the identity of an individual and identify the risks inherent in a particular transaction. This guidance will provide the framework for the identified risks to be mapped to the desired assurance level that the authentication technology selected must satisfy.

As described in OMB Circular A–130, Management of Federal Information Resources, agencies must prepare and update a strategy that identifies and mitigates risks associated with each information system; Section 5 of the GPEA guidance detailed the risk factors agencies should consider in planning and implementing electronic transactions. This new e-authentication guidance expands on Section 5 by—

• Instructing agencies how to implement an e-authentication process by outlining a process for assessing risk, and determining the requisite level of identity assurance; and

• Describing four discrete (and increasing) levels of identity assurance.

2. Assurance Levels

2.1. Description of Assurance Levels

For the purposes of e-government transactions, this guidance describes four assurance levels for authentication. In this context, assurance is defined as how much confidence the relying party has that the electronic identity credential presented is done so by the person whose identity is asserted by the credential. These levels are each appropriate for different classes of electronic transactions. In general, informal or lower value transactions will require less stringent assurance levels. Higher value or legally significant transactions will require more stringent assurance levels.

2.2. How To Determine an Assurance Level

Step 1: Agencies should conduct a systematic risk assessment of the transaction. The risk assessment will determine the required assurance level and will measure the relative severity of the potential harm to the agency or user of the e-government application and other transaction participants in the event of an improperly validated or unauthorized authentication. Each of the 4 levels described in Section 2.4 contains a profile of consequential risks. The more severe the likely consequences, the more confidence required in the asserted electronic identity in order to engage in a transaction, and, therefore, the higher the assurance level required. The definition of each assurance level is directly correlated to the degree of confidence or certainty that the agency must have in the identity of the user. Assurance levels are the vital link between the risk assessments of applications and the selection of authentication solutions.

Agencies should consider a wide range of possible scenarios in seeking to determine what risks are associated with their business process. It is better to be over inclusive than under inclusive in conducting this analysis. Risk analysis is to some extent a creative process, in which agencies must consider harms that might result from, among other causes, technical failures, malignant third parties, public misunderstandings, and human error.

Step 2: Match identified risks with assurance levels. The results of the risk assessment should be summarized, and then

be directly compared to these profiles. The closest match to one of the level profiles will determine the assurance level. In determining the required assurance level, an agency should initially identify risks inherent in the transactional process without considering the particular technologies used to implement authentication for that transaction. For example if during a medical procedure, the misuse of a user's electronic identity/credentials might result in risk to the user's personal safety, then, following this guidance, the agency would assign a level 4 assurance to this transaction, even if potential financial loss or other consequences are minimal. In making this determination, business process owners should seek to use the minimum assurance level that meets their risk requirements.

Step 3: Determine implementation technology based on the e-authentication technical guidance. After the assurance level has been determined, the agency should refer to the e-authentication technical guidance for the process requirements corresponding to that level. After the technical solution is chosen, a final validation should be conducted to confirm that the required assurance level of the end-to-end user to agency process has been operationally achieved. Note that authorization determines whether or not the authenticated has rights to complete the transaction.

Note that some technology solutions may create or compound particular risks. Thus, after selecting a specific solution, the agency should validate that the performance of the authentication process itself actually meets the identity assurance requirements for the transaction as part of required security procedures (*e.g.*, certification and accreditation).

2.3. Assurance Levels: Descriptions and Examples

This section describes the four assurance levels. The levels represent ranges of confidence in an electronic identity presented to an agency by means of a credential. The levels are numbered from 1 to 4, with 1 being minimal assurance and 4 being the highest level of identity assurance.

For each level, there is a description and examples. The description and examples will assist the agency in identifying the appropriate level of assurance required to authorize a transaction. The key part of each description is a risk profile. This is a description of certain consequential risks that may ensue to participants in a transaction when there is an authentication error.

Level 1—Minimal Assurance

Description

At level 1, little or no assurance is placed in the asserted electronic identity of the transacting party. In particular, an authentication error of a user's identity at level 1 might result in at most—

- Minimal inconvenience to any party; and
- No financial loss to any party; and
- Minimal distress being caused to any party; and
- Minimal damage to any party's standing or reputation; and
- No risk of harm to agency programs or other public interests; and
- No risk of civil or criminal violations; and
- No release of personal, U.S. government sensitive, or commercially sensitive data to unauthorized parties; and
- No risk to any party's personal safety.

Examples

Examples of transactions that might merit level 1 authentication include—

- A user presents a self registered user ID or password to the United States Department of Education web page, which allows customization of a Web site to create a ''My.ED.gov'' page. There are some possible risks associated with this situation; for example, a third party who gained unauthorized access to such a user ID and password might be able to draw inferences about the user's business interests or plans or the user's personal situation based on the types of information in which the user has an interest. Unless the website is subject to a high degree of customization, however, these risks are probably very minimal.
- A user participates in an online discussion on the whitehouse.gov website. Assuming that the forum is not one that addresses sensitive or private information, there are no obvious risks associated with this situation.

Level 2—Low Assurance

Description

Level 2 is appropriate for transactions in which it is sufficient that, on the balance of probabilities, there is confidence in the asserted electronic identity of the transacting party. In particular, an authentication error of a user's identity at level 2 might result in—

- Minor inconvenience to any party; or
- Minor financial loss to any party; or
- Minor damage to any party's standing or reputation; or
- Minor distress being caused to any party; or
- Minor risk of harm to agency programs or other public interests; or
- A risk of civil or criminal violations of a nature that would not ordinarily be subject to agency enforcement efforts; or
- A minor release of personal, or commercially sensitive data to unauthorized parties; and
- No release of U.S. government sensitive data to unauthorized parties; and
- No risk to any party's personal safety.

Examples

Examples of transactions that might merit level 2 assurance include—

- A user engages in online learning on the Gov Online Learning Center at golearn.gov. There is a need for authentication such that the user is recognized by the training service and be connected to the appropriate place in the course or given relevant assignment grades, when training affects compensation or promotion. The only risk associated with this transaction is that a third party will gain access to grading information, causing harm to the privacy interests or reputation of the student. If the agency determines, in the context of the particular program, that any such harm will be minor, the transaction is level 2.
- A user accesses their Social Security retirement account information online.

Level 3—Substantial Assurance

Description

Level 3 is appropriate for transactions that are official in nature, and for which there is a need for high confidence in the asserted electronic identity of the transacting party. In particular, an authentication error of a user's identity at level 3 might result in—

- Significant inconvenience to any party; or
- Significant financial loss to any party; or
- Significant damage to any party's standing or reputation; or
- Significant distress being caused to any party; or
- Significant harm to agency programs or other public interests; or
- A risk of civil or criminal violations that may be subject to agency enforcement efforts; or
- A significant release of personal, U.S. government sensitive, or commercially sensitive data to unauthorized parties; and
- No risk to any party's personal safety.

Examples

Examples of transactions that might merit level 3 assurance include:

- A patent attorney company reports and updates data on-line with the Patent and Trademark Office that would be of great value as competitive intelligence.
- A major contractor or supplier maintains an account with a General Services Administration Contracting Officer for a large government procurement involving significant government expenditures.
- A First Responder accesses a disaster management reporting website to report an incident and to share incident operational information, and to coordinate incident response activities.

Level 4—High Assurance

Description

Level 4 is appropriate for transactions that are official in nature for which there is a need for very high confidence in the asserted electronic identity of the transacting party. In particular, an authentication error of a user's identity at level 4 might result in—

- Considerable inconvenience to any party; or
- Considerable financial loss to any party; or
- Considerable damage to any party's standing or reputation; or
- Considerable distress being caused to any party; or
- Considerable harm to agency programs or other public interests; or
- A risk of civil or criminal violations that are of special importance to the agency enforcement program; or
- A damaging release of extensive personal, U.S. government sensitive, or commercially sensitive data to third parties; or
- A risk to any party's personal safety.

Examples

Examples of transactions that may require level 4 assurance include—

• A State or local law enforcement official accesses a law enforcement database containing information about the criminal records of individuals. Unauthorized access would violate the legal privacy rights of individuals or compromise investigations.

• A VA pharmacist dispenses a controlled drug. He/She would need full assurance that a qualified doctor had signed the prescription. In this case, the pharmacist's actions on the transaction carries criminal liability that the prescription was the correct drug(s), in the correct quantity, and that the prescription was validated before filling the prescription.

2.4. Additional Considerations

Each step of the authentication process—from identity proofing, to issuance of a credential, to management and use of the credential in a well-managed secure application, and ultimately to record keeping and auditing—influences whether the process conforms to the desired assurance level. The level of assurance achieved by each step of the process needs to be considered. The step that provides the lowest level of assurance may often determine the assurance level for the entire authentication process. Ideally each step in the authentication process should be consistent in its strength and robustness. A strong identity proofing process, combined with a strong credential and a robust management practice (including a strong archive and audit process) will contribute to the highest level assurance of identity. However, the best authentication process needs to be supported by well-engineered and tested user and agency software applications.

In making the risk assessment, the business process owner must consider all the direct and indirect consequences as presented in the definitions of the levels. Since each assurance level uses the terms ''minimal'', ''minor'', ''significant'', or ''considerable'', the business process owner will need to consider the terms in the context of the parties likely to be affected and their typical views. While it is realized that these terms are subjective, it is expected that these will be solidified through implementation and practice. For example, risk assessments have already been conducted on the E-Government Initiatives to determine their appropriate assurance levels.

As stated in OMB's GPEA guidance, properly implemented technologies can offer degrees of confidence in authenticating identity that are greater than a handwritten signature can offer. However, electronic transactions may in some circumstances affect the risk of criminal and civil violations, increase the harms associated with such violations, and complicate redressing such violations. Legal and law enforcement issues are discussed in the Department of Justice's Guide for Federal Agencies on Implementing Electronic Processes (found at *http://www.cybercrime.gov/ecommerce.html#GFA, November 2000*). Agencies should consider these issues in assigning transactions to particular assurance levels.

Violations of the law can present significant policy issues for an agency. The risk assessment process should consider the potential effects of illegal activities or other process failures in light of the agency's enforcement priorities, the agency's programmatic interests, and such broader public interests as national security, the environment, and the proper functioning of markets. Some of these harms are specifically described in each level (such as financial loss or release of personal information); others will depend on a particular agency's programmatic interests.

The risk analysis reflects this issue by referring to risks of criminal or civil violations and harm to agency programs or the public interest. In assessing this risk and designing a process, agencies should take into account not just the effects of a single violation or other act, but the possibility of a pattern of actions that might affect agency programs. For instance, if sensitive information could be obtained from an agency website, the agency should consider the effects of a possible pattern of such activity, not just a single action, in assessing risk levels. (Note that unauthorized access to an agency website is itself a criminal offense, see, *e.g.,* 18 U.S.C. 1029, 1030. Agencies should consider the effects and risks associated with such unauthorized access, rather than focusing on the unauthorized access itself, in assessing such risks.)

3. Determining Assurance for Credential Service Providers

Credential Service Providers (CSPs) are organizations, both governmental and non-governmental, that issue and in some cases may maintain electronic credentials. CSPs can handle several of the steps in the e-authentication process. Because the CSP's issuance and maintenance policy influences the trustworthiness of an e-authentication process, CSPs will also need to be assessed to determine the e-authentication level to which their credentials pertain. For example, if a CSP follows all process/technology requirements for authentication level 3, a user may use a credential provided by the CSP to authenticate himself for a transaction requiring authentication levels 1, 2, or 3. Additional information on CSPs will be included in both the E-Authentication technical guidance and in separate guidance issued by the E-Authentication E-Government Initiative.

4. Implementing an Authentication Process

4.1. Overview of the E-Authentication Process

When determining e-authentication needs, agencies must consider the entire e-authentication process. An agency cannot simply determine the level of credential that will be required to validate a user's identity without also determining how that credential will be processed by the agency business applications. They must determine the requirements for each step in the e-authentication/authorization process. This process includes the following steps:

- Initial enrollment.
- Repeat visits.
- Verification of identity.
- Transaction management.
- Long term records management.
- Periodic tests of the system.
- Suspension, revocation, reissue.
- Audit.

Each of these steps will be explained in more detail in the e-authentication technical guidance. Responsibility for these steps lies with the individual business process owners or designated agency or cross agency authority.

4.2. Use of Anonymous Credentials

Anonymous credentials may be appropriate when it is not necessary that authentication be associated with a known personal identity (as opposed to identity authentication). To protect privacy, it is important to balance the need to know who is communicating with Government with a citizen's right to privacy. This includes ensuring that information is used only in the manner in which individuals have been assured it will be used. In some cases, it may be desirable to preserve the anonymity of individuals and it may be sufficient for the purposes of an application to authenticate that—

• The user is a member of a group; and/or

• The user is the same individual who supplied or created information in the first place; and/or

• A particular user is entitled to use a particular pseudonym.

These anonymous credentials will have limited application. In some cases, individuals would have an anonymous as well as a non-anonymous credential. Anonymous credentials can be used up until level 3.

4.3. Information Sharing and the Privacy Act

When developing authentication processes, agencies must consider the requirements for managing security in the collection and storage of information associated with the process of validating a user's identity. As required by the E-Government Act of 2002 (Public Law 107–347), section 208, 44 U.S.C. § 3604, agencies are required to conduct privacy impact assessments for electronic information systems and collections, which includes when authentication technology is newly applied to an electronic information system.

The following information is captured in most e-authentication processes:

• Information regarding the individuals/businesses/governments using the E-Gov service.

• Electronic user credentials (*i.e.,* some combination of public key certificates, user identifiers, passwords, and Personal Identification Numbers).

• Transaction information associated with user authentication, including credential validation method.

• Audit Log/Security information.

Some of this information includes personal information as defined by the Privacy Act and, systems that use the information are considered systems of records that must meet all requirements of the Privacy Act and the E-Government Act.

Data collected and stored during the authentication process should only be accessible routinely to systems administrators and to auditors. As required by the Privacy Act, access to the system of

records must be provided to registered users to allow them to see and/or change personal information about them maintained in the system of records. Information from the system of records should not be shared routinely outside of legitimate needs as permitted or required by law for the administration and control of the authentication process.

In order to authenticate a user, it may be necessary for an agency providing an E-Gov service to obtain additional information about that user through the CSP that issued the user his/her credential. In such a case, the CSP must ask the user for permission and be granted that permission by the user to provide the specified information to the e-gov service provider. Disclosure of the additional information by the CSP to the e-gov application or service may also be established prior to the time of the transaction, if it is outlined in the terms of the relationship between the user and the CSP.

4.4. Cost Considerations

In most cases, higher levels of assurance require more costly credentials; however minimizing the number of credentials can create cost savings. Section 3 of the GPEA guidance provides additional information on assessing risks, costs, and benefits. In-person proofing is most likely more expensive. The e-authentication technical guidance will provide alternatives for addressing some of the authentication levels that may help agencies to better manage the costs of authentication.

4.5. Relationship to Other Guidance

4.5.1. Federal Bridge Certification Authority

Federal Bridge levels will be mapped to the assurance levels described in this document. Since these assurance levels take into account a wide range of authentication solutions, the levels described in this guidance differ from the levels established by the Federal Bridge Certification Authority (FBCA) Certificate Policy. For example, levels 1 and 2 in this e-authentication policy are primarily reserved for non-cryptographic authentication solutions not covered by the FBCA. However, it is likely that some public key infrastructure (PKI) solutions and the FBCA Rudimentary Certificate Policy will map to level 1 or level 2. The FBCA Basic Certificate Policies and the FBCA Medium Certificate Policies will fall in level 3, while FBCA High Certificate Policy will fall into level 4.

4.5.2. Federal Information Processing Standards Publication 199

While this E-Authentication Guidance addresses the consequential risk in making an authentication error, NIST is in the process of developing much broader risk levels for Federal information and Information Systems. NIST is in the process of developing a Federal Information Processing Standards Publication (FIPS) 199, ''Standards for Security Categorization of Federal Information and Information Systems'' promulgated under the E-Government Act of 2002 (Public Law 107–347). The standards establish three levels of risk (low, moderate, and high) for each of the stated security objectives (confidentiality, integrity, and availability) relevant to securing Federal information and information systems.

It is expected that these levels established in FIPS 199 will map to the levels in the e-authentication guidance. When an authentication error might cause a loss of confidentiality, integrity or availability, then—

- If the risk as defined in FIPS 199 is low, authentication assurance levels 1 through 4 are sufficient;
- If the risk as defined in FIPS 199 is moderate, authentication assurance level 3 or 4 should be used; and
- If the risk as defined in FIPS 199 is high, authentication assurance level 4 should be used.

5. Effective Dates of This Guidance

The Effective Dates for this guidance is 30 days after issuance as final policy. Additional information can be found in the supplemental information above.

[FR Doc. 03–17634 Filed 7–10–03; 8:45 am]

BILLING CODE 6820–WY–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Disease, Disability, and Injury Prevention and Control Special Emphasis Panel: Research To Improve Smoke Alarm Maintenance and Function, Program Announcement 03100

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the following meeting:

Name: Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): Research to Improve Smoke Alarm Maintenance and Function, Program Announcement 03100.

Times And Dates: 6:30 p.m.–7 p.m., July 27, 2003 (Open). 7 p.m.–8 p.m., July 27, 2003 (Closed). 8:30 a.m.–5 p.m., July 28, 2003 (Closed).

Place: The Swissotel Atlanta Buckhead, 3391 Peachtree Road, NE., Atlanta, GA 30326, Telephone 404.365.0065.

Status: Portions of the meeting will be closed to the public in accordance with provisions set forth in section 552b(c)(4) and (6), Title 5 U.S.C., and the Determination of the Director, Management Analysis and Services Office, CDC, pursuant to Public Law 92–463.

Matters To Be Discussed: The meeting will include the review, discussion, and evaluation of applications received in response to Program Announcement 03100.

FOR FURTHER INFORMATION CONTACT: Jean Langlois, Sc.D., Epidemiologist, Division of Injury and Disability Outcomes and Programs, National Center for Injury Prevention and Control, CDC, 4770 Buford Highway, NE, Atlanta, GA 30341, Telephone 770.488.1478.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both CDC and the Agency for Toxic Substances and Disease Registry.

Dated: July 7, 2003.

Diane C. Allen,

Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 03–17560 Filed 7–10–03; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Disease, Disability, and Injury Prevention and Control Special Emphasis Panel: Community-Based Interventions To Reduce Motor Vehicle-Related Injuries, Program Announcement 03077

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the following meeting:

Name: Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): Community-Based Interventions to Reduce Motor Vehicle-Related Injuries, Program Announcement 03077.

Times and Dates: 6:30 p.m.–7 p.m., July 27, 2003 (Open). 7 p.m.–8: p.m., July 27, 2003 (Closed). 8:30 a.m.–5 p.m., July 28, 2003 (Closed).

Place: The Swissotel Atlanta Buckhead, 3391 Peachtree Road, NE., Atlanta, GA 30326, Telephone 404.365.0065.

Status: Portions of the meeting will be closed to the public in accordance with provisions set forth in section 552b(c)(4) and (6), Title 5 U.S.C., and the Determination of the Director, Management Analysis and Services Office, CDC, pursuant to Public Law 92–463.

Matters to be Discussed: The meeting will include the review, discussion, and evaluation of applications received in response to Program Announcement 03077.

FOR FURTHER INFORMATION CONTACT: Mr. Thomas D. Vogelsonger, Public Health Advisor, Office of the Director, National Center for Injury Prevention and Control, CDC, 4770 Buford Highway, NE., Atlanta, GA 30341, Telephone 770.488.4823.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both CDC and the Agency for Toxic Substances and Disease Registry.

Dated: July 7, 2003.

Diane C. Allen,

Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 03–17562 Filed 7–10–03; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Disease, Disability, and Injury Prevention and Control Special Emphasis Panel: Development and Validation of Measures To Assess Outcomes of Mild Traumatic Brain Injury, Program Announcement 03106

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the following meeting:

Name: Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): Development and Validation of Measures To Assess Outcomes of Mild Traumatic Brain Injury, Program Announcement 03106.

Times and Dates: 6:30 p.m.–7 p.m., July 27, 2003 (Open). 7 p.m.–8 p.m., July 27, 2003 (Closed). 8:30 a.m.–5 p.m., July 28, 2003 (Closed).

Place: The Swissotel Atlanta Buckhead, 3391 Peachtree Road, NE., Atlanta, GA 30326, Telephone 404.365.0065.

Status: Portions of the meeting will be closed to the public in accordance with provisions set forth in section 552b(c) (4) and (6), Title 5 U.S.C., and the Determination of the Director, Management Analysis and Services Office, CDC, pursuant to Public Law 92–463.

Matters To Be Discussed: The meeting will include the review, discussion, and evaluation of applications received in response to Program Announcement 03106.

For Further Information Contact: Ms. Judy Stevens, Epidemiologist, Division of Unintentional Injury Prevention, National Center for Injury Prevention and Control, CDC, 4770 Buford Highway, NE, Atlanta, GA 30341, Telephone 770.488.4649.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both CDC and the Agency for Toxic Substances and Disease Registry.

Dated: July 7, 2003.

Diane C. Allen,

Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 03–17563 Filed 7–10–03; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Tribal Temporary Assistance for Needy Families (TANF) Quarterly Financial Report, ACF–196TT.

OMB No.: New Collection.

Description: The Tribal TANF Quarterly Financial Report provides specific data regarding expenditures and provides a mechanism for Tribes to request grant awards and certify the availability of State matching funds. Failure to collect this data would seriously compromise the Administration for Children and Families' (ACF) ability to monitor expenditures. This information is also used to estimate outlays and may be used to prepare ACF budget submissions to Congress. The following citation should be noted in regard to this collection: 45 CFR 286.255.

Respondents: Tribal TANF Agencies.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
ACF–196TT	20	4	2	160

Estimated Total Annual Burden Hours: 160.

Additional Information: Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Administration, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. E-mail address: *rsargis@acf.hhs.gov.*

OMB Comment: OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register.** Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Attn: Desk Officer for ACF, E-mail address: *lauren_wittenberg@omb.eop.gov.*

Dated: July 7, 2003.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 03–17529 Filed 7–10–03; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

[Program Announcement No. ACF/ACYF/HS–HSGS 2003–04]

Fiscal Year 2003 Discretionary Announcement for Head Start Graduate Student Research Grants; Availability of Funds and Request for Applications

AGENCY: Administration for Children and Families (ACF) DHHS.

ACTION: Announcement of the availability of funds and request for doctoral level graduate student research projects (Priority Area 1.01) in partnership with Head Start programs,

and pre-doctoral level graduate student research partnership development projects (Priority Area 1.02) to develop ongoing research partnerships with Head Start programs.

SUMMARY: The Administration for Children and Families (ACF) Office of Planning, Research and Evaluation (OPRE) announces the availability of funds for Head Start Graduate Student Research Grants to support field-initiated research activities.

CFDA #: The Catalog of Federal Domestic Assistance number for all priority areas is 93.600

DATES: The closing time and date for receipt of applications is 5 p.m. (Eastern Time Zone) August 12, 2003. Regardless of the method by which they are delivered, applications must be received on or before the deadline date.

Late Applications. Applications that do not meet the criteria stated above, will be considered late applications. The Administration for Children and Families (ACF) will notify each late applicant that its application will not be considered in the current competition.

Extension of Deadline. ACF may extend an application deadline for applicants affected by acts of God (such as floods and hurricanes), when there is widespread disruption of mail service, or for other disruption of services that affect the public at large (such as prolonged electrical blackout). Authority to waive or extend deadline requirements rests with the Chief Grants Management Officer.

Mailing and Delivery Instructions: Applications may be sent through the U.S. Postal Service, delivered by private courier, or hand delivered to the ACF Operations Center at the address below. Applications delivered by hand must be received by the Operations Center during the normal working hours of 8 a.m. to 5 p.m., Monday through Friday and no later than 5 p.m. Eastern Time Zone on the deadline date. Applicants will receive a confirmation postcard upon receipt of applications. Head Start Research Support Team, 1749 Old Meadow Road, Suite 600, McLean, VA 22102.

All packages should be clearly labeled as follows: Application for Head Start Graduate Student Research Grants: Priority Area (indicate 1.01 or 1.02).

FOR FURTHER INFORMATION CONTACT: The Head Start Research Support Technical Assistance Team (1–877) 663–0250, is available to answer questions regarding application requirements and to refer you to the appropriate contact person in ACF for programmatic questions. You may e-mail your questions to: *hsr@xtria.com.*

Grants Management Contact: William Wilson, Grants Management Officer, Room 2220 Switzer Building, 330 C Street SW., Washington, DC 20447. Telephone Number (202) 205–8913 or e-mail *WWilson@acf.hhs.gov.*

In order to determine the number of expert reviewers that will be necessary, if you are going to submit an application, *you must send a post card, call or e-mail at least two weeks prior to the submission deadline date with the following information: the name, address, telephone and fax number, e-mail address of the principal investigator, and the name of the university or non-profit institution to:* Head Start Research Support Team, 1749 Old Meadow Road, Suite 600, McLean, VA 22102, (1–877) 663–0250, E-mail *hsr@xtria.com.*

SUPPLEMENTARY INFORMATION: The Supplementary Information section consists of four parts. Part I provides general information about the Head Start research activities, authorities, funding priorities, and the application process. Part II describes the Head Start Graduate Student Research Grants (Priority Area 1.01). Part III describes the Head Start Graduate Student Partnership Development Grants (Priority Area 1.02). Part IV includes two appendices that include all requirements for applications. Appendix 1 provides detailed instructions for preparing and submitting applications. Appendix 2 contains the OMB-approved Uniform Project Description.

Part I. General Information

A. Purpose of Announcement

The purpose of this announcement is to announce the availability of funds for Head Start Graduate Student Research Grants to support field-initiated research activities in partnership with Head Start programs and to develop ongoing research partnerships with Head Start programs.

B. Background

Priority Area 1.01 and 1.02: Head Start Graduate Student Research Grants and Research Partnership Development Grants

Since 1991, ACF has explicitly supported the relationship between established Head Start researchers and their graduate students by awarding research grants, on behalf of specific graduate students, to conduct research in Head Start communities. As many previously funded Head Start graduate students have continued to make significant contributions to the early childhood research field as they have pursued their careers, this funding mechanism is an important research capacity-building effort. To ensure that future research is responsive to the changing needs of low-income families, graduate students need strong and positive role models. Therefore, Head Start's support of the partnership between students and their mentors is essential. The unique partnership that is forged between mentor and student, within the Head Start research context, serves as a model for the establishment of other partnerships within the community (*e.g.,* researcher-Head Start staff, researcher-family, etc.). This foundation helps foster the skills necessary to build a graduate student's trajectory of successful partnership-building and contributions to the scientific community. Within this nurturing and supportive relationship, young researchers are empowered to become autonomous researchers, learning theory, as well as the process of interacting with the various members and relevant organizations within their communities.

ACF further recognizes that effectively developing new research partnerships between researchers and Head Start communities requires considerable planning, effort, and commitment. In order to encourage the development of such new research partnerships, and to facilitate the entry of new mentor/student teams to the field of Head Start research, it is also essential to support the process of partnership development and research conceptualization. Therefore, a new priority area has been added this year for that purpose.

Thus, the goals of the two priority areas within the Head Start Graduate Student Research Grant program can be summarized as follows:

1. Provide direct support for graduate students as a way of encouraging the conduct of research with Head Start populations, thus contributing to the knowledge base about the best approaches for delivering services to diverse, low-income families and their children;

2. Promote mentor-student relationships which support students' graduate training and professional development as young researchers engaged in policy-relevant, applied research;

3. Emphasize the importance of developing true working research partnerships with Head Start programs and other relevant entities within the community, thereby fostering skills necessary to build a student's trajectory of successful partnership-building and

contributions to the scientific community; and

4. Support the active communication, networking and collaboration among graduate students, their mentors and other prominent researchers in the field, both during their graduate training, as well as into the early stages of their research careers.

While the specific topics addressed under these Graduate Student Research Grants are intended to be field-initiated, applicants who address issues of both local and national significance will be most likely to succeed. Some illustrative examples of such topics include, but are not limited to the areas of school readiness, children's mental health, serving an increasingly culturally and linguistically diverse population of children and families and promoting child well-being by strengthening responsible fatherhood and healthy marriages in Head Start families.

C. Statutory Authority and Other Citations

Statutory authority: Section 649 of the Head Start Act, as amended by the Coats Human Services Reauthorization Act of 1998 (Pub. L. 105–285) and 42 U.S.C. 9844.

Paperwork Reduction Act of 1995 (Pub. L. 104–13): Public reporting for this collection of information is estimated to average 40 hours per response, including time for reviewing instructions, gathering and maintaining data needed and reviewing the collection of information.

The project description is approved under OMB control Number 0970–0139 which expires 12/31/03.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid OMB control number.

D. Priority Areas, Number of Awards, Project Duration, and Funding Levels

In Fiscal Year 2003, ACF anticipates funding between 5 and 10 new projects in Priority Area 1.01 and between 2 and 8 new projects in Priority Area 1.02, pending availability of funds and receipt of satisfactory applications. ACF intends to commit up to $200,000 per year to fund new grants in response to both priority areas within this announcement. It is unlikely that any individual mentor will be funded for more than one graduate student research grant if there are at least 10 applications from different mentors/institutions that qualify for support.

Any application that exceeds the maximum dollar range will be considered ''non-responsive'' and subsequently returned to the applicant without further review.

Matching Requirement: There is no matching requirement.

Priority Area 1.01. Head Start Graduate Student Research Grants: The maximum Federal share will range between $10,000–$20,000 for the first 12-month budget period or a maximum of $40,000 for a 2-year project period.

For Priority Area 1.01, requests for a second year of funding within the project period should be identified in the current application (on SF–424A), but such requests will be considered at a later date on a noncompetitive basis, subject to the graduate student's eligibility status, the availability of funds, satisfactory progress of the grantee, and a determination that continued funding would be in the best interest of the Government.

Priority Area 1.02. Head Start Graduate Student Partnership Grants: The maximum Federal share will range between $2,500–$5,000 for the 12-month budget period.

E. Application Process

This announcement includes all of the information needed to apply for funding in each of the priority areas. Detailed instructions for preparing and submitting applications are contained in the appendices. Applicants are cautioned to follow the prescribed content and format in preparing their application packages. Each priority area describes the purpose, goals, technical requirements and evaluation criteria against which proposals will be reviewed. The Standard Federal Forms that must be included in applications can be downloaded from the Internet at *http://www.acf.hhs.gov/programs/ofs/.*

F. Proposal Review, Selection and Award

1. Each application will be screened to determine whether the applicant organization is eligible as specified in each of the priority areas. Applications from ineligible organizations will be excluded from the review.

1.The review will be conducted in Washington, DC. Expert reviewers will include researchers, Federal or State staff, and other individuals experienced in Head Start or related research and evaluation. A panel of at least three reviewers will evaluate each application to determine the strengths and weaknesses of the proposal in terms of the Head Start's research goals and expectations, requirements for the Project Narrative Statement, and evaluation criteria for the priority area under consideration.

3. Given the involvement of non-Federal reviewers, applicants have the option of omitting from the application copies (but not the original), specific salary rates or amounts for individuals specified in the application budget and Social Security Numbers, if otherwise required for individuals. If the applicant omits individual salary information on application copies, the copies must include summary salary information.

4. Panelists will provide written comments and assign numerical scores for each application. The indicated point value for each criterion is the maximum numerical score for that criterion. The assigned scores for each criterion will be summed to yield a total evaluation score for the proposal.

5. In addition to the panel review, ACF may solicit comments from other Federal offices and agencies, States, non-governmental organizations, and individuals whose particular expertise is identified as necessary for the consideration of technical issues arising during the review. ACF will consider their comments, along with those of the panelists, when making funding decisions. ACF will also take into account the best combination of proposed projects to meet overall research goals.

6. The Director of the Office of Planning, Research and Evaluation in the Administration for Children and Families (ACF) will make the final selection of the applicants to be funded. Applications may be funded in whole or in part depending on: (1) The rank order of applicants resulting from the competitive review; (2) staff review and consultations; (3) the combination of projects which best meets the Bureau's research objectives; (4) the funds available; and (5) other relevant considerations.

7. Selected applicants will be notified through the issuance of a Financial Assistance Award. That document establishes the funding level, terms and conditions of the award, reporting requirements, effective date of the award, budget period for which support is given, and total project period for which support is provided.

8. Grants to successful applications will be awarded by September 30, 2003.

G. Type and Frequency of Post-Award Reporting Requirements

All grantees will be required to submit semi-annual progress and fiscal reports as well as a final report.

Part II: Priority Area 1.01 Head Start Graduate Student Research Grants

Eligible Applicants: Institutions of higher education on behalf of *doctoral-*

level graduate students. Doctoral students must have completed their Master's Degree or equivalent in the field of doctoral study and submitted formal notification to ACF by *August 15, 2003.*

To be eligible to administer the grant on behalf of the student, the institution must be fully accredited by one of the regional accrediting commissions recognized by the Department of Education and the Council on Post-Secondary Accreditation. Faith-based institutions are also eligible to apply. Although the faculty mentor is listed as the Principal Investigator, this grant is intended for dissertation research for an individual student. Information about both the graduate student and the student's faculty mentor is required as part of this application. Any resultant grant award is not transferable to another student. The award may not be divided between two or more students.

Private, non-profit institutions are encouraged to submit with their applications the optionally survey located under ''Grant Manuals & Forms'' at *http://www.acf.hhs.gov/programs/ofs/forms.htm.*

Additional Requirements:

• A university faculty member must serve as a mentor to the graduate student; this faculty member is listed as the ''Principal Investigator.'' The application must include a letter from this faculty member stating that s/he has reviewed and approved the application, the status of the project as *dissertation research,* the student's status in the doctoral program, and a description of how the faculty member will regularly monitor the student's work.

• The research project must be an independent study conducted by the individual graduate student or well-defined portion(s) of a larger study currently being conducted by a faculty member. If the project is part of a larger research effort, the proposal must clearly distinguish between the student's portion of the research activities and those of the larger project. The graduate student must have primary responsibility for the proposed study described in the application.

• The graduate student must enter into a partnership with a Head Start or Early Head Start program for the purposes of conducting the research.

• The application must contain (A) a letter from the Head Start or Early Head Start program certifying that they have entered into a research partnership with the applicant (graduate student) and (B) a separate letter certifying that the application has been reviewed and approved by the Head Start Program Policy Council. Notification of approval or pending approval by the Policy Council must be received from the official representative of the Policy Council and not an individual from the Head Start or Early Head Start program itself.

• The graduate student applicant must agree to attend *two* meetings each year of the grant. The first meeting consists of the annual meeting for all Head Start Graduate Students. This annual grantee meeting is typically scheduled during the summer or fall of each year and is held in Washington, DC. The fall 2003 meeting will be held on Oct. 20–21, 2003. During this meeting, each student typically presents a brief overview of his or her study (*e.g.,* the study design, participants, measures, and/or findings, as they become available). The intended goal of the meeting is to stimulate potentially useful and constructive feedback from other students and mentors, as well as to facilitate collaboration, networking and mentoring activities.

The second meeting each year alternates between the biennial Head Start National Research Conference in Washington, DC (June 28 to July 1, 2004) and the biennial meeting of the Society for Research in Child Development-SRCD (April, 2005). At a minimum, students usually are provided the opportunity to present information on their respective studies in a poster session format, although both meetings also provide other networking and mentoring activities. The grant budget should reflect travel and housing funds for the graduate student for all four of these meetings (or two if only applying for only one year of funding).

• Given the strong emphasis that is placed on supporting the mentor-student relationship, the faculty mentors are strongly encouraged to attend and participate in the activities of the annual grantee meeting for all Head Start Graduate Students. The budget should reflect travel funds for such purposes, as appropriate. However, if the faculty mentor does plan to attend the annual Graduate Student grantee meeting, but will utilize another source of travel funds, such arrangements are encouraged and should be noted in the application.

• Due to the small amount of the grant, the applicant's institution is strongly encouraged to waive indirect costs.

• Contact information, including phone numbers, addresses and e-mail addresses, for *both* the graduate student applicant and faculty mentor must be included in the application.

• The graduate student must write the application in its entirety, consistent with the format and style guidelines of the *Publication Manual of the American Psychological Association, 5th ed.* (APA 2001) and the general principles and guidelines of the *Ethical Principles of Psychologists and Code of Conduct 2002 (APA, 2002).*

Project Duration: The announcement for priority area 1.01 is soliciting applications for project periods up to two years. Grant awards, on a competitive basis, will be for a one- to two-year project period, the budget will be funded in one-year increments. It should be noted, that if the graduate student, on whose behalf the University is applying, expects to receive his/her degree by the end of the first one-year budget period, the applicant should request a one-year project period only. A second year budget-period will not be granted if the student has graduated by the end of the first year. Applications for continuation grants funded under these awards beyond the initial one-year budget period, but within the two-year project period, will be entertained in the subsequent year on a non-competitive basis, subject to availability of funds, satisfactory progress of the grantee and a determination that continued funding would be in the best interest of the Government.

Criteria for Priority Area 1.01—Head Start Graduate Student Research Grants—The three criteria that follow will be used to review and evaluate each application under this priority area (presented here in descending order of numerical weighting—see instructions in Appendix 2). Address each in the Project Narrative Section of the application. The point values indicate the maximum numerical weight each criterion will be accorded in the review process. (100 points total).

1. Approach 40 points

• The extent to which there is a discrete project designed by the graduate student. If the proposed project is part of a larger study designed by others, the approach section should clearly delineate the research component to be carried out by the student and how it is distinguished from the larger research project.

• The extent to which the research design is appropriate and sufficient for addressing the questions of the study.

• The extent to which the planned research specifies the measures to be used, their psychometric properties, and contains an adequately detailed description of the proposed analyses to be conducted.

• The extent to which the planned measures have been shown to be appropriate and sufficient for the

questions of the study, and the population to be studied.

• The extent to which the planned measures and analyses are consistent with one another, and reflect knowledge and use of state-of-the-art measures and analytic techniques, or advance the state-of-the-art, as appropriate.

• The extent to which the analytic techniques are appropriate for the specific research question(s) under consideration.

• The extent to which the proposed sample size is sufficient to answer the range of proposed research questions for the study.

• The extent to which the scope of the project is reasonable for the funds available and feasible for the time frame specified.

• The extent to which the planned approach reflects sufficient written input from and partnership with the Head Start program (including the separate required review and written approval from the Head Start program and the Head Start Program Policy Council).

• The extent to which the budget and budget justification are appropriate for carrying out the proposed project.

2. Staff and Position Data 35 points

• The extent to which the faculty mentor and graduate student possess the research expertise necessary to conduct the study as demonstrated in the application and information contained in their vitae.

• The principal investigator/faculty mentor has earned a doctorate or equivalent in the relevant field and has first or second author publications in major research journals.

• The extent to which the faculty mentor and graduate student reflect an understanding of and sensitivity to the issues of working in a community setting and in partnership with Head Start program staff and parents.

• The adequacy of the time devoted to this project by the faculty mentor for mentoring the graduate student. The proposal should include evidence of the faculty mentor's commitment to mentoring the individual graduate student, and as appropriate, willingness to serve as a resource to the broader group of Head Start Graduate Students funded under this award.

3. Results or Benefits Expected 25 points

• The research questions are clearly stated.

• The presentation reflects original work done by the student (consistent with the general principles and guidelines of the *Ethical Principles of Psychologists and Code of Conduct 2002* (APA 2002).

• The extent to which the questions are of importance and relevance for low-income children's development and welfare.

• The extent to which the research study makes a significant contribution to the knowledge base.

• The extent to which the literature review is current and comprehensive and supports the need for the study.

• The extent to which the literature review has a complete set of reference citations and is written consistent with the guidelines of the *Publication Manual of the American Psychological Association, 5th ed.* (APA 2001).

• The extent to which the questions that will be addressed or the hypotheses that will be tested are sufficient for meeting the stated objectives.

• The extent to which the proposed project is appropriate to the student's level of ability and the stated time frame for completing the project.

Part III: Priority Area 1.02 Head Start Graduate Student Research Partnership Development Grants

Eligible Applicants: Institutions of higher education on behalf of *graduate students enrolled in a doctoral program.*

To be eligible to administer the grant on behalf of the student, the institution must be fully accredited by one of the regional accrediting commissions recognized by the Department of Education and the Council on Post-Secondary Accreditation. Faith-based institutions are also eligible to apply. Although the faculty mentor is listed as the Principal Investigator and must be committed to taking a central role in maintaining an ongoing research partnership with a Head Start program, this grant is intended for an individual student to be the primary conduit through which the research-related relationship is forged. Information about both the graduate student and the student's faculty mentor is required as part of this application. Any resultant grant award is not transferable to another student. The award may not be divided between two or more students.

Additional Requirements

• A university faculty member must serve as a mentor to the graduate student; this faculty member is listed as the ''Principal Investigator.'' The application must include a letter from this faculty member stating that s/he has reviewed and approved the application and describing, in as much detail as is possible, the potential for the research partnership development project to lead to a research effort that would include the student's dissertation study. It should also include a statement of the student's status in the graduate program and a description of how the faculty member will regularly monitor the student's work.

• The research partnership development project must be conducted by the individual graduate student or be a well-defined portion(s) of a larger research effort currently being conducted by a faculty member. If the project is part of a larger research partnership-building effort, the proposal must clearly distinguish between the student's portion and the activities of the larger research project. The graduate student must have primary responsibility for the proposed research efforts described in the application.

• The graduate student must begin to forge a research partnership with a Head Start or Early Head Start program. While one of the long-term purposes of the relationship should be to generate a doctoral dissertation research opportunity in the Head Start setting, the student should take an approach that is based in community/ecological/empowerment models, in which research needs are considered in the larger context of program needs, as well as mutually beneficial and empowering relationships. Appropriate activities during the grant period may include, but are not limited to, providing direct services and assistance to Head Start or Early Head Start programs with program activities, conducting assets/needs assessments, conducting focus groups, jointly identifying or defining problems with Head Start partners, training staff and other activities that foster collaborative, reciprocal relationships with Head Start partners.

• Graduate students will be expected to identify (a) a set of goals and objectives for the year, as well as a set of benchmarks for guiding and assessing incremental progress toward attaining these goals and objectives, and (b) specific *products* they expect to generate during the grant period such as community assets/needs assessments, problem descriptions, summaries of focus group findings or training efforts, and/or drafts of dissertation proposals.

• Grant recipients are encouraged to build upon their work by subsequently applying for the Head Start Graduate Student Research Grants (Priority 1.01) to support doctoral dissertation research.

• The application must contain (A) a letter from at least one Head Start or Early Head Start program certifying that they are receptive to exploring a potential research partnership with the applicant and (B) a separate letter

certifying that the proposed partnership project has been reviewed and approved by the Head Start Program Policy Council. Notification of approval or pending approval by the Policy Council must be received from the official representative of the Policy Council and not an individual from the Head Start or Early Head Start program itself.

• The graduate student applicant must agree to attend the annual meeting for all Head Start Graduate Student Research grantees. This annual grantee meeting is typically scheduled during the summer or fall of each year and is held in Washington, DC. The fall 2003 meeting will be held Oct. 20–21, 2003. During this meeting, each student typically presents a brief overview of his or her study or proposed project. The intended goal of the meeting is to stimulate potentially useful and constructive feedback from other students and mentors, as well as to facilitate collaboration, networking and mentoring activities. The grant budget should reflect travel and housing funds for the graduate student for this meeting.

• Due to the small amount of the grant, the applicant's institution is strongly encouraged to waive indirect costs.

• Contact information, including phone numbers, addresses and e-mail addresses, for *both* the graduate student applicant and faculty mentor must be included in the application.

• The graduate student must write the application, consistent with the format and style guidelines of the *Publication Manual of the American Psychological Association, 5th ed.* (APA 2001) and the principles and guidelines from the *Ethical Principles of Psychologists and Code of Conduct (APA 2002).*

Project Duration: The announcement for priority area 1.02 is soliciting applications for project periods up to *one year.*

CRITERIA for Priority Area 1.02—Head Start Graduate Student Research Partnership Development Grants—The three criteria that follow will be used to review and evaluate each application under this priority area. Address each in the Project Narrative Section of the application (presented here in descending order of numerical weighting—see instructions in Appendix 2). The point values indicate the maximum numerical weight each criterion will be accorded in the review process. (100 points total).

1. Approach 40 points

• The extent to which there is a discrete project designed by the graduate student. If the proposed project is part of a larger project designed by others, the approach section should clearly delineate the research partnership development component to be carried out by the student and how it is distinguished from the larger project.

• The extent to which the goals and objectives of the proposed activities, as well as the set of benchmarks for guiding and assessing progress, are clearly articulated and reflect an appropriate understanding of how these activities will fit within the context and complexities of the Head Start program's operations.

• The scope of the project is reasonable for the funds available and feasible for the time frame specified.

• The extent to which the planned approach or proposed research partnership activities reflect sufficient opportunities for written input from and an active partnership with the Head Start program (including the separate required review and written approval of the proposed partnership activities from the Head Start program and the Head Start Program Policy Council).

• The extent to which the budget and budget justification are appropriate for carrying out the proposed research project development activities.

• The extent to which proposed products reflect concrete and measurable steps toward design of a future dissertation project.

2. Staff and Position Data 35 points

• The extent to which the faculty mentor and graduate student possess the expertise necessary to successfully form a research partnership with a Head Start program as demonstrated in the application and information contained in their vitae.

• The principal investigator/faculty mentor has earned a doctorate or equivalent in the relevant field and has first or second author publications in major research journals.

• The extent to which the faculty mentor and graduate student reflect an understanding of and sensitivity to the issues of working in a community setting and in a reciprocal partnership with Head Start program staff and parents.

• The adequacy of the time devoted to this project by the faculty mentor for mentoring the graduate student. The proposal should include evidence of the faculty mentor's commitment to mentoring the individual graduate student, and as appropriate, willingness to serve as a resource to the broader group of Head Start Graduate Students funded under this award.

• The extent to which the mentor-mentee relationship is clearly described and has the potential to continue throughout the student's dissertation process.

3. Results or Benefits Expected 25 points

• The presentation reflects original work done by the student (consistent with the general principles and guidelines of the *Ethical Principles of Psychologists and Code of Conduct 2002* (APA 2002).

• The extent to which the literature review, as well as a description of the needs of the local community if appropriate, is current and comprehensive and supports the need for developing this or similar research partnerships.

• The extent to which proposed goals and objectives for the year address the needs identified.

• The extent to which the specific *products* to be generated through the grant, as well as the benchmarks for assessing progress toward these goals and objectives, are clearly described and will potentially benefit the Head Start and/or research communities.

• The extent to which the literature review has a complete set of reference citations and is written consistent with the guidelines of the *Publication Manual of the American Psychological Association, 5th ed.* (APA 2001).

• The extent to which the proposed project is appropriate to the student's level of ability and the stated time frame for completing the project.

• The extent to which potential research questions are clearly stated and are of importance and relevance for low-income children's development and welfare.

Part IV. Appendices

Appendix 1: Contents and Format of the Application

Clarity and conciseness are of utmost importance. ACF strongly encourages applicants to limit their applications to 100 pages, double-spaced and single-sided, with standard one-inch margins and 12 point fonts. This includes the entire Project Narrative Statement including text, tables, charts, graphs, resumes, corporate statements and appendices.

Applicants are cautioned to include all required forms and materials, organized according to the required format. The application packet must include the following items in order:

1. A cover letter that includes the announcement number, priority area and contact information.

2. Standard Federal Forms

a. Standard Form 424, ''Application for Federal Assistance.'' This form must be completed, signed, and included with the application.

b. Standard Form 424A, ''Budget Information—Non-Construction Programs.'' This form must be completed and included with the application.

c. Standard Form 424B, ''Assurances: Non-Construction Programs.'' This form must be completed, signed, and included with the application.

d. Assurance/Identification/Certification/Declaration Regarding Protection of Human Subjects. This form must be completed, signed, and included with the application.

e. Certifications Regarding Lobbying. Applicants must provide a certification regarding lobbying when applying for an award in excess of $100,000. Applicants must sign and return the certification with their applications.

f. Standard Form LLL, ''Disclosure of Lobbying Activities.'' Applicants must disclose lobbying activities when applying for an award in excess of $100,000. Applicants who have used non-Federal funds for lobbying activities in connection with receiving assistance under this announcement shall complete a disclosure form to report lobbying. Applicants must sign and return the disclosure form, if applicable, with their applications.

g. Certification Regarding Drug-Free Workplace Requirements. Applicants must make the appropriate certification of their compliance with the Drug-Free Workplace Act of 1988. By signing and submitting the application, the applicant is providing the certification and need not mail back the certification with the application.

h. Certification Regarding Debarment, Suspension, and Other Responsibility Matters. Applicants must make the appropriate certification that they are not presently debarred, suspended, or otherwise ineligible for an award. By signing and submitting the application, the applicant is providing the certification and need not mail back the certification with the application.

i. Certification Regarding Environmental Tobacco Smoke. Applicants must make the appropriate certification of their compliance. By signing and submitting the application, the applicant is providing the certification and need not mail back the certification with the application.

3. For-profit entities wishing to receive a grant directly must provide a letter indicating their willingness to waive their profit. Non-profit organizations must submit proof of non-profit status in the application at the time of submission. The applicant can demonstrate proof of non-profit status in any one of five ways, by providing:

a. A copy of the organization's listing in the Internal Revenue Service's (IRS) most recent list of tax-exempt organizations described in Section 501(c3) of the IRS code;

b. A copy of the currently valid IRS tax exemption certificate;

c. A statement from a State taxing body, State attorney general, or other appropriate State official certifying that the applicant organization has a non-profit status and that none of the net earnings accrue to any private shareholders or individuals;

d. A certified copy of the organization's certificate of incorporation or similar document that clearly establishes non-profit status.

e. Any of the items in the subparagraphs immediately above for a State or national parent organization and a statement signed by the parent organization that the applicant organization is a local non-profit affiliate.

Private, non-profit institutions are encouraged to submit with their applications the optional survey located under ''Grant Manuals & Forms'' at *http://www.acf.hhs.gov/programs/ofs/forms.htm.*

4. Administrative requirements: 45 CFR Parts 74 and 92.

5. Executive Order 12372—Single Point of Contact

This program is covered under Executive Order 12372, ''Intergovernmental Review of Federal Programs'', and 45 CFR part 100, ''Intergovernmental Review of Department of Health and Human Services Program and Activities''. Under the Order, States may design their own processes for reviewing and commenting on proposed Federal assistance under covered programs.

All States and Territories except Alabama, Alaska, Arizona, Colorado, Connecticut, Hawaii, Idaho, Indiana, Kansas, Louisiana, Massachusetts, Minnesota, Montana, Nebraska, New Jersey, Ohio, Oklahoma, Oregon, Pennsylvania, South Dakota, Tennessee, Vermont, Virginia, Washington, and Wyoming have elected to participate in the Executive Order process and have established Single Points of Contact (SPOCs). Applicants from these twenty-six jurisdictions need take no action regarding E.O. 12372. Applicants for projects to be administered by Federally-recognized Indian Tribes are also exempt from the requirements of E.O. 12372. Otherwise, applicants should contact their SPOCs as soon as possible to alert them of the prospective applications and receive any necessary instructions. Applicants must submit any required material to the SPOCs as soon as possible so that the program office can obtain and review SPOC comments as part of the award process. It is imperative that the applicant submit all required materials, if any, to the SPOC and indicate the date of this submittal (or the date of contact if no submittal is required) on the Standard Form 424, item 16a.

Under 45 CFR 100.8(a)(2), a SPOC has 60 days from the application deadline to comment on proposed new or competing continuation awards.

SPOCs are encouraged to eliminate the submission of routine endorsements as official recommendations.

Additionally, SPOCs are requested to clearly differentiate between mere advisory comments and those official State process recommendations which may trigger the accommodation or explain rule.

When comments are submitted directly to ACF, they should be addressed to: William Wilson, ACYF's Office of Grants Management, Room 2220 Switzer Building, 330 C Street SW., Washington, DC 20447, Attn: Head Start Discretionary Research Grants Announcement. A list of the Single Points of Contact (SPOCs) for each State and Territory can be found on the following web site: *http://www.whitehouse.gov/omb/grants/spoc.html.*

5. Table of Contents

6. Project Abstract (not to exceed one page) for use in official briefings, decision packages, and public announcement of awards.

7. Project Narrative Statement (*See* instructions in Appendix 2 and Evaluation Criteria for each Priority described in this announcement.)

8. *Appendices:* All supporting materials and documents should be organized into appropriate appendices and securely bound to the application package. Applicants are reminded that the total page limitation applies to both narrative text and supporting materials.

a. Contact Information for all Key Staff

b. Resumes

c. Letters of Support, if appropriate

d. Other

9. *Number of Copies and Binding:* An original and two copies of the complete application packet must be submitted. Each copy of the application should be securely stapled in the upper left-hand corner, clipped, or secured at the top with a two-hole punch fastener. Because each application will be duplicated for the review panel, do not use non-

removable binders. Do not include tabs, plastic inserts, brochures, videos, or any other items that cannot be photocopied.

Appendix 2: Uniform Project Description

Part 1 The Project Description Overview

Purpose

The project description provides a major means by which an application is evaluated and ranked to compete with other applications for available assistance. The project description should be concise and complete and should address the activity for which Federal funds are being requested. Supporting documents should be included where they can present information clearly and succinctly. In preparing your project description, all information requested through each specific evaluation criteria should be provided. Awarding offices use this and other information in making their funding recommendations. It is important, therefore, that this information be included in the application.

General Instructions

ACF is particularly interested in specific factual information and statements of measurable goals in quantitative terms. Project descriptions are evaluated on the basis of substance, not length. Extensive exhibits are not required. Cross-referencing should be used rather than repetition. Supporting information concerning activities that will not be directly funded by the grant or information that does not directly pertain to an integral part of the grant-funded activity should be placed in an appendix.

Pages should be numbered and a table of contents should be included for easy reference.

Part 2 General Instructions for Preparing a Full Project Description

Introduction

Applicants required to submit a full project description shall prepare the project description statement in accordance with the following instructions and the specified evaluation criteria. The instructions give a broad overview of what your project description should include while the evaluation criteria expands and clarifies more program-specific information that is needed.

Project Summary/Abstract

Provide a summary of the project description (a page or less) with reference to the funding request.

Objectives and Need for Assistance

Clearly identify the physical, economic, social, financial, institutional, and/or other problem(s) requiring a solution. The need for assistance must be demonstrated and the principal and subordinate objectives of the project must be clearly stated; supporting documentation, such as letters of support and testimonials from concerned interests other than the applicant, may be included. Any relevant data based on planning studies should be included or referred to in the endnotes/footnotes. Incorporate demographic data and participant/beneficiary information, as needed. In developing the project description, the applicant may volunteer or be requested to provide information on the total range of projects currently being conducted and supported (or to be initiated), some of which may be outside the scope of the program announcement.

Approach

Outline a plan of action which describes the scope and detail of how the proposed work will be accomplished. Account for all functions or activities identified in the application. Cite factors which might accelerate or decelerate the work and state your reason for taking the proposed approach rather than others. Describe any unusual features of the project such as design or technological innovations, reductions in cost or time, or extraordinary social and community involvement.

Provide quantitative monthly or quarterly projections of the accomplishments to be achieved for each function or activity in such terms as the number of people to be served and the number of activities accomplished. When accomplishments cannot be quantified by activity or function, list them in chronological order to show the schedule of accomplishments and their target dates.

If any data is to be collected, maintained, and/or disseminated, clearance may be required from the U.S. Office of Management and Budget (OMB). This clearance pertains to any ''collection of information that is conducted or sponsored by ACF.''

List organizations, cooperating entities, consultants, or other key individuals who will work on the project along with a short description of the nature of their effort or contribution.

Evaluation

Provide a narrative addressing how the results of the project and the conduct of the project will be evaluated. In addressing the evaluation of results, state how you will determine the extent to which the project has achieved its stated objectives and the extent to which the accomplishment of objectives can be attributed to the project. Discuss the criteria to be used to evaluate results, and explain the methodology that will be used to determine if the needs identified and discussed are being met and if the project results and benefits are being achieved. With respect to the conduct of the project, define the procedures to be employed to determine whether the project is being conducted in a manner consistent with the work plan presented and discuss the impact of the project's various activities on the project's effectiveness.

Additional Information

Following are requests for additional information that need to be included in the application:

Staff and Position Data

Provide a biographical sketch for each key person appointed and a job description for each vacant key position. A biographical sketch will also be required for new key staff as appointed.

Organizational Profiles

Provide information on the applicant organization(s) and cooperating partners such as organizational charts, financial statements, audit reports or statements from CPAs/Licensed Public Accountants, Employer Identification Numbers, names of bond carriers, contact persons and telephone numbers, child care licenses and other documentation of professional accreditation, information on compliance with Federal/State/local government standards, documentation of experience in the program area, and other pertinent information. Any non-profit organization submitting an application must submit proof of its non-profit status in its application at the time of submission.

The non-profit agency can accomplish this by providing a copy of the applicant's listing in the Internal Revenue Service's (IRS) most recent list of tax-exempt organizations described in Section 501(c)(3) of the IRS code, or by providing a copy of the currently valid IRS tax exemption certificate, or by providing a copy of the articles of incorporation bearing the seal of the State in which the corporation or association is domiciled.

Letters of Support

Provide statements from community, public and commercial leaders that

support the project proposed for funding. All submissions should be included in the application OR by application deadline.

Budget and Budget Justification

Provide line item detail and detailed calculations for each budget object class identified on the Budget Information form. Detailed calculations must include estimation methods, quantities, unit costs, and other similar quantitative detail sufficient for the calculation to be duplicated. The detailed budget must also include a breakout by the funding sources identified in Block 15 of the SF–424.

Provide a narrative budget justification that describes how the categorical costs are derived. Discuss the necessity, reasonableness, and allocability of the proposed costs.

General

The following guidelines are for preparing the budget and budget justification. Both Federal and non-Federal resources shall be detailed and justified in the budget and narrative justification. For purposes of preparing the budget and budget justification, ''Federal resources'' refers only to the ACF grant for which you are applying. Non-Federal resources are all other resources. It is suggested that budget amounts and computations be presented in a columnar format: first column, object class categories; second column, Federal budget; next column(s), non-Federal budget(s), and last column, total budget. The budget justification should be a narrative.

Personnel

Description: Costs of employee salaries and wages.

Justification: Identify the project director or principal investigator, if known. For each staff person, provide the title, time commitment to the project (in months), time commitment to the project (as a percentage or full-time equivalent), annual salary, grant salary, wage rates, etc. Do not include the costs of consultants or personnel costs of delegate agencies or of specific project(s) or businesses to be financed by the applicant.

Fringe Benefits

Description: Costs of employee fringe benefits unless treated as part of an approved indirect cost rate.

Justification: Provide a breakdown of the amounts and percentages that comprise fringe benefit costs such as health insurance, FICA, retirement insurance, taxes, etc.

Travel

Description: Costs of project-related travel by employees of the applicant organization (does not include costs of consultant travel).

Justification: For each trip, show the total number of traveler(s), travel destination, duration of trip, per diem, mileage allowances, if privately owned vehicles will be used, and other transportation costs and subsistence allowances. Travel costs for key staff to attend ACF-sponsored workshops should be detailed in the budget.

Equipment

Description: ''Equipment'' means an article of non-expendable, tangible personal property having a useful life of more than one year and an acquisition cost which equals or exceeds the lesser of (a) the capitalization level established by the organization for the financial statement purposes, or (b) $5,000. (Note: Acquisition cost means the net invoice unit price of an item of equipment, including the cost of any modifications, attachments, accessories, or auxiliary apparatus necessary to make it usable for the purpose for which it is acquired. Ancillary charges, such as taxes, duty, protective in-transit insurance, freight, and installation shall be included in or excluded from acquisition cost in accordance with the organization's regular written accounting practices.)

Justification: For each type of equipment requested, provide a description of the equipment, the cost per unit, the number of units, the total cost, and a plan for use on the project, as well as use or disposal of the equipment after the project ends. An applicant organization that uses its own definition for equipment should provide a copy of its policy or section of its policy which includes the equipment definition.

Supplies

Description: Costs of all tangible personal property other than that included under the Equipment category.

Justification: Specify general categories of supplies and their costs. Show computations and provide other information which supports the amount requested.

Contractual

Description: Costs of all contracts for services and goods except for those which belong under other categories such as equipment, supplies, construction, etc. Third-party evaluation contracts (if applicable) and contracts with secondary recipient organizations, including delegate agencies and specific project(s) or businesses to be financed by the applicant, should be included under this category.

Justification: All procurement transactions shall be conducted in a manner to provide, to the maximum extent practical, open and free competition. Recipients and subrecipients, other than States that are required to use 45 CFR Parts 92 procedures, must justify any anticipated procurement action that is expected to be awarded without competition and exceed the simplified acquisition threshold fixed at 41 U.S.C. 403(11) (currently set at 100,000). Recipients might be required to make available to ACF pre-award review and procurement documents, such as request for proposals or invitations for bids, independent cost estimates, etc.

Note: Whenever the applicant intends to delegate part of the project to another agency, the applicant must provide a detailed budget and budget narrative for each delegate agency, by agency title, along with the required supporting information referred to in these instructions.

Other

Enter the total of all other costs. Such costs, where applicable and appropriate, may include but are not limited to insurance, food, medical and dental costs (noncontractual), professional services costs, space and equipment rentals, printing and publication, computer use, training costs, such as tuition and stipends, staff development costs, and administrative costs.

Justification: Provide computations, a narrative description and a justification for each cost under this category.

Indirect Charges

Description: Total amount of indirect costs. This category should be used only when the applicant currently has an indirect cost rate approved by the Department of Health and Human Services (HHS) or another cognizant Federal agency.

Justification: An applicant that will charge indirect costs to the grant must enclose a copy of the current rate agreement. If the applicant organization is in the process of initially developing or renegotiating a rate, it should immediately upon notification that an award will be made, develop a tentative indirect cost rate proposal based on its most recently completed fiscal year in accordance with the principles set forth in the cognizant agency's guidelines for establishing indirect cost rates, and submit it to the cognizant agency. Applicants awaiting approval of their indirect cost proposals may also request indirect costs. It should be noted that when an indirect cost rate is requested,

those costs included in the indirect cost pool should not also be charged as direct costs to the grant. Also, if the applicant is requesting a rate which is less than what is allowed under the program, the authorized representative of the applicant organization must submit a signed acknowledgement that the applicant is accepting a lower rate than allowed.

Nonfederal Resources

Description: Amounts of non-Federal resources that will be used to support the project as identified in Block 15 of the SF–424.

Justification: The firm commitment of these resources must be documented and submitted with the application in order to be given credit in the review process. A detailed budget must be prepared for each funding source.

Dated: July 8, 2003.

Howard Rolston,

Director, Office of Planning, Research, and Evaluation, Administration for Children and Families.

[FR Doc. 03–17605 Filed 7–10–03; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N–0017]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Impact of Risk Management Programs on the Practice of Pharmacy

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by August 11, 2003.

ADDRESSES: OMB is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: Fumie Yokota, Desk Officer for FDA, FAX: 202–395–6974.

FOR FURTHER INFORMATION CONTACT: Karen L. Nelson, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1482.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Impact of Risk Management Programs on the Practice of Pharmacy

FDA is requesting OMB approval for the reporting and recordkeeping requirements contained in the survey entitled ''Impact of Risk Management Programs on the Practice of Pharmacy.''

Risk management (RM) programs are reviewed by divisions in the Center for Drug Evaluation and Research (CDER) as part of the new drug application (NDA) review process as well as during the postmarketing period. In an effort to address safety risks associated with drug therapy, several RM programs have been implemented (for example, for clozapine, thalidomide, and bosentan). Many RM programs require pharmacists to actively intervene and implement actions that deviate from their normal work procedures. Currently, the impact of RM programs on the practice of pharmacy in terms of pharmacists' compliance, knowledge, burden, and barriers is not known.

The survey is a small investigator-initiated research project to improve science safety review within CDER. The research is intended to help FDA safety evaluators of drug adverse events understand the larger context of RM programs and how they are perceived and implemented by pharmacists. The study is independent from the Prescription Drug User Fee Act III guidance that is currently under development on RM.

The descriptive survey will be sent to a representative sampling of pharmacists in the United States. Approximately 5,000 pharmacists will be chosen at random from listings of licensed pharmacists obtained from participating U.S. State Boards of Pharmacy. Because the number of licensed pharmacists in each State varies and the number of respondents from each State cannot be predicted, either a simple random or a stratified sample design will be used, depending on whether there is a sufficient number of participating pharmacists to evaluate regional differences. The geographic regions will be classified by location in one of the four geographic regions of the United States corresponding to those used by the U.S. Bureau of Census (northeast, midwest, south, and west).

The survey will be conducted via first-class mail. The survey will be mailed with a cover letter to randomly chosen pharmacists along with a preaddressed, stamped return envelope. To ensure anonymity and confidentiality, no premarkings or numbering systems will be recorded on the survey or return envelope.

From the sample size of approximately 5,000 pharmacists, the desirable response rate is approximately 75 to 85 percent. If needed, actions will be taken to increase the response rate, such as resending the survey approximately 2 weeks after the initial mailing.

In the **Federal Register** of February 12, 2003 (68 FR 7124), FDA published a notice requesting comments on FDA's burden estimates to conduct a descriptive survey of pharmacists to evaluate pharmacists' knowledge of RM programs, identify barriers to compliance, and assess the impact of these programs on the practice of pharmacy. FDA received one comment. A summary of the comment and FDA's responses are in the following paragraphs.

Concerning the issue of sampling methodology, the comment said that the primary focus of the survey should be on community pharmacists who are most likely to dispense medications associated with RM programs.

FDA believes that RM programs may affect pharmacists in all practice settings; during drug dispensing, answering drug information questions, and/or monitoring drug therapy. For this reason, the primary focus of the survey is not on community pharmacists. However, FDA will analyze responses according to pharmacy practice settings (for example, retail, hospital, and long-term care).

The comment said that the sampling frame should be stratified to obtain an equal distribution of pharmacists working in chain versus independent pharmacies.

FDA notes that the primary objective of the survey is not to compare the responses between chain and independent pharmacies. In addition, because the sampling frame does not include the setting information in which the pharmacist works, the agency cannot stratify the sampling frame. However, the survey contains a question regarding the practice setting of surveyed pharmacists and FDA intends to analyze this data.

The comment said that the survey should be accompanied by an explanation or incentive that provides a compelling reason for a pharmacist to complete it.

FDA believes that the cover letter that will accompany the survey will accomplish this suggestion because the cover letter will explain what the survey is about and that it is intended to gain insight from a pharmacist's point of view. The comment said that the sampling size should be reduced.

The survey's sample size was selected by FDA based on a consideration of response rate and cost. FDA is also concerned about the possibility that a large number of pharmacists in the sample may not have encountered RM programs. The agency believes that in a sample size of 5,000, sufficient responses may be received to gain some insight about pharmacists' experiences in dispensing drugs.

Concerning the enhancement of response rates, the comment said that a cover letter explaining why it is important for selected respondents to participate would result in a greater likelihood that sample pharmacists will participate. The letter should include an offer to send a report of the results directly to the respondent and assurance that the responses will be kept confidential.

FDA notes that a cover letter will be included with the survey explaining why the selected respondents should participate. The letter will state that the surveys are not marked and that the respondents are not identifiable. FDA intends to post the results of the survey on FDA's Web site at: *www.fda.gov.*

The comment suggested that disclosures be included on the outside envelope that will make the survey mailing ''stand out'' from the clutter of other mailings.

FDA intends to include FDA's logo on the outside envelope along with a stamped message (for example, ''Important'').

The comment said that a more comprehensive followup plan would result in greater participation.

FDA plans to send two mailings of the same survey to the selected pharmacists. A reminder postcard will be sent between these two mailings to inform the pharmacists that the second mailing will be arriving soon. The reminder postcard will also state that if the survey has already been completed and returned to FDA, the second mailing should be disregarded.

Concerning the enhancement of the quality, utility, and clarity of the information, the comment said that the survey should be revised to include questions about what educational programs might be helpful in facilitating compliance with RM programs.

FDA agrees that educating patients and health care professionals about drug risks is an important component of RM programs. The survey contains questions about existing communication tools (for example, medication guides, dear health professional letters, drug educational material), barriers to compliance, and the ways to improve this communication.

The comment said that question number 20 of the survey should be revised to measure barriers to compliance through the inclusion of: (1) A new section heading and introductory sentence or two to clarify the scope of the queries, and (2) a change to the format that would allow indication of the severity of the problem.

FDA has added self-explanatory section headings to the survey. Because the agency would consider the identification of any barrier to compliance significant, categorizing the severity of the problem would be unnecessary.

The comment said that the survey should include questions that examine the impact on the practice of pharmacy of any of the three different RM components examined (use of special prescription stickers, dear health care professional/pharmacist letters, labeling/patient information/medication guides), because this is the stated goal of the research.

FDA has added a question to the survey specifically addressing the impact of RM programs on the practice of pharmacy. In addition, the format of the question is open-ended so that the response would not be restricted in any way.

FDA estimates that it will take each pharmacist approximately 20 minutes to respond to the survey and return it to FDA.

The burden of this collection of information is estimated as follows:

TABLE 1.—ESTIMATED ONE-TIME REPORTING BURDEN[1]

Number of Respondents	Annual Frequency Per Response	Total Annual Responses	Hours per Response	Total Hours
5,000	1	5,000	.33	1,500

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: July 3, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–17574 Filed 7–10–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Notice of Approval of New Animal Drug Application; Ivermectin Pour-On

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is providing notice that in 2001 it approved a supplemental abbreviated new animal drug application (ANADA) filed by Phoenix Scientific, Inc. The supplemental ANADA provided for topical use of an ivermectin solution on cattle for control of certain internal parasites for 14 days after treatment. The applicable section of the regulation did not require amendment.

FOR FURTHER INFORMATION CONTACT: Lonnie W. Luther, Center for Veterinary Medicine (HFV–104), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 301–827–8549, e-mail: *lluther@cvm.fda.gov.*

SUPPLEMENTARY INFORMATION: In accordance with section 512(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(i)) and 21 CFR 514.105(a) and 514.106(a), FDA is providing notice that in 2001 it approved a supplemental ANADA that was not the subject of a final rule. A final rule was not published because § 524.1193 (21 CFR 524.1193) did not require amendment.

On May 16, 2001, FDA approved a supplement filed by Phoenix Scientific, Inc., 3915 South 48th St. Terrace, St. Joseph, MO 64503, to ANADA 200–219 for PHOENECTIN (ivermectin) Pour-On. The supplemental ANADA provided for topical use of a 0.5 percent ivermectin solution on cattle for control of infections of *Ostertagia ostertagi*,

Haemonchus placei, *Trichostrongylus axei*, *Oesophagostomum radiatum*, *Cooperia punctata*, and *C. oncophora* for 14 days after treatment. This supplemental approval was based on the expiration of marketing exclusivity granted the pioneer product, Merial, Ltd.'s IVOMEC Pour-On for Cattle, in 1997 (62 FR 38907, July 21, 1997). No new data were submitted. The necessary amendment to § 524.1193 was made in a final rule (66 FR 13236, March 5, 2001) for the approval of another generic copy of the pioneer product.

A freedom of information summary containing approved product labeling may be seen in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

Dated: June 25, 2003.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 03–17638 Filed 7–10–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N–0233]

Over-the-Counter Drug Products; Safety and Efficacy Review; Additional Sunscreen Ingredients

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of eligibility; request for data and information.

SUMMARY: The Food and Drug Administration (FDA) is announcing a call-for-data for safety and effectiveness information on the following conditions as part of FDA's ongoing review of over-the-counter (OTC) drug products: Amiloxate (isoamyl p-methoxycinnamate), up to 10 percent, as a sunscreen single active ingredient and in combination with other sunscreen active ingredients; enzacamene (methyl benzylidene camphor), up to 4 percent, as a sunscreen single active ingredient and in combination with other sunscreen active ingredients; and octyl triazone, up to 5 percent, as a sunscreen single active ingredient and in combination with other sunscreen active ingredients. FDA has reviewed time and extent applications (TEAs) for these conditions and determined that they are eligible for consideration in it's OTC drug monograph system. FDA will evaluate the submitted data and information to determine whether these conditions can be generally recognized as safe and effective (GRAS/E) for their proposed OTC use.

DATES: Submit data, information, and general comments by October 9, 2003.

ADDRESSES: Submit written comments, data, and information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments, data, and information to *http://www.fda.gov/dockets/ecomments*.

FOR FURTHER INFORMATION CONTACT: Matthew R. Holman, Center for Drug Evaluation and Research (HFD–560), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–2222.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of January 23, 2002 (67 FR 3060), FDA published a final rule establishing criteria and procedures for additional conditions to become eligible for consideration in the OTC drug monograph system. These criteria and procedures, codified in § 330.14 (21 CFR 330.14), permit OTC drugs initially marketed in the United States after the OTC drug review began in 1972 and OTC drugs without any marketing experience in the United States to become eligible for FDA's OTC drug monograph system. The term ''condition'' means an active ingredient or botanical drug substance (or a combination of active ingredients or botanical drug substances), dosage form, dosage strength, or route of administration, marketed for a specific OTC use (§ 330.14(a)). The criteria and procedures also permit conditions that are regulated as cosmetics or dietary supplements in foreign countries but that would be regulated as OTC drugs in the United States to become eligible for the OTC drug monograph system.

Sponsors must provide specific data and information in a TEA to demonstrate that the condition has been marketed for a material time and to a material extent to become eligible for consideration in the OTC drug monograph system. When the condition is found eligible, FDA publishes a notice of eligibility and request for safety and effectiveness data for the proposed OTC use. The TEAs that the agency reviewed (Refs. 1, 2, and 3) and FDA's evaluation of the TEAs (Refs. 4, 5, and 6) have been placed on public display in the Division of Dockets Management (see **ADDRESSES**) under the docket number found in brackets in the heading of this document.

II. Request for Data and Information

The conditions amiloxate, up to 10 percent; enzacamene, up to 4 percent; and octyl triazone, up to 5 percent, as sunscreen single active ingredients and in combination with other existing monograph sunscreen active ingredients will be evaluated for inclusion in the monograph for OTC sunscreen drug products (21 CFR part 352). Accordingly, FDA invites all interested persons to submit data and information, as described in § 330.14(f), on the safety and effectiveness of these single active ingredients for FDA to determine whether they can be GRAS/E and not misbranded under recommended conditions of OTC use. Additional data (from human clinical studies) should be included to establish the safety and effectiveness of combination sunscreen drug products containing amiloxate, enzacamene, or octyl triazone with other existing sunscreen monograph active ingredients.

Interested persons should submit comments, data, and information to the Divison of Dockets Management (see **ADDRESSES**) by October 9, 2003. Three copies of all comments, data, and information are to be submitted. Individuals submitting written information or anyone submitting electronic comments may submit one copy. Submissions are to be identified with the docket number found in brackets in the heading of this document and may be accompanied by supporting information. Received submissions may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday. Information submitted after the closing date will not be considered except by petition under § 10.30 (21 CFR 10.30).

III. Marketing Policy

Under § 330.14(h), any product containing the condition for which data and information are requested may not be marketed as an OTC drug in the United States at this time unless it is the subject of an approved new drug application or abbreviated new drug application.

IV. References

The following references are on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. TEA for amiloxate (isoamyl p-methoxycinnamate) submitted by Haarmann & Reimer Corp. dated August 14, 2002.

2. TEA for enzacamene (methyl benzylidene camphor) submitted by

Buchanan Ingersoll on behalf of Merck KGaA dated August 21, 2002.

3. TEA for octyl triazone submitted by Morgan, Lewis & Bockius LLP on behalf of BASF AG dated August 21, 2002.

4. FDA's evaluation and comments on the TEA for amiloxate.

5. FDA's evaluation and comments on the TEA for enzacamene.

6. FDA's evaluation and comments on the TEA for octyl triazone.

Dated: July 5, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–17637 Filed 7–10–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N–0069]

Release of Task Force Report; Guidance for Industry and FDA: Interim Evidence-Based Ranking System for Scientific Data; Interim Procedures for Health Claims on the Labeling of Conventional Human Food and Human Dietary Supplements; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the report of its Task Force on Consumer Health Information for Better Nutrition (the Task force) and two final guidance documents entitled ''Guidance for Industry and FDA: Interim Evidence-Based Ranking System for Scientific Data'' and ''Guidance for Industry and FDA: Interim Procedures for Health Claims in the Labeling of Conventional Human Food and Human Dietary Supplements.'' These documents further update the agency's approach on how it intends to implement the Court of Appeals decision in *Pearson* v. *Shalala*. FDA is taking this action to inform interested persons of the release of the Task Force report and to make available the guidances announced in the Task Force report in accordance with FDA's good guidance practices.

DATES: The guidances are final on July 11, 2003. However, you may submit written or electronic comments on the guidances at any time.

ADDRESSES: Submit written requests for single copies of the Task Force report and the final guidances to the Office of Nutritional Products, Labeling, and Dietary Supplements (HFS–800), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740. Send one self-addressed adhesive label to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the Task Force report and the final guidances.

Submit written comments on the final guidances to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Please identify whether you are commenting on one or both of the guidances when you submit your written comments. Submit electronic comments to *http://www.fda.gov/dockets/ecomments.*

FOR FURTHER INFORMATION CONTACT: Kathleen Ellwood, Office of Nutritional Products, Labeling, and Dietary Supplements (HFS–800), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–1450.

SUPPLEMENTARY INFORMATION:

I. Background

On December 18, 2002, FDA announced a major new initiative, the Consumer Health Information for Better Nutrition Initiative, to make available more and better information about conventional human food and human dietary supplements to help American consumers improve their health and prevent diseases by making sound dietary decisions. This initiative has as its central focus improving the public availability and consumer understanding of up-to-date scientific evidence on how dietary choices can affect health. FDA announced on January 16, 2003, that one element of this initiative was to set up an FDA Task Force and to issue a report of that Task Force approximately 6 months after the initiative was launched. The Task Force includes representatives from FDA, the Federal Trade Commission (FTC), and the National Institutes of Health.

The Task Force was charged with: (1) Reporting on how the agency can improve consumer understanding of the health consequences of their dietary choices and increase competition by product developers in support of healthier diets, including how the agency should evaluate scientific evidence for qualified health claims in order to achieve these goals; (2) developing a framework of regulations that will give these principles the force and the effect of law; (3) identifying procedures for implementing the initiative, as well as determining the organizational staffing needs necessary for the timely review of qualified health claim petitions; and (4) developing a consumer studies research agenda designed to identify the most effective ways to present scientifically-based, truthful and nonmisleading information to consumers and to identify the kinds of information known to be misleading to consumers.

On March 13, 2003, the Task Force established a public docket (docket number 2003N–0069) to receive views and comments from interested stakeholders. As part of FDA's continued commitment to ensure that stakeholders remain fully informed of our progress as we implement this initiative, FDA is making available the Task Force report, which includes nine attachments (Attachments A through I). Refer to section II of this document for a brief description of the attachments. The Task Force report entitled ''Consumer Health Information for Better Nutrition Initiative—Task Force Report—July 2003'' is available on FDA's Web sites at *http://www.fda.gov/oc/mcclellan/chbn.html* or *http://www.fda.gov/ohrms/dockets/default.htm* and by requesting paper copies from the contact person (see **FOR FURTHER INFORMATION CONTACT**). The final guidances are available at *http://www.cfsan.fda.gov/guidance.html* or *http://www.fda.gov/ohrms/dockets/default.htm.*

II. Task Force Report

The Task Force report includes a transmittal memorandum from the Chair and Vice Chair of the Task Force to the Commissioner of Food and Drugs, an executive summary, and the following attachments:

A. Possible Regulatory Frameworks for Qualified Health Claims in the Labeling of Conventional Human Food and Human Dietary Supplements

This attachment describes three options or alternatives for regulating health claims that do not meet the ''significant scientific agreement'' standard of evidence by which the health claims regulations require FDA to evaluate the scientific validity of claims.

B. Guidance: Interim Evidence-Based Ranking System for Scientific Data

This interim evidence-based ranking system describes a process for systematically evaluating the scientific evidence relevant to a substance/disease relationship that is the subject of a petition for a qualified health claim. The scientific rating system provides a means by which the totality of the publicly available scientific evidence relevant to a substance/disease

relationship can be assigned to one of four ranked levels.

C. Resources for Review of Scientific Data

This attachment describes a process to augment the agency's limited scientific review resources on an as-needed basis by using outside contractors.

D. Consumer Studies Research Agenda—Improving Consumer Understanding and Product Competition on the Health Consequences of Dietary Choices

This attachment sets forth the consumer research studies planned, pending Office of Management and Budget (OMB) approval, to provide the agency with information about consumers' reactions to qualified health claims.

E. Guidance: Interim Procedures for Qualified Health Claims in the Labeling of Conventional Human Food and Human Dietary Supplements

This attachment describes the interim procedures for qualified health claims in the labeling of conventional human food and human dietary supplements.

F. ''One-Year'' Time Line for Qualified Health Claim Activities

This attachment consolidates the main activities for June 30, 2003, through June 1, 2004.

The Task Force report also contains the list of the Task Force members, a summary of the four stakeholder meetings the Task Force held, and a summary of public comments submitted to the docket on this initiative (see Task Force report attachments G, H, and I, respectively).

III. Final Guidances

A. Background

After the enactment of the Nutrition Labeling and Education Act of 1990 (NLEA), FDA issued regulations establishing general requirements for health claims in food labeling (58 FR 2478, January 6, 1993 (conventional foods); 59 FR 395, January 4, 1994 (dietary supplements)). By regulation, FDA adopted the same procedure and standard for health claims in dietary supplement labeling that Congress had prescribed in the NLEA for health claims in the labeling of conventional foods (see 21 U.S.C. 343(r)(3) and (r)(4)). The procedure requires the evidence supporting a health claim to be presented to FDA for review before the claim may appear in labeling (§ 101.14(d) and (e) (21 CFR 101.14(d) and (e) and 101.70)). The standard requires a finding of ''significant scientific agreement'' (SSA) before FDA may authorize a health claim by regulation (§ 101.14(c)). FDA's current regulations, which mirror the statutory language in 21 U.S.C. 343(r)(3)(B)(i), provide that this standard is met only if FDA determines that there is SSA, among experts qualified by scientific training and experience to evaluate such claims; and that the claim is supported by the totality of publicly available scientific evidence, including evidence from well-designed studies conducted in a manner that is consistent with generally recognized scientific procedures and principles (§ 101.14(c)). Without a regulation authorizing use of a particular health claim, a food bearing the claim is subject to regulatory action as a misbranded food (see 21 U.S.C. 343(r)(1)(B)), a misbranded drug (see 21 U.S.C. 352(f)(1)), and an unapproved new drug (see 21 U.S.C. 355(a)).

NLEA required that FDA itself initially consider health claims for 10 substance/disease relationships. FDA determined that there was SSA concerning a number of these specified substance/disease relationships and in turn authorized eight claims. Not all relationships that Congress specified to be reviewed were found to meet the standard of SSA, and so not all were authorized by FDA.

Several of the substance/disease relationships for which FDA failed to find significant scientific agreement became the subject of a lawsuit brought by a dietary supplement manufacturer. The case is known as *Pearson* v. *Shalala (Pearson)*. In *Pearson*, the plaintiffs challenged FDA's general health claims regulations for dietary supplements and FDA's decision not to authorize health claims for four specific substance/disease relationships. The district court ruled for FDA (14 F. Supp. 2d 10 (D.D.C. 1998)). However, the U.S. Court of Appeals for the D.C. Circuit reversed the lower court's decision (164 F.3d 650 (D.C. Cir. 1999)).[1] The appeals court held that, on the administrative record compiled in the challenged rulemakings, the first amendment does not permit FDA to reject health claims that the agency determines to be potentially misleading unless the agency also reasonably determines that no disclaimer would eliminate the potential deception.

The court of appeals further stated that it did not ''rule out the possibility that where evidence in support of a claim is outweighed by evidence against the claim, the FDA could deem it incurable by a disclaimer and ban it outright.'' (Id. at 659.) Also, the court saw ''no problem with the FDA imposing an outright ban on a claim where evidence in support of the claim is qualitatively weaker than the evidence against the claim.'' (Id. at 659 and n.10.) This language was the genesis of the ''weight-of-the evidence'' criterion discussed in this document.

In the **Federal Register** of October 6, 2000 (65 FR 59855), FDA published a notice announcing its intention to exercise enforcement discretion with regard to certain categories of dietary supplement health claims that do not meet the SSA standard in § 101.14(c). The notice set forth criteria for when the agency would consider exercising enforcement discretion for a qualified health claim in dietary supplement labeling, including as a criterion whether the scientific evidence in support of a given claim outweighed the scientific evidence against it.

As discussed previously, on December 18, 2002, FDA announced the Consumer Health for Better Nutrition Initiative to encourage the flow of high quality, science-based information regarding the health benefits of conventional foods and dietary supplements to consumers. In the **Federal Register** of December 20, 2002 (67 FR 78002), FDA announced that it would apply *Pearson* to health claims in the labeling of conventional foods as well as dietary supplements. The agency also announced the availability of guidance concerning when FDA intended to consider exercising enforcement discretion with respect to health claims that do not meet the standard of SSA. Based on *Pearson*, the December 2002 guidance, like the October 2000 **Federal Register** notice stating FDA's intention to consider exercising enforcement discretion with respect to dietary supplement health claims that do not meet SSA, included as a criterion whether the scientific evidence in support of the claim outweighs the scientific evidence against the claim.

Six days after publication of the December 20, 2002, notice and the guidance, the U.S. District Court for the District of Columbia issued its decision in *Whitaker* v. *Thompson*, 248 F. Supp.2d 1 (*Whitaker*). In *Whitaker*, the district court interpreting *Pearson*, found that ''credible evidence,'' rather than ''weight of the evidence'' is the appropriate standard for FDA to apply in evaluating qualified health claims. In light of *Whitaker*, FDA believes that the weight of the evidence standard in the

[1] On March 1, 1999, the Government filed a petition for rehearsing en banc (reconsideration by the full court of appeals). The U.S. Court of Appeals for the D.C. Circuit denied the petition for rehearsing on April 2, 1999 (172 F.3d 72 (D.C. Cir. 1999)).

October 2000 **Federal Register** notice and the December 2002 guidance must be tempered by the test of credible evidence. Communication of that or any other level of evidence to consumers in a nonmisleading way remains of critical importance.

The reason for the decision to apply *Pearson* to conventional foods is to provide consumers with better health/nutrition information so they can make better dietary choices. By making clear that manufacturers may label foods with truthful and nonmisleading health claims, FDA believes that the guidance will precipitate greater communication in food labeling of the health benefits of consuming particular foods, thereby enhancing the public's health, because consumers will respond to health claims in food labeling by making better informed dietary choices (67 FR 78002).

The decision announced in the December 2002 notice was also based on a desire to avoid further litigation over the constitutionality of the health claims provisions of the NLEA applicable to conventional food labeling to the extent that these provisions do not permit qualified claims. As explained previously, the appeals court held that, on the administrative record compiled in the challenged rulemakings, the first amendment does not permit FDA to reject health claims that the agency determines to be potentially misleading unless the agency also reasonably determines that no disclaimer would eliminate the potential deception. The agency, however, did not have any consumer data to show that a disclaimer would not eliminate the potential deception.

Pearson and subsequent related cases including *Whitaker*, concern dietary supplement labeling, but as stated previously, FDA by regulation adopted the same procedure and standard for health claims for dietary supplement labeling that Congress prescribed in the NLEA for health claims in conventional food labeling. These dietary supplement regulations, like the NLEA provisions in question, do not provide for qualified claims. Hence, based on *Pearson* and related cases, a court faced with a decision by FDA to not permit a qualified health claim for a conventional food might well find the same tension between the NLEA provisions and the first amendment. It is possible that consumer data will show that potentially misleading health claims cannot be cured by disclaimers in at least some cases, but the agency does not have such data for conventional foods, as it did not (and does not) have such data for dietary supplements. Within the next year, the agency will be completing research in this area. The results of this research, together with further evaluation of the regulatory alternatives identified by the Task Force, and evaluation of any additional alternatives, will inform any rulemaking FDA initiates.

In the interim, FDA intends to use the procedures and evidence-based ranking systems for scientific data set out in the below-described guidances on these matters, and consider the exercise of enforcement discretion on a case-by-case basis with respect to qualified health claims in conventional human food and human dietary supplement labeling under certain circumstances. (See *Heckler* v. *Chaney*, 470 U.S. 821 (1985); *Community Nutrition Institute* v. *Young*, 818 F.2d 943, 949–50 (D.C. Cir. 1987)).

FDA believes that its interim approach to qualified claims is a reasonable effort to combine the spirit of the NLEA with the current public health and legal circumstances, and one that reflects practical common sense. And, as the Court of Appeals for the District of Columbia Circuit observed in *Niagara Mohawk Power Corp.* v. *FPC*, 379 F.2d 153, 160, ''Courts are loath to say that good sense is not good law.''

B. Guidance for Industry and FDA: Interim Evidence-Based Ranking System for Scientific Data

This interim evidence-based ranking system describes a process for systematically evaluating the scientific evidence relevant to a substance/disease relationship that is the subject of a petition for a qualified health claim. The scientific rating system provides a means by which the totality of the publicly available scientific evidence relevant to a substance/disease relationship can be assigned to one of four ranked levels. The evidence-based ranking system presupposes that FTC's requirement of ''competent and reliable scientific evidence'' to substantiate an advertising claim related to health or safety has been met. FTC defines ''competent and reliable scientific evidence'' as ''tests, analyses, research, studies, or other evidence'' based upon the expertise of professionals in the relevant area, that has been ''conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted'' in the profession to ''yield accurate and reliable results.'' *In Re: Great Earth International, Inc.*, 110 F.T.C. 188 (1988). In applying the system, FDA intends to consider scientific evidence only if it is competent and reliable. FDA intends to use this interim system, beginning in September 2003, for qualified health claims in the labeling of conventional human food and human dietary supplements. See the **ADDRESSES** section of this notice for information on submitting comments on this final guidance.

C. Guidance for Industry and FDA: Interim Procedures for Qualified Health Claims in the Labeling of Conventional Human Food and Human Dietary Supplements

FDA intends to use these interim procedures, beginning in September 2003, for qualified health claims in the labeling of conventional human food and human dietary supplements. See the **ADDRESSES** section of this notice for information on submitting comments on this final guidance.

D. The Final Guidances Are Being Issued as Level 1 Guidance under FDA's Good Guidances Practices (GGPs) Regulation (§ 10.115 (21 CFR 10.115))

Consistent with GGPs, the agency will accept comment, but it is implementing these guidance documents immediately in accordance with section 10.115(g)(2) because the agency has determined that prior public participation is not feasible or appropriate. FDA tentatively concludes that the guidances contain no new collection of information. Therefore, clearance by OMB under the Paperwork Reduction Act of 1995 is not required.

IV. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding the guidances. Submit a single copy of the electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The Task Force report, two final guidances, and received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

V. Electronic Access

Interested persons may also access the guidance documents at *http://www.cfsan.fda.gov/guidance.html* or *http://www.fda.gov/ohrms/dockets/default.htm.*

VI. Future Agency Activities

FDA emphasizes that it intends to use the evidence-based ranking system and the procedures on an interim basis. In the near future, the agency intends to publish an advance notice of proposed

rulemaking consistent with the recommendations of the Task Force. As also recommended by the Task Force, FDA intends, within 1 year, to initiate notice-and-comment rulemaking to establish scientific review criteria and procedures for qualified health claim petitions. By that time, FDA expects to complete the consumer studies research as described in the Task Force report (attachment D). The results of this research, together with further evaluation of the regulatory alternatives identified by the Task Force, with the benefit of public comment, and evaluation of any additional alternatives that stakeholders suggest in response to the advance notice of proposed rulemaking, will inform the rulemaking FDA intends to initiate.

Dated: July 8, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–17702 Filed 7–10–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Fiscal Year 2003 Competitive Application Cycle for Operational Health Center Networks (OHCN) CFDA Number 93.224, HRSA–03–105

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice of availability of funds.

SUMMARY: The Health Resources and Services Administration (HRSA) announces the availability of up to $2,100,000 to support costs associated with the operation of a practice management or managed care network or plan, including the purchase or lease of equipment (including the costs of amortizing the principal of, and paying the interest on, loans for equipment).

Authorizing Legislation: Section 330(e)(1)(C) of the Public Health Service Act, as amended authorizes support to health centers that receive assistance under section 330, or at the request of the health centers, directly to a managed care or practice management network or plan that is at least majority controlled and, as applicable, at least majority owned by such health centers receiving assistance under section 330 for the costs associated with the operation of such network or plan, including the purchase or lease of equipment (including the costs of amortizing the principal of, and paying the interest on, loans for equipment). Operational networks are defined as a group of three or more health centers that can demonstrate that an essential, mission-critical function is performed at the network level for the network members, enabling the member centers to perform their business and clinical operations more efficiently and effectively.

DATES: The intended time lines for application submission, review, and award are as follows:

Application Deadline: August 11, 2003.

Grant awards announced: September 30, 2003.

Applications will be considered on time if they are: (1) received by 5 p.m. Eastern Standard Time on August 11, 2003; or (2) postmarked on or before the deadline date given in the **Federal Register** notice and received in time for orderly processing. Applications submitted after the deadline date will be returned to the applicant and not processed. Applicants should obtain a legibly dated receipt from a commercial carrier or the U.S. Postal Service or request a legibly dated U.S. Postal Service postmark. Private metered postmarks shall not be accepted as proof of timely mailing. Applications sent to any address other than that specified below are subject to being returned. Applicants should note that HRSA anticipates accepting grant applications online in the last quarter of the fiscal year (July through September). Please refer to the HRSA grants schedule at *http://www.hrsa.gov/grants.htm* for more information.

Where to request and send an application: To obtain a complete application kit, (*i.e.,* application instructions, necessary forms, and application review criteria), contact the HRSA Grants Application Center (GAC) at: HRSA Grants Application Center, 901 Russell Avenue, Suite 450, Gaithersburg, Maryland 20879, Phone: 1–877–HRSA–123 (1–877–477–2123), Fax: 1–877–HRSA–345 (1–877–477–2345), Email: *hrsagac@hrsa.gov.*

When contacting the HRSA GAC please use the following program announcement when requesting application materials: HRSA–03–105, citing ''Operational Health Center Networks.'' Send the original and two copies of the application to the HRSA GAC. Applicants will receive a letter acknowledging the receipt of their application.

Eligible applicants: The following entities are eligible to apply for funding under this announcement:

1. A health center, as defined and funded under section 330 of the Public Health Service Act, acting on behalf of the member health centers and the network.

(A) A health center applying on behalf of a managed care network or plan must have received Federal grants under subsection (e)(1)(A) of section 330 for at least the two consecutive preceding years.

(B) A health center (Community Health Center, Migrant Health Center, Health Care for the Homeless, Public Housing Primary Care and Healthy Schools, Healthy Communities) applying on behalf of a practice management network must have received Federal grants under section 330 for at least the two consecutive preceding years.

2. Operational networks, controlled by and acting on behalf of the health center(s) as defined and funded under section 330 of the Public Health Service Act. At the request of all the member health centers, a network may apply for direct funds if it is at least majority controlled and, as applicable, at least majority owned, by such health centers.

3. Eligibility is limited to public and non-profit organizations, including faith-based and community organizations.

Matching or cost sharing requirement: Grantees must provide at least 60 percent of the total approved cost of the project. The total approved cost of the project is the sum of the HRSA share and the non-Federal share. Applicants must demonstrate that at least 30 percent of the cost sharing requirement is met through cash contributions. The remaining non-Federal share may be met by cash or in-kind contributions.

Application review and funding criteria: Each application submitted by the deadline will be reviewed initially for completeness and eligibility. Applications that are determined to be ineligible, incomplete, or non-responsive will be returned to the applicant without further consideration. Those applications that are determined to be eligible and responsive to the requirements will be reviewed by a panel of reviewers comprised of non-Federal experts using the following objective review criteria:

1. Appropriateness in meeting expectations of the Integrated Shared Development Initiative—extent to which the application effectively demonstrates the integration and coordination of primary care across business and clinical functions of network members.

2. Appropriateness to State Environment and Marketplace—extent to which the application demonstrates both the (a) appropriateness of the network to the State marketplace and/or

environment, and (b) strengthened position (*i.e.,* financial condition, competitive position) of its member health centers in the State marketplace and/or environment.

3. Strength of Collaboration—extent to which commitment (as evidenced by the contribution of time, resources, cash, *etc.*) by each network member is demonstrated in the business plan, implementation plan, strategic plan, budget spreadsheet and accompanying narrative, and operational agreement.

4. Network Operation: Core Strength and Competencies—extent to which the network design is suited to the organizational/administrative capacity of the network members based on operational history of the network.

5. Capacity of the Network to Support Shared/Integrated Operations—extent to which network members have shared and/or integrated functions or components of their systems.

Funding preference: A funding preference is defined as the funding of a specific category or group of approved applications ahead of other categories of applications. A preference will be given to applicants proposing to serve sparsely populated rural or frontier areas.

Estimated amount of available funds: For fiscal year 2003, up to $2,100,000 will be available for this program.

Estimated project period: 3 years.

Estimated number of awards: This is a new program; the estimated number of awards may range from 5 to 7 in fiscal year 2003.

Estimated or average size of each award: This is a new grant program; the estimated costs are expected to vary considerably with a range from $150,000 to $300,000.

Information contact: Applicants may contact Christie Brown by phone at 301–594–4314 or by email at *CBrown1@hrsa.gov.*

Paperwork Reduction Act: The application for Operational Health Center Networks has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act. The OMB clearance number is 0920–0428.

Public health system reporting requirements: Under these requirements (approved by the Office of Management and Budget under OMB number 0937–0195), a community-based, non-governmental applicant must prepare and submit a Public Health System Impact Statement to the head of the appropriate State and local health agencies in the area(s) to be impacted no later than the Federal application receipt due date. This statement must include:

1. A copy of the face page of the application (SF 424) and

2. A summary of the project, not to exceed one page, which provides:

a. A description of the population to be served,

b. A summary of the services to be provided, and

c. A description of the coordination planned with the appropriate State and local health agencies.

Executive Order 12372: This program has been determined to be a program that is subject to the provisions of Executive Order 12372 concerning intergovernmental review of Federal programs by appropriate health planning agencies, as implemented by 45 CFR Part 100. Executive Order 12372 allows States the option of setting up a system for reviewing applications from within their States for assistance under certain Federal programs. The application packages pursuant to this notice will contain a listing of States with review systems and will provide a single point of contact (SPOC) in the State for review. A SPOC list is also available at *http://www.whitehouse.gov/omb/grants/spoc.html.* Applicants (other than federally-recognized Indian tribal governments) should contact their SPOCs as early as possible to alert them to the prospective applications and receive any necessary instructions on the State process. For proposed projects serving more than one State, the applicant is advised to contact the SPOC of each affected State. The due date for State process recommendations is 60 days after the applicable Federal application receipt due date. The granting agency does not guarantee to ''accommodate or explain'' its responses to State process recommendations received after the due date. (*See* ''Intergovernmental Review of Federal Programs,'' Executive Order 12372, and 45 CFR part 100, for a description of the review process and requirements.)

Dated: June 25, 2003.

Elizabeth M. Duke,

Administrator.

[FR Doc. 03–17530 Filed 7–10–03; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Indian Health Service Contract Health Service; Purchase-Delivery Order for Health Service

AGENCY: Indian Health Service, HHS.

ACTION: Request for public comment: 30-day proposed information collection: Indian Health Service Contract Health Service Purchase-Delivery Order for Health Service.

SUMMARY: The Indian Health Service, as part of its continuing effort to reduce paperwork and respondent burden, conducts a pre-clearance consultation program to provide the general public and Federal agencies with an opportunity to comment on proposed and/or continuing collections of information in accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3506(c)(2)(A)). This program helps to ensure that requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements on respondents can be properly assessed. As required by section 3507(a)(1)(D) of the Act, the proposed information collection has been submitted to the Office of Management and Budget (OMB) for review and approval.

The IHS received no comments in response to the 60-day **Federal Register** notice (67 FR 77800) published on December 19, 2002. The purpose of this notice is to allow an additional 30 days for public comment to be submitted directly to OMB.

Proposed Collection

Title: 0917–0002, re-titled ''Indian Health Service Contract Health Service Purchase-Delivery Order for Health Service.'' *Type of Information Collection Request:* Reinstatement, without change, of a previously approved collection for which approval has expired. *Form number:* IHS–843–1A. *Need and Use of Information Collection:* Respondents certify that they have performed the health care services authorized by the IHS. Information is used to manage, administer and plan for the provisions of health care services to eligible American Indians, process payments to providers, obtain program data, provide program statistics, and serve as a legal document for health care services rendered. *Affected Public:* Businesses or other for-profit, Individuals or Households, Not-for-profit institutions, and State, local or Tribal Government. *Type of Respondents:* Health care providers.

The table below provides the following: types of data collection instructions, estimated number of respondents, number of responses per respondent, annual number of responses, average burden hour per response, and total annual burden hours.

Data collection instrument	Estimated number of respondents	Respones per respondent	Annual number of responses	Average burden hours per response*	Total annual burden hours
IHS–843–1A	7,087	42	299,149	0.05 (3 mins)	14,957
Tribal use	528	36	19,112	0.05 (3 mins)	956
IDS**	20,142	1	20,142	0.05 (3 mins)	1,007
Total	27,757				16,920

* For ease of understanding, burden hours are also provided in actual minutes.
** Inpatient Discharge Summary (IDS).

There are no Capital Costs, Operating Costs and/or Maintenance Costs to report.

Request for Comments: Your written comments and/or suggestions are invited on one or more of the following points: (a) Whether the information collection activity is necessary to carry out an agency function; (b) whether the agency processes the information collected in a useful and timely fashion; (c) the accuracy of the public burden estimate (the estimated amount of time needed for individual respondents to provide the requested information); (d) whether the methodology and assumptions used to determine the estimate are logical; (e) ways to enhance the quality, utility, and clarity of the information being collected; and (f) ways to minimize the public burden through the use of automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Direct Comments to OMB: Send your written comments and suggestions regarding the proposed information collection contained in this notice, especially regarding the estimated public burden and associated response time, directly to: Office of Management and Budget, Office of Regulatory Affairs, New Executive Office Building, Room 10235, Washington, DC 20503, Attention: Allison Eydt, Desk Officer for IHS. Send requests for more information on the proposed collection or to obtain a copy of the data collection instrument(s) and instructions to: Ms. Christine Ingersoll, IHS Reports Clearance Officer, 12300 Twinbrook Parkway, Suite 450, Rockville, MD 20852–1601, call non-toll free (301) 443–5938, send via facsimile to (301) 443–2316, or send your E-mail requests, comments, and return address to: *cingerso@hqe.ihs.gov.*

FOR FURTHER INFORMATION CONTACT: For information on the proposed data collection instrument and/or the process for handling the form IHS–843–1A, please contact Mr. Clayton Old Elk, 801 Thompson Avenue, Suite 300, Rockville, MD 20852–1627, Telephone 301–443–2694.

Comment Due Date: Your comments regarding this information collection are best assured to having their full effect if received within 30-days of the date of this publication.

Dated: June 30, 2003.

Charles W. Grim,

Assistant Surgeon General, Interim Director.

[FR Doc. 03–17639 Filed 7–10–03; 8:45 am]

BILLING CODE 4160–16–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Fiscal Year (FY) 2003 Funding Opportunity

AGENCY: Substance Abuse and Mental Health Services Administration, HHS.

ACTION: Notice of funding availability for a Supplement to Expand the Cooperative Agreement for the National Center for Child Traumatic Stress (NCCTS)

SUMMARY: The Substance Abuse and Mental Health Services Administration (SAMHSA), Center for Mental Health Services (CMHS), announces the availability of FY 2003 funds for the cooperative agreement described below. A synopsis of this funding opportunity, as well as many other Federal Government funding opportunities, is also available at the Internet site: *http://www.fedgrants.gov.*

This notice is not a complete description of the program; potential applicants must obtain a copy of the Request for Applications (RFA), including Part I, Supplement to Expand the Cooperative Agreement for the National Center for Child Traumatic Stress (NCCTS), Part II, General Policies and Procedures Applicable to all SAMHSA applications for Discretionary Grants and Cooperative Agreements, and the PHS 5161–1 (Rev. 7/00) application form before preparing and submitting an application.

Funding Opportunity Title: Supplement to Expand the Cooperative Agreement for the National Center for Child Traumatic Stress (NCCTS)—Short Title: NCCTS Supplement.

Funding Opportunity Number: SM 03–010.

Catalog of Federal Domestic Assistance (CFDA) Number: 93.243.

Authority: Section: 582 of the Public Health Service Act, as amended and subject to the availability of funds.

Funding Opportunity Description: The Substance Abuse and Mental Health Services Administration (SAMHSA), Center for Mental Health Services (CMHS), is accepting an application for fiscal year 2003 to expand the cooperative agreement for the National Center for Child Traumatic Stress (NCCTS). The NCCTS currently coordinates the National Child Traumatic Stress Network (NCTSN) and provides leadership and focus for 10 Intervention Development and Evaluation Centers (IDE) and 26 Community Treatment and Service Centers (CTS). These funds will enable NCCTS to strengthen its ability to support results-oriented collaborative projects within the NCTSN and support the development and dissemination of high-priority products essential for the success of the Initiative.

Eligible Applicants: Eligibility is limited to the University of California at Los Angeles (UCLA). UCLA (in partnership with Duke University) has operated the currently funded NCCTS in its first 2 years. The NCCTS has proven capable and effective in carrying out activities in pursuit of the goals of the NCTSI. This success is reflected in the expansion and supplementation of funding for NCTSI for FY 2002 and 2003. The Government's interest in building on the capacity and infrastructure already developed with Government funds is a compelling argument for continuing the NCTSI coordination activities through the UCLA-Duke NCCTS. Further, duplication of effort and substantial confusion would result if a second ''National Center'' were established with a primary mission of networking and collaboration building in the NCTSI. For these reasons, only the currently funded

NCCTS, operated by UCLA, may apply for this award.

Due Date for Application: August 7, 2003.

Estimated Funding Available/Number of Awards: It is expected that up to $1 million will be available for this one-year supplemental award in FY 2003 (both direct and indirect costs). Actual funding levels will depend on the availability of funds. If the application proposes a budget that exceeds $1 million, it will be returned without review.

Is Cost Sharing Required: No.

Period of Support: One year.

How to Get Full Announcement and Application Materials: Complete application kits may be obtained by calling: the SAMHSA Mental Health Information Center at (800) 789–2647, Monday through Friday, 8:30 a.m. to 5 p.m., e.d.t.; TDD: (301) 443–9006; Fax: (301) 984–8796; P.O. Box 42490, Washington, DC 20015. The PHS 5161–1 application form and the full text of the funding announcement are also available electronically via SAMHSA's World Wide Web Home Page: *http://www.samhsa.gov* (Click on ''Grant Opportunities'').

When requesting an application kit, the applicant must specify the funding opportunity title and number for which detailed information is desired. All information necessary to apply, including where to submit applications and application deadline instructions, are included in the application kit.

FOR FURTHER INFORMATION CONTACT: Robert DeMartino, M.D., Substance Abuse and Mental Health Services Administration, Center for Mental Health Services, Division of Prevention, Traumatic Stress, and Special Programs, 5600 Fishers Lane, Room 17C–26, Rockville, MD 20857, (301) 443–2940, E-mail: *rdemarti@samhsa.gov.*

Dated: July 7, 2003.

Anna Marsh,

Acting Executive Officer, Substance Abuse and Mental Health Services Administration.

[FR Doc. 03–17640 Filed 7–10–03; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Fiscal Year (FY) 2003 Funding Opportunity

AGENCY: Substance Abuse and Mental Health Services Administration, HHS.

ACTION: Notice of funding availability for a Cooperative Agreement to Supplement the Technical Assistance Resource Center for the Prevention of Violence and Behavioral Health Problems.

SUMMARY: The Substance Abuse and Mental Health Services Administration (SAMHSA), Center for Mental Health Services (CMHS), announces the availability of FY 2003 funds for the cooperative agreement described below. A synopsis of this funding opportunity, as well as many other Federal Government funding opportunities, is also available at the Internet site: *http://www.fedgrants.gov.*

This notice is not a complete description of the program; potential applicants must obtain a copy of the Request for Applications (RFA), including Part I, Cooperative Agreement to Supplement the Technical Assistance Resource Center for the Prevention of Violence and Behavioral Health Problems, Part II, General Policies and Procedures Applicable to all SAMHSA applications for Discretionary Grants and Cooperative Agreements, and the PHS 5161–1 (Rev. 7/00) application form before preparing and submitting an application.

Funding Opportunity Title: Cooperative Agreement to Supplement the Technical Assistance Resource Center for the Prevention of Violence and Behavioral Health Problems—Short Title: Supplement to the Behavioral Health Promotion TA Center.

Funding Opportunity Number: SM 03–013.

Catalog of Federal Domestic Assistance (CFDA) Number: 93.243.

Authority: Section: 520A and 581 of the Public Health Service Act, as amended and subject to the availability of funds.

Funding Opportunity Description: The Substance Abuse and Mental Health Services Administration (SAMHSA), Center for Mental Health Services (CMHS), is accepting a program supplement to enhance the existing Resource Center's capacity to work with Safe Schools/Healthy Students (SS/HS) grantees on three distinct projects: (1) to work with project directors and local evaluators to develop a monograph that documents local evaluation efforts to disseminate the monograph; (2) to develop a SS/HS project directors manual; and (3) to continue research on sustainability issues specific to SS/HS.

Eligible Applicants: Only the Education Development Center, Inc., 55 Chapel Street, Newton, MA 02458 can apply.

The Safe Schools Healthy Students (SS/HS) initiative first received funding in 1999. Each grantee is required to evaluate its SS/HS activities to ensure that it is meeting the goals and objectives presented in its application as well as the initiative as a whole. Some grantees include measures that attempt to determine whether the initiative has been successful in preventing or reducing youth violence. While a national evaluation of the SS/HS initiative is under way, no organization has reviewed the evaluations conducted by local grant sites. The activities of this RFA are designed to supplement and complement the national evaluation effort. In order to answer questions from Congress and the General Accounting Office, this effort must be completed rapidly. Given the compressed timeframe in which this activity is needed and the limited resources, SAMHSA believes it is more efficient and cost effective to use an organization already firmly grounded in the objectives of the SS/HS initiative and one that has existing relationships with the SS/HS grantee sites. This familiarity with the program and the grantees will allow the current technical assistance center to more rapidly complete the needed work.

Additionally, this Request for Applications (RFA) proposes that the grantee organization will develop a manual for SS/HS project directors as well as identifying sustainability issues and resources unique to the SS/HS initiative. Since the identified applicant organization will be required to collaborate with the SS/HS project directors to identify requisite material for this manual and to develop guidance on sustaining the initiative after Federal funding, it is most beneficial to the Government to use an organization with an already established relationship with these project directors. The identified organization is the current technical assistance provider for this initiative and has the experience, background, and relationship with these grantees to collaborate with them on the tasks outlined in this RFA and meet the Government's needs in an expedited fashion. In order to eliminate the potential for confusion that could stem from multiple entities contacting grantees for similar activities, it is in the best interest of the Government to use the existing technical assistance provider.

Due Date for Application: August 15, 2003.

Estimated Funding Available/Number of Awards: It is expected that up to $445,000 will be available for one award in FY 2003 (both direct and indirect costs). If the application proposes a budget that exceeds $445,000, it will be returned without review.

Is Cost Sharing Required: No.

Period of Support: Funding may be requested for up to 2 years. The continuation award will depend on the availability of funds and progress achieved.

How to Get Full Announcement and Application Materials: Complete application kits may be obtained by calling: the SAMHSA Mental Health Information Center at (800) 789–2647, Monday through Friday, 8:30 a.m. to 5 p.m., e.d.t.; TDD: (301) 443–9006; Fax: (301) 984–8796; P.O. Box 42490, Washington, DC 20015. The PHS 5161–1 application form and the full text of the funding announcement are also available electronically via SAMHSA's World Wide Web Home Page: *http://www.samhsa.gov* (Click on ''Grant Opportunities'').

When requesting an application kit, the applicant must specify the funding opportunity title and number for which detailed information is desired. All information necessary to apply, including where to submit applications and application deadline instructions, are included in the application kit.

FOR FURTHER INFORMATION CONTACT: Brenda Bruun, Substance Abuse and Mental Health Services Administration, Center for Mental Health Services, 5600 Fishers Lane, Room 17C–26, Rockville, MD 20857, (301) 443–4669, E-mail: *bbruun@samhsa.gov.*

Dated: July 7, 2003.

Anna Marsh,

Acting Executive Officer, Substance Abuse and Mental Health Services Administration.

[FR Doc. 03–17641 Filed 7–10–03; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HOMELAND SECURITY

Human Resource Management System Senior Review Advisory Committee

AGENCY: Directorate for Management, DHS.

ACTION: Notice of meeting.

SUMMARY: The Human Resource Management System Senior Review Advisory Committee (Committee or SRC) will meet in its inaugural session on Friday, July 25, 2003. The SRC is charged with reviewing the work of the Department of Homeland Security/Office of Personnel Management (DHS/OPM) Design Team and providing options to the Secretary of DHS and the Director of OPM for their consideration in establishing the new Human Resource Management System provided for in section 841 of the Homeland Security Act. The entire meeting will be open to the public.

DATES: The SRC will meet July 25, 2003 from 8:30 a.m. to 1 p.m. Notice of this meeting is published less than 15 days in advance (14 days notice is provided) in order to accommodate the schedules of several SRC members who will be unavailable to meet until the next anticipated meeting in September. Requests by members of the public to make oral presentations at the meeting and written statements for the SRC should reach the Designated Federal Official at DHS on or before July 21, 2003. Written statements may also be filed with the SRC at the meeting. All written submissions will become part of the Committee record and deliberations.

ADDRESSES: The SRC meeting will be held at the Radisson Barcelo Hotel Washington, 2121 P Street NW., Washington DC 20037. Send written statements and requests to make an oral presentation to the SRC Designated Federal Officer (DFO) at: Department of Homeland Security, Washington, DC 20528. For delivery services such as Fedex, UPS, *etc.,* the address is: Department of Homeland Security, Attn: Under Secretary for Management/CHCO/Melissa Allen, Via: Remote Delivery Site (RDS), 245 Murray Drive, Bldg 410, Washington, DC 20528.

FOR FURTHER INFORMATION CONTACT: Ms. Kay Frances Dolan, Director Human Resource Policy, DHS, and Ms. Melissa Allen, Senior Human Resource Advisor, DHS, have been designated as DFOs for the SRC. They can be reached on 202–692–4272; *KayFrances.Dolan@dhs.gov* or *Melissa.Allen@dhs.gov;* and at the addresses listed above.

SUPPLEMENTARY INFORMATION:

Objective. The purpose of this meeting is to (1) welcome and introduce the members of the Committee; (2) receive briefings by senior members of the HR Design Team on the research strategy and status; (3) hold discussions among the SRC members on the guiding principles and system elements for development of human resource system options; (4) discuss and review the template for presentation of the options at future meetings. Following these formal agenda items, the Committee will hear from members of the public.

Public Presentations. Requests to make oral presentations should reach the Designated Federal Official at DHS on or before July 21, 2003. Oral presentations will be limited to approximately 3 minutes to allow sufficient time for any questions from the Committee. Oral presentations may be supplemented by written statements; there is no limit to written statements submitted for the record. If there is insufficient time to honor all requests for oral presentations, the Designated Federal Official (DFO) will seek to ensure a full range of views and opinions are heard. Members of the public who wish to file a written statement with the SRC may do so in person or send it to the DFO (see **ADDRESSES** above); written statements should be received on or before July 21, 2003. All written submissions will become part of the Committee record and deliberations.

Information on Services for Individuals with Disabilities. For information on facilities or services for individuals with disabilities, or to request special assistance at the meeting, please notify the Designated Federal Official as soon as possible by phone or e-mail.

Dated: July 8, 2003.

Janet Hale,

Under Secretary for Management.

[FR Doc. 03–17595 Filed 7–10–03; 8:45 am]

BILLING CODE 4410–10–P

DEPARTMENT OF HOMELAND SECURITY

Bureau of Customs and Border Protection

[CBP Decision 03—06]

Customs Accreditation of Intertek Testing Services/Caleb Brett as a Commercial Laboratory

AGENCY: Customs and Border Protection, Department of Homeland Security.

ACTION: Notice of Accreditation of Intertek Testing Services/Caleb Brett of Texas City, Texas, as a Commercial Laboratory.

SUMMARY: Intertek Testing Services/Caleb Brett of Texas City, Texas has applied to Customs and Border Protection under part 151.12 of the Customs Regulations for an extension of accreditation as a commercial laboratory to analyze petroleum products under Chapter 27 and Chapter 29 of the Harmonized Tariff Schedule of the United States (HTSUS). Customs has determined that this company meets all of the requirements for accreditation as a commercial laboratory. Specifically, Intertek Testing Services/Caleb Brett has been granted accreditation to perform the following test methods at their Texas City, Texas site: (1) Distillation of Petroleum Products, ASTM D86; (2) Flash-Point by Pensky Martens Closed Cup Tester, ASTM D93; (3) API Gravity by Hydrometer, ASTM D287; (4) Kinematic Viscosity of Transparent and Opaque Liquids, ASTM D445; (5)

Sediment in Crude Oils and Fuel Oils by Extraction, ASTM D473; (6) Water in Crude Oil by Distillation, ASTM D4006; (7) Water and Sediment in Crude Oil by the Centrifuge Method, ASTM D4007; (8) Percent by Weight of Sulfur by Energy-Dispersive X-Ray Fluorescence, ASTM D4294; (9) Water in Crude Oils by Coulometric Karl Fischer Titration, ASTM D4928; (10) Density and Relative Density of Crude Oils by Digital Density Analyzer, ASTM D 5002; (11) Vapor Pressure of Petroleum Products, ASTM D5191; and (12) Pour Point of Crude Oils, ASTM D 5853. Therefore, in accordance with part 151.12 of the Customs Regulations, Intertek Testing Services/Caleb Brett of Texas City, Texas is hereby accredited to analyze the products named above.

LOCATION: Intertek Testing Services/ Caleb Brett accredited site is located at: 101 20th Street South, Texas City, TX 77590.

EFFECTIVE DATE: July 1, 2003.

FOR FURTHER INFORMATION CONTACT: Arlene Faustermann, Science Officer, Laboratories and Scientific Services, Customs and Border Protection, 1300 Pennsylvania Avenue, NW., Suite 1500 North, Washington, DC 20229, (202) 927–1060.

Dated: July 1, 2003.

Ira S. Reese,

Executive Director, Laboratories and Scientific Services.

[FR Doc. 03–17550 Filed 7–10–03; 8:45 am]

BILLING CODE 4820–02–P

DEPARTMENT OF HOMELAND SECURITY

Bureau of Customs and Border Proctection

[CBP Decision 03—07]

Customs Accreditation of Alchem Laboratory, Inc., as a Commercial Laboratory

AGENCY: Customs and Border Protection, Department of Homeland Security.

ACTION: Notice of Accreditation of Alchem Laboratory, Inc. of Ponce, Puerto Rico, as a Commercial Laboratory.

SUMMARY: Alchem Laboratory, Inc. of Ponce, Puerto Rico has applied to Customs and Border Protection under part 151.12 of the Customs Regulations for an extension of accreditation as a commercial laboratory to analyze petroleum products under Chapter 27 and Chapter 29 of the Harmonized Tariff Schedule of the United States (HTSUS). Customs has determined that this company meets all of the requirements for accreditation as a commercial laboratory. Specifically, Alchem Laboratory, Inc. has been granted accreditation to perform the following test methods at their Ponce, Puerto Rico site: (1) Distillation of Petroleum Products, ASTM D86; (2) Kinematic Viscosity of Transparent and Opaque Liquids, ASTM D445; (3) Density, Relative Density (Specific Gravity), or API Gravity of Crude Petroleum and Liquid Petroleum Products by Hydrometer Method, ASTM D1298; (4) Percent by Weight of Sulfur by Energy-Dispersive X-Ray Fluorescence, ASTM D4294. Therefore, in accordance with part 151.12 of the Customs Regulations, Alchem Laboratory, Inc. of Ponce, Puerto Rico is hereby accredited to analyze the products named above.

LOCATION: Alchem Laboratory, Inc. accredited site is located at: Sabanetas Industrial Park, Building M–1380, Ponce, PR 00731.

EFFECTIVE DATE: July 1, 2003.

FOR FURTHER INFORMATION CONTACT: Arlene Faustermann, Science Officer, Laboratories and Scientific Services, Customs and Border Protection, 1300 Pennsylvania Avenue, NW., Suite 1500 North, Washington, DC 20229, (202) 927–1060.

Dated: July 1, 2003.

Ira S. Reese,

Executive Director, Laboratories and Scientific Services.

[FR Doc. 03–17527 Filed 7–10–03; 8:45 am]

BILLING CODE 4820–02–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–4809–N–28]

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: July 11, 2003.

FOR FURTHER INFORMATION CONTACT: Mark Johnston, Department of Housing and Urban Development, Room 7262, 451 Seventh Street SW., Washington, DC 20410; telephone (202) 708–1234; TTY number for the hearing— and speech-impaired (202) 708–2565, (these telephone numbers are not toll-free), or call the toll-free Title V information line at 1–800–927–7588.

SUPPLEMENTARY INFORMATION: In accordance with the December 12, 1988 court order in *National Coalition for the Homeless* v. *Veterans Administration,* No. 88–2503–OG (D.D.C.), HUD publishes a Notice, on a weekly basis, identifying unutilized, underutilized, excess and surplus Federal buildings and real property that HUD has reviewed for suitability for use to assist the homeless. Today's Notice is for the purpose of announcing that no additional properties have been determined suitable or unsuitable this week.

Dated: July 3, 2003.

Mark R. Johnston,

Deputy Director, Office of Special Needs Assistance Programs.

[FR Doc. 03–17393 Filed 7–10–03; 8:45 am]

BILLING CODE 4210–29–M

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Notice of Availability of the Tumbling Creek Cavesnail (*Antrobia culveri*) Draft Recovery Plan for Review and Comment

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of document availability.

SUMMARY: The U.S. Fish and Wildlife Service (Service) announces availability for public review of the draft recovery plan for the Tumbling Creek cavesnail (*Antrobia culveri*), a species that is federally listed as endangered under the Endangered Species Act of 1973 (Act), as amended (16 U.S.C. 1531 *et. seq.*). The purpose of this plan is to recover this species in order that it can be removed from the list of Threatened and Endangered Species. This species occurs only in Tumbling Creek Cave in Taney County, Missouri. The Service solicits review and comment from the public on this draft plan.

DATES: Comments on the draft recovery plan must be received on or before August 11, 2003.

ADDRESSES: Persons wishing to review the draft recovery plan may obtain a copy by contacting the Field Supervisor, U.S. Fish and Wildlife Service, Columbia, Missouri Ecological Services Field Office, 608 E. Cherry St., Room 200, Columbia, Missouri 65201–7712 or by accessing the Web site: *http://midwest.fws.gov/Endangered.*

FOR FURTHER INFORMATION CONTACT: Dr. Paul McKenzie at the above address, or

telephone at (573) 876–1911, ext. 107. TTY users may contact Dr. McKenzie through the Federal Relay Service at (800) 877–8339.

SUPPLEMENTARY INFORMATION:

Background

Restoring an endangered or threatened animal or plant to the point where it is again a secure, self-sustaining member of its ecosystem is a primary goal of the Service's endangered species program. To help guide the recovery effort, the Service is working to prepare recovery plans for most of the federally listed threatened and endangered species native to the United States. Recovery plans describe actions considered necessary for conservation of the species, establish criteria for reclassification and delisting, and provide estimates of the time and costs for implementing the recovery measures needed.

The Act requires the development of recovery plans for listed species unless such a plan would not promote the conservation of a particular species. Section 4(f) of the Act, as amended in 1988, requires that public notice and opportunity for public review and comment be provided during recovery plan development. The Service will consider all information presented during a public comment period prior to approval of each new or revised recovery plan. The Service and other Federal agencies will also take these comments into consideration in the course of implementing approved recovery plans.

The Tumbling Creek cavesnail was listed as endangered on August 14, 2002. The number of cavesnails has significantly decreased over the past few decades, to the point where only one individual was found within survey areas between January 11, 2001, and April 22, 2003. A small population containing approximately 40 individuals exists in a small area upstream of the area that is regularly surveyed. Tumbling Creek cavesnail lives on the underside of rocks in areas of Tumbling Creek that have little or no silt. Little is known about the species and its life history, but it is believed to feed on microscopic animals in the stream. Although the exact reason for this species' precipitous decline is unknown, it is believed to be linked to habitat degradation through diminished water quality from upstream locations within the cave's delineated recharge zone.

We propose that the Tumbling Creek cavesnail be considered for reclassification from endangered to threatened when the following criteria have been met: (1) The population is stable or increasing for 10 consecutive years with at least 1,500 individuals; the population shall be considered stable when a linear regression analysis of population numbers estimated within an established survey area reveals no significant decline in numbers; (2) a minimum of 80% of the surface habitat within the recharge area of Tumbling Creek Cave, including a minimum of 75% of all riparian corridors, sinkholes, and losing streams, is properly managed, restored, rehabilitated, or stabilized through long-term voluntary land owner agreements, such as stewardship plans, easements, or memorandums of agreements that promote best management practices; and (3) water quality monitoring including, but not limited to, Tumbling Creek, fails to detect any contaminant or water quality parameter likely to be detrimental to the species for five consecutive years following established water quality criteria set by the Environmental Protection Agency (EPA), and criteria for sediment and suspended organic matter deposition established by EPA are not exceeded for five consecutive years.

We propose that the Tumbling Creek cavesnail be considered for delisting when the downlisting criteria have been met and the following additional criteria have been achieved: (1) The population is stable or increasing for an additional 10 consecutive years with at least 5,000 individuals; the population shall be considered stable when a linear regression analysis of population numbers estimated within an established survey area reveals no significant decline in numbers; (2) a minimum of 90% of the surface habitat within the recharge area of Tumbling Creek Cave, including a minimum of 85% of all riparian corridors, sinkholes, and losing streams, is properly managed, restored, rehabilitated, or stabilized through long-term voluntary land owner agreements, such as stewardship plans, easements, or memorandums of agreements that promote best management practices; and (3) water quality monitoring including, but not limited to, Tumbling Creek, fails to detect any contaminant or water quality parameter likely to be detrimental to the species for an additional five consecutive years following established water quality criteria set by EPA, and criteria for sediment and suspended organic matter deposition established by EPA are not exceeded for an additional five consecutive years.

Because an estimated 75% of the 9.02 square-mile delineated recharge area of Tumbling Creek Cave is under private ownership, many of recovery actions proposed in the draft recovery plan focus on working cooperatively with private land owners to help facilitate recovery of the Tumbling Creek cavesnail. Such cooperation can be achieved by: (1) Encouraging the voluntary enrollment of private land owners into landowner incentive programs that promote good land use while providing financial and technical assistance to participating enrollees, or (2) through voluntary land management agreements that promote beneficial land management practices. Approximately 25% of the recharge area for Tumbling Creek Cave is managed by multiple Federal agencies that have jurisdictional responsibilities under the Act. Such agencies will be encouraged to develop management plans that will contribute to their responsibilities under sections 2(c)(1) and 7(a)(1) of the Act to carry out programs that will assist in the recovery of the Tumbling Creek cavesnail.

Public Comments Solicited

The Service solicits written comments on the proposed draft recovery plan. All comments received by the date specified will be considered prior to approval of the plan. Written comments and materials regarding the plan should be sent to the Field Supervisor, Ecological Services Field Office, and comments received will be available for public inspection by appointment during normal business hours (*see* **ADDRESSES** section.)

Authority: The authority for this action is section 4 (f) of the Endangered Species Act, 16 U.S.C. 1533(f).

Dated: June 18, 2003.

Charles M. Wooley,

Assistant Regional Director, Ecological Services, Region 3.

[FR Doc. 03–17565 Filed 7–10–03; 8:45 am]

BILLING CODE 4310–55–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Issuance of Permit for Incidental Take of Threatened Species for the Mayhoffer/Singletree Trail, Boulder County, CO

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Issuance of Permit for Incidental Take of Endangered Species.

SUMMARY: On April 4, 2003, a notice was published in the **Federal Register** (68 FR 16543) that an application had been filed with the Fish and Wildlife Service

(Service) by the Boulder County Parks and Open Space Department, Colorado, for a permit to incidentally take, pursuant to section 10(a)(1)(B) of the Endangered Species Act of 1973, as amended (Act) (16 U.S.C. 1539), Preble's meadow jumping mouse, pursuant to the terms of the Environmental Assessment/Habitat Conservation Plan for Issuance of an Endangered Species Section 10(a)(1)(B) Permit for the Incidental Take of the Preble's Meadow Jumping Mouse (*Zapus hudsonius preblei*) for the Mayhoffer/Singletree Trail in Boulder County, Colorado.

Notice is hereby given that on June 18, 2003, as authorized by the provisions of the Act, the Service issued a permit (TE–073325–0) to the above named party subject to certain conditions set forth therein. The permit was granted only after the Service determined that it was applied for in good faith, that granting the permit will not be to the disadvantage of the threatened species, and that it will be consistent with the purposes and policy set forth in the Act.

Additional information on this permit action may be requested by contacting the Colorado Ecological Services Field Office at 755 Parfet Street, Suite 361, Lakewood, Colorado 80215, telephone (303) 275–2370, between the hours of 7 a.m. and 4:30 p.m. weekdays.

Dated: June 25, 2003.

John A. Blankenship,

Regional Director, Region 6.

[FR Doc. 03–17577 Filed 7–10–03; 8:45 am]

BILLING CODE 4310–55–P

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

Tribal Consultation on Indian Education Topics

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Notice of tribal consultation meetings.

SUMMARY: Notice is hereby given that the Bureau of Indian Affairs (BIA) will conduct consultation meetings to obtain oral and written comments concerning potential issues in Indian Education Programs. The potential issues which will be set forth in a tribal consultation booklet to be issued prior to the meetings are the Office of Facility Management and Construction's proposed revision of the Student Enrollment Projection process, the proposed revision of the Education Space Guidelines used in School Construction planning, the Office of Indian Education Programs' possible realignment of the Education Line Offices, The No Child Left Behind Act of 2001 (NCLB), section 1121(d), School Consolidation and Closure, section 1122, National Criteria for Home Living Standards, section 1125, discussion regarding whether to use the existing Negotiated Rulemaking Committee or establish a separate Negotiated Rulemaking Committee for Facilities Construction regulations. Additionally, participants will be able to suggest other items for comment.

DATES: Comments are due on or before September 30, 2003. The meeting dates will be August 11 through 22, 2003 for all locations listed. All meetings will begin at 9 a.m. and continue until 3 p.m. (Local time) or until all meeting participants have an opportunity to make comments.

ADDRESSES: Send or hand-deliver written comments to William A. Mehojah, Jr., Director, Office of Indian Education Programs, Bureau of Indian Affairs, MS–3512–MIB, 1849 C Street, NW., Washington, DC 20240. Submissions by facsimile should be sent to (202) 273–0030.

FOR FURTHER INFORMATION CONTACT: Mr. Kenneth Whitehorn at (202) 208–4976.

SUPPLEMENTARY INFORMATION: The meetings are a follow-up to similar meetings conducted by the OIEP/BIA since 1990.

The purpose of the consultation, as required by 25 U.S.C. 2011(b), is to provide Indian tribes, Indian school boards, Indian organizations, parents, student organizations, school employees, Bureau employees and other interested parties with an opportunity to comment on potential issues raised during this or previous consultation meetings.

MEETING SCHEDULE

Dates	Location	Local contact	Phone number
August 12, 2003	Hondah, AZ	Kevin Skenandore	(928) 338–5441
August 13, 2003	Aberdeen, SD	Cherie Farlee	(605) 964–8722
August 13, 2003	Gallup, NM	Bea Woodward	(505) 786–6150
August 14, 2003	Albuquerque, NM	Benjamin Atencio	(505) 346–2431
August 14, 2003	Nashville, TN	Ernest Clark	(615) 695–4101
August 14, 2003	Tacoma, WA	John Reimer	(503) 872–2743
August 15, 2003	Oklahoma City, OK	Joy Martin	(405) 605–6051
August 19, 2003	Anchorage, AK	Benito Lopez	(907) 271–4120
August 19, 2003	Billings, MT	Levon French	(406) 247–7953
August 19, 2003	Minneapolis, MN	Terry Portra	(612) 713–4400
August 20, 2003	Sacramento, CA	Fayetta Babby	(916) 978–6057

A consultation booklet for the meetings is being distributed to Federally recognized Indian tribes, Bureau Regional and Agency Offices and Bureau-funded schools. The booklets will also be available from local contact persons at each meeting.

Comments, including names, street addresses, and other contact information of respondents, will be available for public review at the address listed under the **ADDRESSES** section during regular business hours (7:45 a.m. to 4:15 p.m. EDT), Monday through Friday, except Federal holidays.

Individual respondents may request confidentiality. If you wish us to withhold your name, street address, and other contact information (such as fax or phone number) from public review or from disclosure under the Freedom of Information Act, you must state this prominently at the beginning of your comment. We will honor your request to the extent allowable by law. We will make available for public inspection in their entirety all submissions from organizations or businesses, and from individuals identifying themselves as representatives or officials of organizations or businesses.

This notice is published in accordance with the authority delegated

by the Secretary of the Interior to the Assistant Secretary—Indian Affairs by 209 DM 8.1.

Dated: July 4, 2003.

Aurene Martin,

Acting Assistant Secretary—Indian Affairs.

[FR Doc. 03–17576 Filed 7–10–03; 8:45 am]

BILLING CODE 4310–6W–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

Colorado: Filing of Plats of Survey; (50% to CO–956–1420–BJ–0000–241A), (35% to CO–956–1910–BJ–4720–241A), and (15% to CO–956–9820–BJ–CO01–241A)

July 1, 2003.

Summary: The plats of survey of the following described land will be officially filed in the Colorado State Office, Bureau of Land Management, Lakewood, Colorado, effective 10 am., July 1, 2003. All inquiries should be sent to the Colorado State Office, Bureau of Land Management, 2850 Youngfield Street, Lakewood, Colorado 80215–7093.

The plat representing the dependent resurvey and survey in the N½ NW¼, Section 30, Township 45 North, Range 5 East, New Mexico Principal Meridian, Group 1263, Colorado, was accepted April 14, 2003.

The plat representing the dependent resurvey and survey in Section 13, Township 1 North, Range 80 West, Sixth Principal Meridian, Group 1373, Colorado, was accepted April 28, 2003.

The plat representing the dependent resurvey and survey, in Township 3 North, Range 86 West, Sixth Principal Meridian, Group 1374, Colorado, was accepted April 29, 2003.

The plat representing the dependent resurvey and survey in Township 42 North, Range 18 West, New Mexico Principal Meridian, Group 1331, Colorado, was accepted April 29, 2003.

The plat representing the dependent resurvey and survey in Township 34 North, Range 7 West, New Mexico Principal Meridian, Group 1342, Colorado, was accepted April 15, 2003.

The plat, of the entire record, representing the dependent resurvey in Township 33 South, Range 65 West, Sixth Principal Meridian, Group 1361, Colorado, was accepted May 8, 2003.

The plat, of the entire record, representing the dependent resurvey and survey in Township 51 North, Range 10 East, New Mexico Principal Meridian, Group 1321, Colorado, was accepted May 8, 2003.

The plat representing the corrective dependent resurvey in Township 33 North, Range 9 West, New Mexico Principal Meridian, Group 1138, Colorado, was accepted June 3, 2003.

The supplemental plat, creating new lots 19 and 20 from old lot 13 and new lots 21 and 22 from old lot 18, in section 20, Township 13 South, Range 72 West, Sixth Principal Meridian, Colorado, was accepted May 14, 2003.

These surveys and plats were requested by the Bureau of Land Management for administrative and management purposes.

The plat representing the dependent resurvey, corrective resurvey and survey, in Sections 30 and 31, Township 41 North, Range 2 East, New Mexico Principal Meridian, Group 1367, Colorado, was accepted April 8, 2003.

This survey and plat was requested by the Forest Supervisor, Rio Grande National Forest, to identify the boundaries between forest and patented lands, and management purposes.

The plat representing the dependent resurvey, and surveys, Township 24 South, Range 68 West, Sixth Principal Meridian, Group 1250, Colorado, was accepted June 3, 2003.

The plat, of the entire record, representing the remonumentation of certain original corners in Township 10 South, Range 72 West, Sixth Principal Meridian, Group 750, Colorado, was accepted June 23, 2003.

The plat, of the entire record, representing the remonumentation of certain original corners in Township 14 South, Range 80 West, Sixth Principal Meridian, Group 750, Colorado, was accepted June 26, 2003.

The plat, of the entire record, representing the remonumentation of certain original corners in Township 31 South, Range 68 West, Sixth Principal Meridian, Group 750, Colorado, was accepted June 26, 2003.

The plat, of the entire record, representing the remonumentation of certain original corners in Township 14 South, Range 68 West, Sixth Principal Meridian, Group 750, Colorado, was accepted June 26, 2003.

The plat, of the entire record, representing the remonumentation of certain original corners in Township 14 South, Range 69 West, Sixth Principal Meridian, Group 750, Colorado, was accepted June 26, 2003.

These surveys, plats and remonumentations were requested by the Forest Supervisor, Pike and San Isabel National Forests, to identify forest boundaries for administrative and management purposes.

The plat representing the dependent resurvey and survey in Township 9 North, Range 102 West, Sixth Principal Meridian, Group 1368, Colorado, was accepted April 24, 2003.

The plat representing the dependent resurvey and survey in Township 10 North, Range 103 West, Sixth Principal Meridian, Group 1368, Colorado, was accepted April 24, 2003.

The plat representing the dependent resurvey and survey in Township 10 North, Range 104 West, Sixth Principal Meridian, Group 1368, Colorado, was accepted April 24, 2003.

These surveys and plats were requested by the U.S. Fish and Wildlife Service, Regional Office, Denver, to identify the Public Land boundaries of the Browns Park Wildlife Refuge, in NW Colorado.

The plat (in two sheets), representing the dependent resurvey and surveys in Township 48 North, Range 4 West, New Mexico Principal Meridian, Group 1344, Colorado, was accepted June 23, 2003.

This survey and plats were requested by the National Park Service, Superintendent, Curecanti National Recreation Area and Black Canyon of the Gunnison National Park, to identify the Public Land boundaries for management purposes.

Darryl A. Wilson,

Chief Cadastral Surveyor for Colorado.

[FR Doc. 03–17538 Filed 7–10–03; 8:45 am]

BILLING CODE 4310–JB–P

DEPARTMENT OF THE INTERIOR

National Park Service

Notice of Availability of the Wilderness Study, Draft Environmental Impact Statement, Apostle Islands National Lakeshore, Wisconsin

AGENCY: National Park Service, Interior.

ACTION: Notice of availability.

SUMMARY: Pursuant to section 102(2) of the National Environmental Policy Act (NEPA) of 1969, the National Park Service (NPS) announces the availability of the draft wilderness study/environmental impact statement (EIS) for Apostle Islands National Lakeshore, Wisconsin. This notice is being furnished as required by NEPA Act Regulations 40 CFR 1501.7.

DATES: There will be a 90-day public review period for comments on this document. Comments on the draft wilderness study/EIS must be received no later than 90 days after the Environmental Protection Agency publishes its notice of availability in the **Federal Register**. As required under section 3(d) (1) of the Wilderness Act, a public hearing will be held on the

draft wilderness study on August 27, from 2–4:30 p.m. and from 6–8 p.m. at the Northern Great Lakes Visitor Center. The center is located on County Road G, one-half mile west of the junction of U.S. 2 and State Highway 13, west of Ashland, Wisconsin. In addition, public open houses for information about, or to make comment on, the draft wilderness study/EIS will be held in the region during the comment period. These open houses will be announced in the local media and on the park Web site when they are scheduled. Information about meeting times and places will be available by contacting the park's headquarters at 715–779–3398, extension 102, or visiting the park's Web site at *http://www.nps.gov/apis/wstudy.htm.*

ADDRESSES: Copies of the draft wilderness study/EIS are available by request by writing to Mr. Jim Nepstad, Wilderness Study Coordinator, Apostle Islands National Lakeshore, Route 1, Box 4, Bayfield, Wisconsin 54814, by phone 715–779–3398, extension 102, or by e-mail message at *apis_comments@nps.gov.* The document can be picked-up in person at the park's headquarters at 415 Washington Avenue, Bayfield, Wisconsin.

FOR FURTHER INFORMATION CONTACT: Mr. Jim Nepstad, Wilderness Study Coordinator, Apostle Islands National Lakeshore, Route 1, Box 4, Bayfield, Wisconsin 54814, or by calling 715–779–3198, extension 102.

SUPPLEMENTARY INFORMATION: The Wilderness Act and the NPS management policies require all lands administered by the NPS be evaluated for their suitability for inclusion within the national wilderness preservation system. The purpose of this wilderness study is to determine if and where lands and waters within the Apostle Islands National Lakeshore should be proposed for wilderness designation. The study identifies four possible wilderness configurations within the park, including a no wilderness alternative, and evaluates their effects. Based on the findings of this study, a formal wilderness proposal may be submitted to the Director of the NPS for approval and subsequent consideration by the Department of the Interior, the President, and Congress under the provisions of the Wilderness Act.

Persons wishing to comment may do so by any one of several methods. They may attend the public hearing or open houses noted above. They may mail comments to Mr. Jim Nepstad, Wilderness Study Coordinator, Apostle Islands National Lakeshore, Route 1, Box 4, Bayfield, Wisconsin 54814. They also may comment via e-mail to *apis_comments@nps.gov* (please include name and return address in the e-mail message). Finally, they may hand-deliver comments to the Apostle Islands National Lakeshore headquarters at 415 Washington Avenue, Bayfield, Wisconsin.

It is the practice of the NPS to make comments, including names and home addresses of respondents, available for public review during regular business hours. Individual respondents may request we withhold their home address from the record, which we will honor to the extent allowable by law. There also may be circumstances in which we would withhold from the record a respondent's identify, 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.

The responsible official is Mr. Ernest Quintana, Acting Midwest Regional Director, NPS.

Dated: June 6, 2003.

David N. Given,

Acting Regional Director, Midwest Region.

[FR Doc. 03–17549 Filed 7–10–03; 8:45 am]

BILLING CODE 4310–97–P

DEPARTMENT OF THE INTERIOR

National Park Service

Long Walk National Historic Trail Study, Environmental Impact Statement, Arizona, New Mexico

AGENCY: National Park Service, Department of the Interior.

ACTION: Notice of Intent to prepare an Environmental Impact Statement for the Long Walk National Historic Trail Study.

SUMMARY: Pursuant to the National Environmental Policy Act of 1969, 42 U.S.C. 4332(C), the National Park Service (NPS) is preparing an Environmental Impact Statement for the Long Walk National Historic Trail Study, Arizona and New Mexico. This effort will result in a study that recommends to Congress whether the Long Walk of the Mescalero Apache and Navajo People should be designated a national historic trail. It will also propose alternative means of commemoration should it not be recommended for national historic trail designation. The plan will be developed in consultation with the Mescalero Apache Tribe, the Navajo Nation, the associated American Indian Tribes in the southwest, local communities along the routes of the Long Walk, other federal and state agencies and all other interested and affected organizations and individuals. The area involved includes but is not limited to: the Navajo Reservation in northeastern Arizona from the Grand Canyon area east to the New Mexico state line including Chinle and Window Rock, Arizona. The area in New Mexico includes but is not limited to: the vicinity of Gallup, Grants, Bosque Farms, Albuquerque, Santa Fe, Galisteo, Las Vegas, Fort Union National Monument, Anton Chico, Fort Sumner, and Mescalero, New Mexico. Alternatives to be considered include no-action, designation as a national historic trail, alternative means of commemoration other than national historic trail designation, and other ideas that come out of the public process.

Major issues include: routes of the Long Walk, resources to be preserved along the route, whether the Mescalero Apache Tribe and the Navajo Nation are in favor of national historic trail designation, and how best to preserve and interpret the related events of that period.

A scoping newsletter has been prepared that gives times, places, and dates of public meetings that will be held on the study. It also details the issues identified to date. Copies of that newsletter may be obtained from Harry Myers, NPS, P.O. Box 728, 1100 Old Santa Fe Trail, Santa Fe, New Mexico 87504–0728, (505) 988–6717, *harry_myers@nps.gov.*

DATES: The Park Service will accept comments from the public through August 11, 2003.

ADDRESSES: Information will be available for public review and comment in the office of the Superintendent, and at the following locations: Jere Krakow, Superintendent, IMR National Trails System Office, P.O. Box 728, 1100 Old Santa Fe Trail, Santa Fe, New Mexico 87504–0728, (505) 988–6888.

FOR FURTHER INFORMATION CONTACT: Harry Myers, P.O. Box 728, Santa Fe, New Mexico 87504–0728, (505) 988–6717, *harry_myers@nps.gov.*

SUPPLEMENTARY INFORMATION: If you wish to comment on the scoping brochure or on any other issues associated with the plan, you may submit your comments by any one of

several methods. You may mail comments to Harry Myers, National Trails System Office—Santa Fe, P.O. Box 728, Santa Fe, New Mexico 87504–0728. You may also comment via the Internet to *harry_myers@nps.gov.* Please submit Internet comments as an ASCII file avoiding the use of special characters and any form of encryption. Please also include ''Attn: Long Walk'' 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 us directly at National Trails System Office—Santa Fe, (505) 988–6717. Finally, you may hand-deliver comments to National Park Service, Old Santa Fe Trail Building Room 116, 1100 Old Santa Fe Trail, Santa Fe, New Mexico, 87501. Our practice is to make comments, including names and home addresses of respondents, available for public review during regular business hours. Individual respondents may request that we withhold their home address from the record, which we will honor to the extent allowable by law. There also may be circumstances in which we would withhold from the record a respondent's identity, as allowable by law. If you wish us to withhold your address, you must state this prominently at the beginning of your comment. 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.

Dated: June 9, 2003.

Michael D. Snyder,

Deputy Director, Intermountain Region, National Park Service.

[FR Doc. 03–17548 Filed 7–10–03; 8:45 am]

BILLING CODE 4310–14–P

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

Notice of Proposed Information Collection for 1029–0094 and 1029–0098

AGENCY: Office of Surface Mining Reclamation and Enforcement.

ACTION: Notice and request for comments.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the Office of Surface Mining Reclamation and Enforcement (OSM) is announcing its intention to request approval to continue the collections of information for general provisions at 30 CFR part 700, and the petition process for the designation of Federal lands as unsuitable for all or certain types of surface coal mining operations and for termination of previous designations found at 30 CFR part 769. These information collection activities were previously approved by the Office of Management and Budget (OMB), and assigned them clearance numbers 1029–0094 and –0098, respectively.

DATES: Comments on the proposed information collection must be received by September 9, 2003, to be assured of consideration.

ADDRESSES: Comments may be mailed to John A. Trelease, Office of Surface Mining Reclamation and Enforcement, 1951 Constitution Ave., NW., Room 210–SIB, Washington, DC 20240. Comments may also be submitted electronically to *jtreleas@osmre.gov.*

FOR FURTHER INFORMATION CONTACT: To request a copy of the information collection requests, explanatory information and related forms, contact John A. Trelease, at (202) 208–2783.

SUPPLEMENTARY INFORMATION: OMB regulations at 5 CFR 1320, which implementing provisions of the Paperwork Reduction Act of 1995 (Pub. L. 104–13), require that interested members of the public and affected agencies have an opportunity to comment on information collection and recordkeeping activities (*see* 5 CFR 1320.8(d)). This notice identifies information collections that OSM will be submitting to OMB for approval. These collections are contained in (1) 30 CFR 700, General (1029–0094); and (2) 30 CFR part 769, Petition process for designation of Federal lands as unsuitable for all or certain types of surface coal mining operations and for termination of previous designations. OSM will request a 3-year term of approval for each information collection activity.

Comments are invited on: (1) The need for the collection of information for the performance of the functions of the agency; (2) the accuracy of the agency's burden estimates; (3) ways to enhance the quality, utility and clarity of the information collection; and (4) ways to minimize the information collection burden on respondents, such as use of automated means of collection of the information. A summary of the public comments will accompany OSM's submission of the information collection requests to OMB.

The following information is provided for the information collection: (1) Title of the information collection; (2) OMB control number; (3) summary of the information collection activity; and (4) frequency of collection, description of the respondents, estimated total annual responses, and the total annual reporting and recordkeeping burden for the collection of information.

Title: General, 30 CFR Part 700.

OMB Control Number: 1029–0094.

Summary: This Part establishes procedures and requirements for terminating jurisdiction of surface coal mining and reclamation operations, petitions for rulemaking, and citizen suits filed under the Surface Mining Control and Reclamation Act of 1977.

Bureau Form Number: None.

Frequency of Collection: Once.

Description of Respondents: State and tribal regulatory authorities, private citizens and citizen groups, and surface coal mining companies.

Total Annual Responses: 6.

Total Annual Burden Hours: 84.

Title: Petition Process for Designation of Federal Lands as Unsuitable for All or Certain Types of Surface Coal Mining Operations and for Termination of Previous Designations, 30 CFR Part 769.

OMB Control Number: 1029–0098.

Summary: This Part establishes the minimum procedures and standards for designating Federal lands unsuitable for certain types of surface mining operations and for terminating designations pursuant to a petition. The information requested will aid the regulatory authority in the decision making process to approve or disapprove a request.

Bureau Form Number: None.

Frequency of Collection: Once.

Description of Respondents: People who may be adversely affected by surface mining on Federal lands.

Total Annual Responses: 1.

Total Annual Burden Hours: 950.

Dated: July 8, 2003.

Sarah E. Donnelly,

Acting Chief, Division of Regulatory Support.

[FR Doc. 03–17594 Filed 7–10–03; 8:45 am]

BILLING CODE 4310–05–M

DEPARTMENT OF LABOR

Employment Standards Administration; Wage and Hour Division

Minimum Wages for Federal and Federally Assisted Construction; General Wage Determination Decisions

General wage determination decisions of the Secretary of Labor are issued in accordance with applicable law and are based on the information obtained by the Department of Labor from its study

of local wage conditions and data made available from other sources. They specify the basic hourly wage rates and fringe benefits which are determined to be prevailing for the described classes of laborers and mechanics employed on construction projects of a similar character and in the localities specified therein.

The determination 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 supersedeas 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 date may be obtained by writing to the U.S. Department of Labor, Employment Standards Administration, Wage and Hour Division, Division of Wage Determinations, 200 Constitution Avenue, NW., Room S–3014, Washington, DC 20210.

Modification to General Wage Determination Decisions

The number of the decisions listed to 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

None.

Volume III

None.

Volume IV

None.

Volume V

None.

Volume VI

None.

Volume VII

None.

General Wage Determination Publication

General wage determinations issued under the Davis-Bacon and related Acts, including those noted above, may be found in the Government Printing Office (GPO) document entitled ''General Wage Determinations Issued Under the Davis-Bacon And Related Acts''. This publication is available at each of the 50 Regional Government Depository Libraries and many of the 1,400 Government Depository Libraries across the country.

General wage determinations issued under the Davis-Bacon and related Acts are available electronically at no cost on the Government Printing Office site at *http://www.access.gpo.gov/davisbacon.* They are also available electronically by subscription to the Davis-Bacon Online Services (*http://davisbacon.fedworld.gov*) of the National Technical Information Service (NTIS) of the U.S. Department of Commerce at 1–800–363–2068. This subscription offers value-added features such as electronic delivery of modified wage decisions directly to the user's desktop, the ability to access prior wage decisions issued during the year, extensive Help Desk Support, etc.

Hard-copy subscriptions may be purchased from: Superintendent of Documents, Government Printing Office, Washington, DC 20402, (202) 512–1800.

When ordering hard-copy subscription(s), be sure to specify the State(s) of interest, since subscriptions may be ordered for any or all of the six separate Volumes, arranged by State. Subscriptions include an annual edition (issued in January or February) which includes all current general wage determinations for the States covered by each volume. Throughout the remainder of the year, regular weekly updates will be distributed to subscribers.

Signed at Washington, DC This 1st Day of July 2003.

Carl Poleskey,

Chief, Branch of Construction Wage Determinations.

[FR Doc. 03–17187 Filed 7–10–03; 8:45 am]

BILLING CODE 4510–27–M

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

[Docket No. ICR–1218–0184(2003)]

4,4′-Methylenedianiline (MDA) General Industry Standard (29 CFR 1910.1050); Extension of the Office of Management and Budget's (OMB) Approval of Information-Collection (Paperwork) Requirements

AGENCY: Occupational Safety and Health Administration (OSHA); Labor.

ACTION: Request for comment.

SUMMARY: OSHA solicits comments concerning its proposal to increase the existing burden-hours estimates, and to extend OMB approval of the information-collection requirements of the 4,4′-Methylenedianiline General Industry Standard (the ''MDA General Industry Standard'') (29 CFR

1910.1050).[1] The standard protects employees from adverse health effects from occupational exposure to MDA, including cancer and liver disease.

DATES: Comments must be submitted by the following dates:

Hard Copy: Your comments must be submitted (postmarked or received) by September 9, 2003.

Facsimile and electronic transmission: Your comments must be sent by September 9, 2003.

ADDRESSES:

I. Submission of Comments

Regular mail, express delivery, hand-delivery, and messenger service: Submit your comments and attachments to the OSHA Docket Office, Docket No. ICR–1218–0184(2003), Room N–2625, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210. OSHA Docket Office and Department of Labor hours of operation are 8:15 a.m. to 4:45 p.m., EST.

Facsimile: If your comments, including any attachments, are 10 pages or fewer, you may fax them to the OSHA Docket Office at (202) 693–1648. You must include the docket number ICR 1218–0184(2003), in your comments.

Electronic: You may submit comments, but not attachments, through the Internet at *http://ecomments.osha.gov.*

II. Obtaining Copies of the Supporting Statement for the Information Collection Request

The Supporting Statement for the Information Collection Request is available for downloading from OSHA's website at *www.osha.gov.* The supporting statement is available for inspection and copying in the OSHA Docket Office, at the address listed above. A printed copy of the supporting statement cab be obtained by contacting Todd Owen at (202) 693–2222.

FOR FURTHER INFORMATION CONTACT: Todd Owen, Directorate of Standards and Guidance, OSHA, U.S. Department of Labor, Room N–3641, 200 Constitution Avenue, NW., Washington, DC 20210; telephone: (202) 693–2222. A copy of the Agency's Information-Collection Request (ICR) supporting the need for the information-collection requirements specified in the MDA General Industry Standard is available for inspection and copying in the Docket Office, or by requesting a copy from Todd Owen at (202) 693–2222. For electronic copies of the ICR contact OSHA on the Internet at *http://www.osha.gov/comp-links.html,* and select ''Information Collection Requests.''

SUPPLEMENTARY INFORMATION:

I. Background

The Department of Labor, as part of its continuing effort to reduce paperwork and respondent (*i.e.,* employer) burden, conducts a preclearance consultation program to provide the public with an opportunity to comment on proposed and continuing information-collection requirements in accordance with the Paperwork Reduction Act of 1995 (PRA–95) (44 U.S.C. 3506(c)(2)(A)). This program ensures that information is in the desired format, reporting burden (time and cost) is minimal, collection instruments are clearly understandable, and OSHA's estimate of the information-collection burden is correct. The Occupational Safety and Health Act of the 1970 (the Act) authorizes information collection by employers as necessary or appropriate for enforcement of the Act or for developing information regarding the causes and prevention of occupational injuries, illnesses, and accidents (29 U.S.C. 657).

The information-collection requirements specified in the MDA General Industry Standard protect employees from the adverse health effects that may result from their exposure to MDA. The major information-collection requirements of the MDA General Industry Standard require employers to perform exposure monitoring; exposure monitoring includes initial monitoring to determine the extent of employee exposure to MDA; periodic (*i.e.*, at least semi-annually) monitoring if the employees' MDA exposures is at or below the permissible exposure limit but above the action level; and additional monitoring if any changes occur in MDA-production processes, control equipment, personnel or work practices that may result in new or increased employee exposures to MDA. Employers must routinely inspect the hands, face and forearms of employees potentially exposed to MDA for dermal exposure to MDA. Employers must also notify each employee in writing, either individually or by posting results, within 15 days after receiving exposure-monitoring results, establish written compliance program, institute a respiratory-protection program in accordance with 29 CFR 1910.134 (OSHA's Respiratory Protection Standard); and develop a written emergency plan for any workplace that could have an emergency (*i.e.* an unexpected and potentially hazardous release of MDA).

Other paperwork requirements of the Standard specify that employers must provide employees with medical examinations, including initial examinations for new employees prior to their initial job assignment; follow-up annual examinations for employees receiving initial medical examinations; and emergency examinations if employees receive potentially hazardous MDA exposures under emergency conditions. As part of the medical-surveillance program, employers must provided specific written information to the examining physicians, and obtain from these physicians a written opinion regarding the employee's medical results and exposure limitations.

Additional provisions of the Standard require employers to train employees exposed to MDA at the time of their initial assignment and at least annually thereafter. In addition, employers must post warning signs at entrances or access ways to regulated areas; and label any material or products containing MDA, this includes any containers storing MDA-contaminated protective clothing and equipment. Personnel who launder MDA-contaminated clothing must be informed by the employer that the clothing is contaminated and the potentially harmful effects of MDA.

The Standard also requires employers to establish and maintain exposure-monitoring and medical-surveillance records for each employee who is subject to these respective requirements, make any record required by the Standard available to OSHA compliance officers and the National Institute for Occupational Safety and Health (NIOSH) for examination and copying, and provides exposure-monitoring and medical-surveillance records to employees and their designated representatives. Finally, employers who cease to do business without a successor employer to receive and retain records for the require periods, and employers who plan to dispose of records at the end of the required retention periods, must transfer these records to NIOSH.

II. Special Issues for Comment

OSHA has a particular interest in comments on the following issues:

—Whether the information-collection requirements are necessary for the proper performance of the Agency's functions, including whether the information is useful;

[1] Based on its assessment of the paperwork requirements contained in this standard, the Agency estimates that the total burden hours increased compared to its previous burden-hour estimate. Under this notice, OSHA is *not* proposing to revise these paperwork requirements in any substantive manner, only to increase the burden hours imposed by the existing paperwork requirements.

—The accuracy of the Agency's estimate of the burden (time and costs) of the information-collection requirements, including the validity of the methodology and assumptions used;

—The quality, utility, and clarity of the information collected; and

—Ways to minimize the burden on employers who must comply; for example, by using automated or other technological information-collection and -transmission techniques.

III. Proposed Actions

OSHA proposes to extend the Office of Management and Budget's (OMB) approval of the collection-of-information requirements specified by the Standards on 4, 4'-Methylenedianiline in General Industry (29 CFR 1910.1050). The Agency will summarize the comments submitted in response to this notice, and will include this summary in its request to OMB to extend the approval of these information-collection requirements.

Type of Review: Extension of currently approved information-collection requirements.

Title: MDA General Industry Standard (29 CFR 1910.1050).

OMB Number: 1218–0184(2003).

Affected Public: Business or other for-profit; not-for-profit institutions; Federal government; State, local or tribal Governments.

Number of Respondents: 15.

Frequency: On occasion.

Total Responses: 807.

Average Time per Response: Varies from 5 minutes to provide information to the examining physician to 2 hours to conduct exposure-monitoring.

Estimated Total Burden Hours: 387 hours.

Estimated Cost (Operation and Maintenance): $11,430.

III. Authority and Signature

John L. Henshaw, Assistant Secretary of Labor for Occupational Safety and Health, directed the preparation of this notice. The authority for this notice is the Paperwork Reduction Act of 1995 (44 U.S.C. 3506) and Secretary of Labor's Order No. 5–2002 (67 FR 65008).

Dated: Signed at Washington, DC, on July 7, 2003.

John L. Henshaw,

Assistant Secretary of Labor.

[FR Doc. 03–17633 Filed 7–10–03; 8:45 am]

BILLING CODE 4510–26–M

INTERNATIONAL BOUNDARY AND WATER COMMISSION, UNITED STATES AND MEXICO

United States Section; Notice of Availability of Draft Environmental Impact Statement for Alternative Vegetation Maintenance Practices for the Lower Rio Grande Flood Control Project in Cameron, Hidalgo, and Willacy Counties, TX

AGENCY: United States Section, International Boundary and Water Commission, United States and Mexico.

ACTION: Notice of availability of draft environmental impact statement.

SUMMARY: Pursuant to section 102(2)(c) of the National Environmental Policy Act (NEPA) of 1969, as amended, the United States Section, International Boundary and Water Commission (USIBWC), in cooperation with the United States Fish and Wildlife Service (USFWS) and the Texas Parks and Wildlife Department, has prepared a Draft Environmental Impact Statement (DEIS) on Alternative Vegetation Maintenance Practices for the Lower Rio Grande Flood Control Project in Cameron, Hidalgo, and Willacy Counties, Texas. The DEIS analyzes the Continued Maintenance Alternative (No-Action), comprising the current USIBWC vegetation maintenance program, and the impacts of three vegetation maintenance alternatives which vary from the current USIBWC vegetation maintenance practices along the Lower Rio Grande Valley.

DATES: Written comments are requested by August 29, 2003. A public meeting will be conducted from 5 to 7 p.m. CDT on Wednesday, July 30, 2003, in Weslaco, Texas. See Addresses below for location and time.

ADDRESSES: Comments should be addressed to: Carolyn Murphy, Chief, Environmental Section, CESWG–PE–PR, Department of the Army, Galveston District, Corps of Engineers, P.O. Box 1229, Galveston, Texas 77553–1229 (courier deliveries: 2000 Fort Point Rd. Galveston, Texas 77550). A public meeting will be conducted from 5 to 7 p.m. CDT on Wednesday, July 30, 2003, at the Texas A&M Agricultural Research and Extension Center, Hoblitzelle Auditorium, 2415 East Highway 83, Weslaco, Texas, to present your verbal or written comments.

Copies of the DEIS are available for inspection and review at the following locations: Brownsville Public Library, 2600 Central Boulevard, Brownsville, Texas; Harlingen Public Library, 410 '76 Drive, Harlingen, Texas; McAllen Public Library, 601 North Main Street, McAllen, Texas; USIBWC Mercedes Field Office, 325 Golf Course Rd, Mercedes, Texas; Santa Ana National Wildlife Refuge, FM 307, 7 miles south of Alamo, TX and 1/4-mile east of U.S. 281; and USIBWC HQ, 4171 N. Mesa Street, Ste C–315, El Paso, Texas. The DEIS is also available on the USIBWC Home Page at *http://www.ibwc.state.gov* under ''What's New,'' and at the United States Army Corps of Engineers, Galveston District, Home Page at: *http://www.swg.usace.army.mil/.*

FOR FURTHER INFORMATION CONTACT: Mr. Douglas Echlin, Environmental Protection Specialist, Environmental Management Division, USIBWC, 4171 North Mesa Street, C–100, El Paso, Texas 79902 or call (915) 832–4741, e-mail: *dougechlin@ibwc.state.gov.*

SUPPLEMENTARY INFORMATION: The USIBWC vegetation maintenance program is performed along the United States portion of the Lower Rio Grande Flood Control Project (LRGFCP). The vegetation maintenance program was established to fulfill the United States Government's obligations under International Boundary and Water Commission (IBWC) Minute No. 212 and No. 238 and to protect life and properties in the United States and Mexico from Rio Grande flooding events.

Under Minute No. 212, the United States and Mexico agreed to annual concurrent channel bank mowing to reduce heavy brush growth in the river reach and to ensure a river channel capacity of 20,000 cfs at the Brownsville-Matamoros area. This maintenance mowing was considered necessary to prevent flooding in Brownsville and Matamoros for the design flood and to ensure that brush did not deflect river flood flows toward either country, thus altering the international boundary alignment by erosion. Minute No. 238 called for equally dividing flood flows into interior floodways in each country, thereby ensuring the 20,000 cfs maximum flow at Brownsville and Matamoros.

On November 1, 1989, the Sierra Club, Frontera Audubon Society, and National Audubon Society filed a civil action suit against the USIBWC alleging vegetation maintenance program violations of the Endangered Species Act (ESA) and the National Environmental Policy Act (NEPA). The plaintiffs alleged that the USIBWC had not prepared an Environmental Assessment or Environmental Impact Statement (EIS) relative to the operation and maintenance activities for the

United States portion of the LRGFCP as required by NEPA. The plaintiffs also alleged that the USIBWC had not entered into formal consultation with the USFWS pursuant to section 7 of the ESA with respect to the impacts of the United States portion of the LRGFCP on federally-listed threatened or endangered species.

In a 1990 Consent Decree administered by the United States District Court of the District of Columbia, the USIBWC agreed to enter into formal consultation with the USFWS regarding the impacts of all vegetation clearing activities of the LRGFCP on federally listed species. The consultation process resulted in an issuance by the USFWS of a Biological Opinion (BO) on May 6, 1993. The USFWS has recently reissued a new BO. In addition to formal consultation with USFWS, USIBWC agreed to the preparation of this EIS, which specifically addresses alternative vegetation maintenance practices.

This DEIS presents and analyzes the impacts of current and alternative USIBWC vegetation maintenance practices to fulfill commitments under the IBWC Minutes, the Consent Decree, and the new BO. The pertinent elements of the LRGFCP vegetation maintenance program are based on the need to:

- Maintain channel banks to provide adequate flood conveyance.
- Equitably divert flood flows into interior floodways.
- Remove brush and other obstructions within floodways.
- Maintain a wildlife corridor per the USFWS BO and the 1994 LRGFCP Off-River Wildlife Travel Corridor Plan.

Four potential vegetation maintenance alternatives, including the current USIBWC maintenance program, are considered and analyzed in the DEIS. The Preferred Alternative is the Continued Maintenance Alternative (No-Action), representing the continuation of the current USIBWC vegetation maintenance program.

A copy of the DEIS has been filed with the Environmental Protection Agency (EPA) in accordance with 40 CFR parts 1500–1508 and USIBWC procedures. Written comments concerning the DEIS will be accepted at the address provided above until August 29, 2003.

Dated: July 2, 2003.

Mario Lewis,

General Counsel.

[FR Doc. 03–17564 Filed 7–10–03; 8:45 am]

BILLING CODE 4710–03–P

NATIONAL SCIENCE FOUNDATION

Sunshine Act Meetings

AGENCY HOLDING MEETING: National Science Foundation, National Science Board.

PLACE: The National Science Foundation, 4201 Wilson Boulevard—Room 130, Arlington, VA 22230, *http//www.nsf.gov/nsb.*

CONTACT FOR INFORMATION: Robert Webber (703) 292–7000.

STATUS: This meeting will be open to the public.

MATTERS TO BE CONSIDERED: Teleconference of the NSB Education and Human Resources Committee Undergraduate Working Group.

Open

Discussion of Undergraduate Working Group plans and activities.

Robert Webber,

Policy Analyst, NSBO.

[FR Doc. 03–17695 Filed 7–9–03; 10:20 am]

BILLING CODE 7555–01–M

NUCLEAR REGULATORY COMMISSION

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: U. S. Nuclear Regulatory Commission (NRC).

ACTION: Notice of pending NRC action to submit an information collection request to OMB and solicitation of public comment.

SUMMARY: The NRC is preparing a submittal to OMB for review of continued approval of information collections under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35).

Information pertaining to the requirement to be submitted:

1. *The title of the information collection:* 10 CFR part 71, ''Packaging and Transportation of Radioactive Material.''

2. *Current OMB approval number:* 3150–0008.

3. *How often the collection is required:* Applications for package certification may be made at any time. Required reports are collected and evaluated on a continuing basis as events occur.

4. *Who is required or asked to report:* All NRC specific licensees who place byproduct, source, or special nuclear material into transportation, and all persons who wish to apply for NRC approval of package designs for use in such transportation.

5. *The estimated number of annual respondents:* 250 licensees.

6. *The number of hours needed annually to complete the requirement or request:* 42,301 hours (37,301 hours for reporting requirements and 5,000 for recordkeeping requirements).

7. *Abstract:* NRC regulations in 10 CFR part 71 establish requirements for packing, preparation for shipment, and transportation of licensed material, and prescribe procedures, standards, and requirements for approval by NRC of packaging and shipping procedures for fissile material and for quantities of licensed material in excess of Type A quantities.

Submit, by September 9, 2003, comments that address the following questions:

1. Is the proposed collection of information necessary for the NRC to properly perform its functions? Does the information have practical utility?

2. Is the burden estimate accurate?

3. Is there a way to enhance the quality, utility, and clarity of the information to be collected?

4. How can the burden of the information collection be minimized, including the use of automated collection techniques or other forms of information technology?

A copy of the draft supporting statement may be viewed free of charge at the NRC Public Document Room, One White Flint North, 11555 Rockville Pike, Room O–1 F21, Rockville, MD 20852. OMB clearance requests are available at the NRC worldwide Web site: *(http://www.nrc.gov/public-involve/doc-comment/omb/index.html).* The document will be available on the NRC home page site for 60 days after the signature date of this notice.

Comments and questions about the information collection requirements may be directed to the NRC Clearance Officer, Brenda Jo. Shelton, U.S. Nuclear Regulatory Commission, T–6 E6, Washington, DC 20555–0001, by telephone at (301) 415–7233, or by Internet electronic mail at *INFOCOLLECTS@NRC.GOV.*

Dated at Rockville, Maryland, this 7th day of July, 2003.

For the Nuclear Regulatory Commission.

Beth St. Mary,

Acting NRC Clearance Officer, Office of the Chief Information Officer.

[FR Doc. 03–17581 Filed 7–10–03; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket Nos. 50–369 and 50–370]

Duke Power Company, McGuire Nuclear Station, Units 1 and 2; Exemption

1.0 Background

Duke Power Company (the licensee) is the holder of Facility Operating License Nos. NPF–9 and NPF–17 that authorizes operation of the McGuire Nuclear Station, Units 1 and 2 (McGuire). The license provides, among other things, that the facility is subject to all rules, regulations, and orders of the U.S. Nuclear Regulatory Commission (NRC, the Commission) now or hereafter in effect.

The facility consists of two pressurized water reactors located in Mecklenburg County, North Carolina.

2.0 Request/Action

Title 10 of the Code of Federal Regulations (10 CFR) section 50.60(a), requires that the fracture toughness and material surveillance requirements of Appendix G to part 50 must be met for the reactor coolant pressure boundary. Appendix G to part 50 requires that pressure and temperature (P/T) limits be established for reactor pressure vessels (RPVs) during normal operating and hydrostatic or leak rate testing conditions. Specifically, section IV.A.2.a of Appendix G to 10 CFR part 50 states that ''The appropriate requirements on both the pressure-temperature limits and the minimum permissible temperature must be met for all conditions.'' Further, section IV.A.2.b of Appendix G to 10 CFR part 50 requires that these P/T limits must be at least as conservative as limits obtained by following the methods of analysis and the margins of safety of Appendix G to section XI of the American Society of Mechanical Engineers (ASME) Boiler and Pressure Vessel Code (Code). The current ASME Code of Record for McGuire is the 1995 edition through 1996 addenda of the ASME Code. The McGuire Code of Record does not incorporate the provisions of ASME Code Case N–641. Although the provisions of ASME Code Case N–641 were incorporated into Appendix G to section XI of the ASME Code in the 1998 edition through 2000 addenda, which is the latest edition and addenda codified in 10 CFR 50.55a, McGuire has not adopted this edition and consequently must meet its Code of Record to comply with Appendix G to part 50. Therefore, in this case, the licensee is still required to obtain an exemption to apply Code Case N–641.

In order to address provisions of amendments to the McGuire Technical Specification (TS) P/T limit curves, the licensee requested in its submittal dated December 12, 2002, as supplemented by letters dated March 27 and April 23, 2003, that the NRC staff exempt McGuire from application of specific requirements of 10 CFR 50.60 and Appendix G to 10 CFR part 50, and substitute the use of ASME Code Case N–641. ASME Code Case N–641 permits the use of an alternate reference fracture toughness curve for RPV materials and permits the postulation of a circumferentially-oriented flaw for the evaluation of circumferential RPV welds when determining the P/T limits. The proposed exemption request is consistent with, and is needed to support, the McGuire TS amendment that was contained in the same submittal. The proposed McGuire TS amendment will revise the P/T limits for heatup, cooldown, and inservice test limitations for the reactor coolant system (RCS) through 34 effective full power years of operation.

Code Case N–641

The licensee has proposed an exemption to allow the use of ASME Code Case N–641 in conjunction with Appendix G to ASME section XI, 10 CFR 50.60(a) and 10 CFR part 50, Appendix G, to establish the P/T limits for the McGuire, Units 1 and 2 RPVs.

The proposed TS amendment to revise the P/T limits for McGuire, Units 1 and 2, relies in part, on the requested exemption. These revised P/T limits have been developed using the lower bound K_{IC} fracture toughness curve shown in ASME, section XI, Appendix A, Figure A–2200–1, in lieu of the lower bound K_{IA} fracture toughness curve of ASME, section XI, Appendix G, Figure G–2210–1, as the basis fracture toughness curve for defining the McGuire P/T limits. In addition, the revised P/T limits have been developed based on the use of a postulated circumferentially-oriented flaw for the evaluation of RPV circumferential welds in lieu of the axially-oriented flaw that would be required by Appendix G to section XI of the ASME Code. The other margins involved with the ASME section XI, Appendix G, process of determining P/T limit curves remain unchanged.

Use of the K_{IC} curve as the basis fracture toughness curve for the development of P/T operating limits is technically correct. The K_{IC} curve appropriately implements the use of a relationship based on static initiation fracture toughness behavior to evaluate the controlled heatup and cooldown process of a RPV, whereas the K_{IA} fracture toughness curve codified into Appendix G to section XI of the ASME Code was developed from more conservative crack arrest and dynamic fracture toughness test data. The application of the K_{IA} fracture toughness curve was initially codified in Appendix G to section XI of the ASME Code in 1974 to provide a conservative representation of RPV material fracture toughness. This initial conservatism was necessary due to the limited knowledge of RPV material behavior in 1974. However, additional knowledge has been gained about RPV materials that demonstrates the lower bound on fracture toughness provided by the K_{IA} fracture toughness curve is well beyond the margin of safety required to protect the public health and safety from potential RPV failure.

Likewise, the use of a postulated circumferentially-oriented flaw in lieu of an axially-oriented one for the evaluation of a circumferential RPV weld is more technically correct. The size of flaw required to be postulated for P/T limit determination has a depth of one-quarter of the RPV wall thickness and a length six times the depth. Based on the direction of welding during the fabrication process, the only technically reasonable orientation for such a large flaw is for the plane of the flaw to be circumferentially-oriented (*i.e.*, parallel to the direction of welding). Prior to the development of ASME Code Case N–641 (and the similar ASME Code Case N–588), the required postulation of an axially-oriented flaw for the evaluation of a circumferential RPV weld has provided an additional, unnecessary level of conservatism to the overall evaluation.

In addition, P/T limit curves based on the K_{IC} fracture toughness curve and postulation of a circumferentially-oriented flaw for the evaluation of RPV circumferential welds will enhance overall plant safety by expanding the P/T operating window with the greatest safety benefit being in the region of low temperature operations. The operating window through which the operator heats up and cools down the RCS is determined by the difference between the maximum allowable pressure determined by Appendix G of ASME section XI, and the minimum required pressure for the reactor coolant pump seals adjusted for instrument uncertainties. A narrow operating window could potentially have an adverse safety impact by increasing the possibility of inadvertent overpressure protection system actuation due to

pressure surges associated with normal plant evolutions such as RCS pump starts and swapping operating charging pumps with the RCS in a water-solid condition.

Since application of ASME Code Case N–641 provides appropriate procedures to establish maximum postulated defects and to evaluate those defects in the context of establishing RPV P/T limits, this application of the Code Case maintains an adequate margin of safety for protecting RPV materials from brittle failure. The NRC staff has reviewed the exemption request submitted by the licensee and has concluded that an exemption should be granted from the requirements of 10 CFR 50.60 and section IV.A.2.b of Appendix G to 10 CFR part 50 to permit the licensee to use the provisions of ASME Code Case N–641 for the purpose of developing the McGuire Units 1 and 2 RPV P/T limit curves. However, the NRC staff does not agree with the special circumstances cited by the licensee in its December 12, 2002, application regarding the basis for granting the exemption. The NRC staff did not conclude that the circumstances cited above constitute ''undue hardship or other costs that are significantly in excess of those contemplated when the regulation was adopted, or that are significantly in excess of those incurred by others similarly situated,'' pursuant to 10 CFR 50.12(a)(2)(iii). Rather, the NRC staff concluded that the application of the technical provisions of ASME Code Case N–641 provided sufficient margin in the development of RPV P/T limit curves such that the underlying purpose of the regulations, Appendix G to 10 CFR part 50, will continue to be met and that the specific conditions required by the regulations (*i.e.*, use of all provisions in Appendix G to section XI of the ASME Code) were not necessary. Therefore, the NRC staff grants the requested exemption to the licensee based on the special circumstances of 10 CFR 50.12(a)(2)(ii), ''[a]pplication of the regulation in the particular circumstances would not serve the underlying purpose of the rule or is not necessary to achieve the underlying purpose of the rule.''

In summary, the ASME section XI, Appendix G, procedure was conservatively developed based on the level of knowledge existing in 1974 concerning reactor coolant pressure boundary materials and the estimated effects of operation. Since 1974, the level of knowledge about the fracture mechanics behavior of RCS materials has been greatly expanded, especially regarding the effects of radiation embrittlement and the understanding of fracture toughness properties under static and dynamic loading conditions. The NRC staff concurs that this increased knowledge permits relaxation of the ASME section XI, Appendix G requirements by application of ASME Code Case N–641, while maintaining, pursuant to 10 CFR 50.12(a)(2)(ii), the underlying purpose of the ASME Code and the NRC regulations to ensure an acceptable margin of safety against brittle failure of the RPV.

The NRC staff has reviewed the exemption request submitted by the licensee and has concluded that an exemption should be granted from the requirements of 10 CFR 50.60(a) and section IV.A.2.b of Appendix G to 10 CFR part 50 to permit the licensee to utilize the provisions of ASME Code Case N–641 for the purpose of developing McGuire Units 1 and 2 RPV P/T limit curves.

3.0 Discussion

Pursuant to 10 CFR 50.12, the Commission may, upon application by any interested person or upon its own initiative, grant exemptions from the requirements of 10 CFR part 50 when (1) the exemptions are authorized by law, will not present an undue risk to public health or safety, and are consistent with the common defense and security; and (2) when special circumstances are present.

Special circumstances, pursuant to 10 CFR 50.12(a)(2)(ii), are present in that continued operation of McGuire, Units 1 and 2, pursuant to the requirements of 10 CFR 50.60 and section IV.A.2.b of Appendix G to 10 CFR part 50, using P/T curves developed in accordance with ASME section XI, Appendix G, without the relief provided by ASME Code Case N–641, is not necessary to achieve the underlying purpose of 10 CFR 50.60 and Appendix G to 10 CFR part 50. Application of ASME Code Case N–641 in lieu of the requirements of ASME Code section XI, Appendix G, provides an acceptable alternate methodology that will continue to meet the underlying purpose of 10 CFR 50.60 and Appendix G to 10 CFR part 50. The underlying purpose of the regulations in 10 CFR 50.60 and Appendix G to 10 CFR part 50 is to provide an acceptable margin of safety against brittle failure of the RCS during any condition of normal operation to which the pressure boundary may be subjected over its service lifetime.

The NRC staff examined the licensee's rationale to support the exemption request, and accepts the licensee's determination that an exemption would be required to approve the use of Code Case N–641. The NRC staff agrees that the use of ASME Code Case N–641 would meet the underlying intent of 10 CFR 50.60 and Appendix G to 10 CFR part 50. The NRC staff concludes that the application of the technical provisions of ASME Code Case N–641 provides sufficient margin in the development of RPV P/T limit curves such that the underlying purpose of the regulations (10 CFR 50.60 and Appendix G to 10 CFR part 50) continues to be met and that the specific conditions required by the regulations (*i.e.*, use of all provisions in Appendix G to section XI of the ASME Code) were not necessary. Therefore, the NRC staff concludes that the exemption requested by the licensee is justified based on the special circumstances of 10 CFR part 50(a)(2)(ii), ''[a]pplication of the regulation in the particular circumstances would not serve the underlying purpose of the rule or is not necessary to achieve the underlying purpose of the rule.''

Based upon a consideration of the conservatism that is explicitly incorporated into the methodologies of Appendix G to 10 CFR part 50; Appendix G to section XI of the ASME Code; and Regulatory Guide 1.99, Revision 2; the NRC staff concludes that application of ASME Code Case N–641, as described, will provide an adequate margin of safety against brittle failure of the RPV. This conclusion is also consistent with the determination that the NRC staff has reached for other licensees under similar conditions based on the same considerations. Therefore, the NRC staff concludes that granting the exemption under the special circumstances of 10 CFR 50.12(a)(2)(ii) is appropriate, and that the methodology of Code Case N–641 may be used to revise the P/T limits for the McGuire, Unit 1 and 2 RPVs.

4.0 Conclusion

Accordingly, the Commission has determined that, pursuant to 10 CFR 50.12(a), the exemption is authorized by law, will not present an undue risk to the public health and safety, and is consistent with the common defense and security. Also, special circumstances are present. Therefore, the Commission hereby grants the licensee an exemption from the requirements of 10 CFR 50.60(a), and 10 CFR part 50, Appendix G, section IV.A.2.b, to allow application of ASME Code Case N–641 in establishing TS requirements for the RPV limits for McGuire, Units 1 and 2.

Pursuant to 10 CFR 51.32, the Commission has determined that the granting of this exemption will not have a significant effect on the quality of the human environment (68 FR 31735).

This exemption is effective upon issuance.

Dated at Rockville, Maryland, this 3rd day of July 2003.

For the Nuclear Regulatory Commission.

Ledyard B. Marsh,

Acting Director, Division of Licensing Project Management, Office of Nuclear Reactor Regulation.

[FR Doc. 03–17580 Filed 7–10–03; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket No. 72–22–ISFSI]

In the Matter of Private Fuel Storage, L.L.C. (Independent Spent Fuel Storage Installation); Notice of Appointment of Adjudicatory Employee

Commissioners: Nils J. Diaz, Chairman, Edward McGaffigan, Jr., Jeffrey S. Merrifield.

Pursuant to 10 CFR 2.4, notice is hereby given that Dr. Yong Li of the NRC's Office of Research has been appointed as a Commission adjudicatory employee within the meaning of section 2.4, to advise the Commission regarding issues relating to the pending petition for review of LBP–03–08 in the matter of *Private Fuel Storage, L.L.C.* Dr. Li has not previously performed any investigative or litigating function in connection with this or any related proceeding. Until such time as a final decision is issued in this matter, interested persons outside the agency and agency employees performing investigative or litigating functions in this proceeding are required to observe the restrictions of 10 CFR 2.780 and 2.781 in their communications with Dr. Li.

It is so ordered.

Dated at Rockville, Maryland, this 3rd day of July, 2003.

For the Commission.

J. Samuel Walker,

Acting Secretary of the Commission.

[FR Doc. 03–17584 Filed 7–10–03; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket Nos. STN 50–528, STN 50–529, STN 50–530]

Arizona Public Service Company, et al.: Palo Verde Nuclear Generating Station, Units 1, 2 and 3; Environmental Assessment and Finding of No Significant Impact

The U.S. Nuclear Regulatory Commission (NRC) is considering issuance of an amendment to Title 10 of the Code of Federal Regulations (10 CFR) part 50, for Facility Operating License Nos. NPF–41, NPF–51, NPF–74, issued to Arizona Public Service Company (the licensee), for operation of the Palo Verde Nuclear Generating Station (PVNGS), Units 1, 2, and 3, located in Maricopa County, Arizona. Therefore, as required by 10 CFR 51.21, the NRC is issuing this environmental assessment and finding of no significant impact.

Environmental Assessment

Identification of the Proposed Action

The proposed action would extend the expiration date of the operating license from December 31, 2024, to June 1, 2025, for Unit 1; from December 9, 2025, to April 24, 2026, for Unit 2; and from March 25, 2027, to November 25, 2027, for Unit 3.

The proposed action is in accordance with the licensee's application dated August 28, 2002.

The Need for the Proposed Action

The proposed action would allow the licensee to operate PVNGS, Units 1, 2, and 3, until June 1, 2025, April 24, 2026, and November 25, 2027, respectively. This would allow the licensee to recapture approximately six months of additional plant operation for each unit.

Environmental Impacts of the Proposed Action

The NRC has completed its evaluation of the proposed action and concludes that there are no significant environmental considerations involved with the proposed action. The extension of the operating licenses does not affect the design or operation of the plants, does not involve any modifications to the plants or any increase in the licensed power for the plants, and will not create any new or unreviewed environmental impacts that were not considered in the Final Environmental Statement (FES) related to the operation of PVNGS, Units 1, 2, and 3, NUREG–0841, dated February 1982. The evaluations presented in the FES were the environmental impacts of generating power at PVNGS and the basis for granting a 40-year operating license for PVNGS. The environmental impacts of the proposed action are based on the evaluations in the FES. The FES also considered the environmental impacts of operating Units 1, 2, and 3.

The FES which in general, assesses various impacts associated with operation of the facility in terms of annual impacts and balances these against the anticipated annual energy production benefits.

The offsite exposure from releases during postulated accidents has been previously evaluated in the Updated Final Safety Analysis Report (UFSAR) for PVNGS. The results are acceptable when compared with the criteria defined in 10 CFR part 100, as documented in the Commission's Safety Evaluation Report, NUREG–0857, dated November 1981, and its 12 supplements.

This conservative design-basis evaluation is a function of four parameters: (1) The type of accident postulated, (2) the radioactivity calculated to be released during the accident, (3) the assumed meteorological conditions at the site, and (4) the population distribution versus distance from the plant. An environmental assessment of accidents is also provided in section 5.9.2 of the FES. The type of accidents and the calculated radioactivity released do not change with the proposed action. The site meteorology as defined in Chapter 2 of the UFSAR is essentially constant. The NRC staff has concluded that the population size and distribution will not change significantly.

The NRC staff has concluded that the impacts associated with the addition of approximately six to eight months to each unit are not significantly different from operating license duration assessed in the PVNGS FES. Therefore, the staff concluded that the FES sufficiently addresses the environmental impacts associated with a full 40-year operating period for each unit.

The annual occupational exposure of workers at the plant, station employees and contractors, is reported in the Annual Operating Report submitted by the licensee. The lowest exposure value is for a year without a refueling outage and the highest value is for a year with a refueling outage. In section 5.9.1.1.1 of the FES, the average occupational exposure for a pressurized water reactor was reported as 440 person-rems. Therefore, the expected annual occupational exposure for the proposed extended period of operation does not

change previous conclusions presented in the FES on occupational exposure.

The offsite exposure from releases during routine operations has been previously evaluated in section 5.9.1 of the FES. During the low-power license, the plant was restricted to no more than 5 percent of rated power and the generation of radioactivity at the plants was significantly smaller than would have occurred if the plants were at full-power operation. Therefore, the addition of approximately six to eight months of operation per plant that the licensee has requested does not change previous conclusions presented in the FES on annual public doses.

The proposed action will not significantly increase the probability or consequences of accidents, no changes are being made in the types of effluents that may be released off site, and there is no significant increase in occupational or public radiation exposure. Therefore, there are no significant radiological environmental impacts associated with the proposed action.

With regard to potential nonradiological impacts, the proposed action does not have a potential to affect any historic sites. It does not affect nonradiological plant effluents and has no other environmental impact. Therefore, there are no significant nonradiological environmental impacts associated with the proposed action.

Accordingly, the NRC concludes that there are no significant environmental impacts associated with the proposed action.

Environmental Impacts of the Alternatives to the Proposed Action

As an alternative to the proposed action, the staff considered denial of the proposed action (*i.e.*, the ''no-action'' alternative). Denial of the application would result in no change in current environmental impacts. The environmental impacts of the proposed action and the alternative action are similar.

Alternative Use of Resources

The action does not involve the use of any different resource than those previously considered in the FES [or more recently, the Environmental Impact Statement] for the PVNGS, Units 1, 2, and 3.

Agencies and Persons Consulted

On July 3, 2003, the staff consulted with the Arizona State official, Mr. William Wright, of the Arizona Radiation Regulatory Agency, regarding the environmental impact of the proposed action. The State official had no comments.

Finding of No Significant Impact

On the basis of the environmental assessment, the NRC concludes that the proposed action will not have a significant effect on the quality of the human environment. Accordingly, the NRC has determined not to prepare an environmental impact statement for the proposed action.

For further details with respect to the proposed action, see the licensee's letter dated August 28, 2002. Documents may be examined, and/or copied for a fee, at the NRC's Public Document Room (PDR), located at One White Flint North, Public File Area O1 F21, 11555 Rockville Pike (first floor), Rockville, Maryland. Publicly available records will be accessible electronically from the Agencywide Documents Access and Management System (ADAMS) Public Electronic Reading Room on the Internet at the NRC Web site, *http://www.nrc.gov/reading-rm/adams.html.* Persons who do not have access to ADAMS or who encounter problems in accessing the documents located in ADAMS, should contact the NRC PDR Reference staff by telephone at 1–800–397–4209 or 301–415–4737, or by e-mail to *pdr@nrc.gov.*

Dated at Rockville, Maryland, this 7th day of July 2003.

For the Nuclear Regulatory Commission.

Stephen Dembek,

Chief, Section 2, Project Directorate IV, Division of Licensing Project Management, Office of Nuclear Reactor Regulation.

[FR Doc. 03–17579 Filed 7–10–03; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

Draft Regulatory Guide; Issuance; Availability Correction

On June 6, 2003, the NRC published a Notice of Availability on Draft Regulatory Guide DG–1121, ''Guidelines for Categorizing Structures, Systems, and Components in Nuclear Power Plants According to their Safety Significance,'' that contained a number of errors. This Notice of Availability is being reprinted to correct these errors.

The Nuclear Regulatory Commission (NRC) has issued for public comment a proposed guide in its Regulatory Guide Series. Regulatory guides are developed to describe and make available to the public such information as methods acceptable to the NRC staff for implementing specific parts of the NRC's regulations, techniques used by the staff in evaluating specific problems or postulated accidents, and data needed by the staff in its review of applications for permits and licenses.

The draft guide is temporarily identified by its task number, DG–1121, which should be mentioned in all correspondence concerning this draft guide. Draft Regulatory Guide DG–1121, ''Guidelines for Categorizing Structures, Systems, and Components in Nuclear Power Plants According to their Safety Significance,'' is being developed to describe a process that is acceptable to the NRC staff for the development and assessment of evaluation models that may be used to comply with the NRC's regulations with respect to the categorization of structures, systems, and components that are considered in risk-informing special treatment requirements. This guide conforms to a proposed amendment to 10 CFR 50.69 that was published in the **Federal Register** (68 FR 26511) on May 16, 2003.

This draft guide has not received complete staff approval and does not represent an official NRC staff position.

Comments will be most helpful if received by August 1, 2003. You may submit comments by any one of the following methods. Please include the draft guide number (DG–1121) in the subject line of your comments. Comments on regulatory guides submitted in writing or in electronic form will be made available to the public in their entirety on the NRC rulemaking Web site. Personal information will not be removed from your comments.

Mail comments to: Rules and Directives Branch, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

E-mail comments to: *NRCREP@nrc.gov.* You may also submit comments via the NRC's rulemaking Web site at *http://ruleforum.llnl.gov.* Address questions about our rulemaking Web site to Carol Gallagher (301) 415–5905; e-mail *CAG@nrc.gov.* Address questions about the content of the draft guide to Mr. David Diec, (301) 415–2834; e-mail *dtd@nrc.gov.*

Hand deliver comments to: Rules and Directives Branch, Office of Administration, 11555 Rockville Pike, Rockville, Maryland 20852, between 7:30 am and 4:15 p.m. on Federal workdays.

Fax comments to: Rules and Directives Branch, Office of Administration, U.S. Nuclear Regulatory Commission at (301) 415–5144.

Publicly available documents related to this regulatory guide may be examined and copied for a fee at the

NRC's Public Document Room (PDR), Public File Area O1F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland. The regulatory guide and related documents, including comments, can be viewed and downloaded electronically via the NRC's rulemaking Web site at *http://ruleforum.llnl.gov*.

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

Although a deadline is given for comments on this draft guide, comments and suggestions in connection with items for inclusion in guides currently being developed or improvements in all published guides are encouraged at any time. Requests for single copies of draft or final regulatory guides (which may be reproduced) or for placement on an automatic distribution list for single copies of future draft guides in specific divisions should be made in writing to the U.S. Nuclear Regulatory Commission, Washington, DC 20555, Attention: Reproduction and Distribution Services Section, or by fax to (301) 415–2289; e-mail *Distribution@nrc.gov*. Telephone requests cannot be accommodated. Regulatory guides are not copyrighted, and NRC approval is not required to reproduce them.

(5 U.S.C. 552(a))

Dated at Rockville, Maryland, this 3rd day of July 2003.

For the Nuclear Regulatory Commission.

Karen M. Fitch,

Deputy Director, Program Management, Policy Development and Analysis Staff, Office of Nuclear Regulatory Research.

[FR Doc. 03–17582 Filed 7–10–03; 8:45 am]

BILLING CODE 7590–01–P

POSTAL SERVICE BOARD OF GOVERNORS

Sunshine Act Meeting

Board Votes To Close July 21, 2003, Meeting

At its meeting on June 2, 2003, and by paper vote July 3–7, 2003, the Board of Governors of the United States Postal Service voted unanimously to close to public observation its meeting scheduled for July 21, 2003, in McLean, Virginia.

ITEMS TO BE CONSIDERED:

1. Strategic Planning.
2. Personnel Matters.

GENERAL COUNSEL CERTIFICATION: The General Counsel of the United States Postal Service has certified that the meeting was properly closed under the Government in the Sunshine Act.

FOR FURTHER INFORMATION CONTACT: Requests for information about the meeting should be addressed to the Secretary of the Board, William T. Johnstone, at (202) 268–4800.

William T. Johnstone,

Secretary

[FR Doc. 03–17775 Filed 7–9–03; 3:27 pm]

BILLING CODE 7710–12–M

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–48129; File No. SR–ISE–2003–16]

Self-Regulatory Organizations; Notice of Filing and Immediate Effectiveness of Proposed Rule Change by the International Securities Exchange, Inc., Relating to Fee Changes

July 3, 2003.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on June 4, 2003, the International Securities Exchange, Inc. (''ISE'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II and III below, which Items have been prepared by the ISE. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange is proposing changes to its Schedule of Fees in order to extend the term of certain existing fee waivers, to remove language to a fee waiver that has expired, and to eliminate the fee for the Rule 11Ac1–6 Order Report.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below and is set forth in Sections A, B, and C below.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange is proposing changes to its Schedule of Fees in order to extend the term of certain existing fee waivers, to remove language referring to a certain fee waiver that is not being renewed and to eliminate the fee for the Rule 11Ac1–6 Order Report.

With respect to the fee waivers, the Exchange is proposing to extend the terms, as follows: (i) the waiver of customer Execution Fees is extended through June 30, 2004;[3] (ii) the waiver of firm proprietary Execution Fees in the iShares S&P 100 Index Fund is extended through June 30, 2004;[4] (iii) the waiver of the firm proprietary Surcharge in the iShares S&P 100 Index Fund is extended through June 30, 2004;[5] (iv) the waiver of the Marketing Fee is extended until December 31, 2003;[6] (v) the waiver of the Comparison Fee for customer trades is extended through June 30, 2004;[7] (vi) the waiver of the Click®/Trade Review Terminal Software License & Maintenance Fee for a second and subsequent terminals is extended through June 30, 2004;[8] and (vii) the waiver of the EAM/Trade Review Terminal Session/API Fee associated with a second and

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] Initial fee waiver made in Securities Exchange Act Release No. 42473 (February 29, 2000), 65 FR 11818 (March 6, 2000).

[4] Initial fee waiver made in Securities Exchange Act Release No. 46698 (October 21, 2002), 67 FR 65818 (October 28, 2002).

[5] *Id.*

[6] Initial fee waiver made in Securities Exchange Act Release No. 46189 (July 11, 2002), 67 FR 47587 (July 17, 2002).

[7] Initial fee waiver made in Securities Exchange Act Release No. 42473 (February 29, 2000), 65 FR 11818 (March 6, 2000).

[8] Initial fee waiver made in Securities Exchange Act Release No. 45840 (April 29, 2002), 67 FR 30408 (May 6, 2002).

subsequent Click terminals is extended through June 30, 2004.[9] The Exchange represents that it is extending the term of the fee waivers for competitive purposes. The Exchange is also removing language in its Schedule of Fees that relates to a fee waiver that expired on May 31, 2003 and has not been renewed—namely, firm proprietary Execution Fees for trades executed in the Block Order Mechanism.

With respect to the fee elimination, the Exchange is proposing to eliminate the fee for preparing a Rule 11Ac1–6 Order Report, or specialized best execution report, that the Exchange currently offers to members who specifically request this report. The Exchange is eliminating the fee since the Exchange has recovered the technical development costs associated with producing the report, as well as for competitive purposes.

2. Statutory Basis

The basis under the Act for this proposed rule change is the requirement under Section 6(b)(4) of the Act that an exchange have an equitable allocation of reasonable dues, fees and other charges among its members and other persons using its facilities.[10]

B. Self-Regulatory Organization's Statement on Burden on Competition

The proposed rule change does not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received from Members, Participants or Others

The Exchange has not solicited, and does not intend to solicit, comments on this proposed rule change. The Exchange has not received any unsolicited written comments from members or other interested parties.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing proposed rule change has been designated as a fee change pursuant to Section 19(b)(3)(A)(ii) of the Act[11] and Rule 19b–4(f)(2) thereunder.[12] Accordingly, the proposal will take effect upon filing with the Commission. At any time within 60 days of the filing of the proposed rule change, the Commission may summarily abrogate such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposal 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 communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Room.

Copies of such filing will also be available for inspection and copying at the principal office of the ISE. All submissions should refer to File No. SR–ISE–2003–16 and should be submitted by August 1, 2003.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[13]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 03–17588 Filed 7–10–03; 8:45 am]

BILLING CODE 8010–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–48122; File No. SR–NSCC–2003–14]

Self-Regulatory Organizations; National Securities Clearing Corporation; Notice of Filing of a Proposed Rule Change Relating to Anonymity Features on Trading Systems

July 2, 2003.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] notice is hereby given that on June 19, 2003, the National Securities Clearing Corporation (''NSCC'') filed with the Securities and Exchange Commission (''Commission''), and on June 23, 2003, amended the proposed rule change as described in Items I, II, and III below, which items have been prepared primarily by NSCC. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The proposed rule change would modify NSCC's procedures to accommodate the reporting of trades executed on a system that provides trading anonymity.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, NSCC 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. NSCC has prepared summaries, set forth in sections (A), (B), and (C) below, of the most significant aspects of such statements.[2]

(A) Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

NSCC may receive locked-in trade data from an SRO that operates a trading system that provides anonymity. At the request of the SRO, NSCC may report back to members such trades identifying an acronym selected by the SRO instead of naming the actual contraside. The purpose of the proposed rule filing is to add language to section II.C.1 of NSCC Rules and Procedures that would provide that in such an event the contraside is one of the members eligible to execute trades on the anonymous trading system. New language would also be added to that section that would provide that if NSCC ceases to act for the unnamed contraside, the applicable entity providing the anonymous trading system will be responsible for identifying to members which of their trades are with the affected member.

The National Association of Securities Dealers, Inc. (''NASD'') recently filed a proposed rule change that would allow it to add an anonymity feature to the Nasdaq Stock Market's SuperMontage trading system.[3] NSCC's proposed rule

[9] *Id.*

[10] 15 U.S.C. 78f(b)(4).

[11] 15 U.S.C. 78s(b)(3)(A)(ii).

[12] 17 CFR 240.19b–4(f)(2).

[13] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] The Commission has modified parts of these statements.

[3] File No. SR–NASD–2003–85 (filed May 22, 2003).

change will initially accommodate trades executed on the SuperMontage platform and therefore will need to be approved at the same time as the NASD's proposed rule change.

NSCC believes that the proposed rule change is consistent with the requirements of Section 17A of the Act and the rules and regulations thereunder applicable to NSCC because by allowing NSCC to accommodate trades executed on an anonymous platform it will promote the prompt and accurate clearance and settlement of securities transactions.

(B) Self-Regulatory Organization's Statement on Burden on Competition

NSCC perceives no adverse impact on competition by reason of the proposed rule change.

(C) Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received from Members, Participants, or Others

Comments from NSCC members or others have not been solicited or received on the proposed rule change. NSCC will notify the Commission of any written comments received by it.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within thirty-five days of the date of publication of this notice in the **Federal Register** or within such longer period (i) as the Commission may designate up to ninety days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

(a) by order approve the proposed rule change or

(b) institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street NW., Washington, DC 20549–0609. Comments may also be submitted electronically at the following e-mail address: *rule-comments@sec.gov.* All comment letters should refer to File No. SR–NSCC–2003–14. This file number should be included on the subject line if e-mail is used. To help us process and review comments more efficiently, comments should be sent in hardcopy or by e-mail but not by both methods. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Section, 450 Fifth Street NW., Washington, DC 20549. Copies of such filing will also be available for inspection and copying at the principal office of NSCC. All submissions should refer to the File No. SR–NSCC–2003–14 and should be submitted by August 1, 2003.

For the Commission by the Division of Market Regulation, pursuant to delegated authority.[4]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 03–17589 Filed 7–10–03; 8:45 am]

BILLING CODE 8010–01–P

[4] 17 CFR 200.30–3(a)(12).

SMALL BUSINESS ADMINISTRATION

Reporting and Recordkeeping Requirements Under OMB Review

AGENCY: Small Business Administration.

ACTION: Notice of reporting requirements submitted for OMB review.

SUMMARY: Under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35), agencies are required to submit proposed reporting and recordkeeping requirements to OMB for review and approval, and to publish a notice in the **Federal Register** notifying the public that the agency has made such a submission.

DATES: Submit comments on or before August 11, 2003. If you intend to comment but cannot prepare comments promptly, please advise the OMB Reviewer and the Agency Clearance Officer before the deadline.

Copies: Request for clearance (OMB 83–1), supporting statement, and other documents submitted to OMB for review may be obtained from the Agency Clearance Officer.

ADDRESSES: Address all comments concerning this notice to: Agency Clearance Officer, Jacqueline White, Small Business Administration, 409 3rd Street, SW., 5th Floor, Washington, DC 20416; and OMB Reviewer, Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Jacqueline White, Agency Clearance Officer, (202) 205–7044.

SUPPLEMENTARY INFORMATION:

Title: Disaster Home Loan Application.

No's: 5C and 739.

Frequency: On Occasion.

Description of Respondents: Applicant's requesting SBA Disaster Home Loan.

Responses: 47,962.

Annual Burden: 71,943.

Jacqueline White,

Chief, Administrative Information Branch.

[FR Doc. 03–17553 Filed 7–10–03; 8:45 am]

BILLING CODE 8025–01–P

SMALL BUSINESS ADMINISTRATION

Reporting and Recordkeeping Requirements Under OMB Review

AGENCY: Small Business Administration.

ACTION: Notice of reporting requirements submitted for OMB review.

SUMMARY: Under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35), agencies are required to submit proposed reporting and recordkeeping requirements to OMB for review and approval, and to publish a notice in the **Federal Register** notifying the public that the agency has made such a submission.

DATES: Submit comments on or before August 11, 2003. If you intend to comment but cannot prepare comments promptly, please advise the OMB Reviewer and the Agency Clearance Officer before the deadline.

Copies: Request for clearance (OMB 83–1), supporting statement, and other documents submitted to OMB for review may be obtained from the Agency Clearance Officer.

ADDRESSES: Address all comments concerning this notice to: Agency Clearance Officer, Jacqueline White, Small Business Administration, 409 3rd Street, SW., 5th Floor, Washington, DC 20416; and OMB Reviewer, Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Jacqueline White, Agency Clearance Officer, (202) 205–7044.

SUPPLEMENTARY INFORMATION:

Title: SBA Counseling Evaluation.
No: 1419.
Frequency: On Occasion.
Description of Respondents: Small Business Clients.
Responses: 15,000.
Annual Burden: 3,000.

Jacqueline White,

Chief, Administrative Information Branch.

[FR Doc. 03–17554 Filed 7–10–03; 8:45 am]

BILLING CODE 8025–01–P

SMALL BUSINESS ADMINISTRATION

Reporting and Recordkeeping Requirements Under OMB Review

AGENCY: Small Business Administration.

ACTION: Notice of reporting requirements submitted for OMB review.

SUMMARY: Under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35), agencies are required to submit proposed reporting and recordkeeping requirements to OMB for review and approval, and to publish a notice in the **Federal Register** notifying the public that the agency has made such a submission.

DATES: Submit comments on or before August 11, 2003. If you intend to comment but cannot prepare comments promptly, please advise the OMB Reviewer and the Agency Clearance Officer before the deadline.

Copies: Request for clearance (OMB 83–1), supporting statement, and other documents submitted to OMB for review may be obtained from the Agency Clearance Officer.

ADDRESSES: Address all comments concerning this notice to: Agency Clearance Officer, Jacqueline White, Small Business Administration, 409 3rd Street, SW., 5th Floor, Washington, DC 20416; and OMB Reviewer, Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Jacqueline White, Agency Clearance Officer, (202) 205–7044.

SUPPLEMENTARY INFORMATION: *Title:* Training Program Evaluation.
No: 20.
Frequency: On Occasion.
Description of Respondents: Small Business Clients.
Responses: 200,000.
Annual Burden: 40,000.

Jacqueline White,

Chief, Administrative Information Branch.

[FR Doc. 03–17555 Filed 7–10–03; 8:45 am]

BILLING CODE 8025–01–P

SMALL BUSINESS ADMINISTRATION

[Declaration of Disaster #3519]

State of Georgia

DeKalb County and the contiguous counties of Clayton, Fulton, Gwinnett, Henry and Rockdale in the State of Georgia constitute a disaster area due to damages caused by severe storms and flooding that occurred on June 16–17, 2003. Applications for loans for physical damage as a result of this disaster may be filed until the close of business on September 2, 2003 and for economic injury until the close of business on April 5, 2004 at the address listed below or other locally announced locations:

U.S. Small Business Administration, Disaster Area 2 Office, One Baltimore Place, Suite 300, Atlanta, GA 30308.

The interest rates are:

	Percent
For Physical Damage:	
Homeowners With Credit Available Elsewhere	5.625
Homeowners Without Credit Available Elsewhere	2.812
Businesses With Credit Available Elsewhere	5.906
Businesses and Non-Profit Organizations Without Credit Available elsewhere	2.953
Others (Including Non-Profit Organizations) With Credit Available Elsewhere	5.500
For Economic Injury:	
Businesses and Small Agricultural Cooperatives Without Credit Available Elsewhere	2.953

The number assigned to this disaster for physical damage is 351911 and for economic damage is 9W1900.

(Catalog of Federal Domestic Assistance Program Nos. 59002 and 59008)

Dated: July 3, 2003.

Hector V. Barreto,

Administrator.

[FR Doc. 03–17603 Filed 7–10–03; 8:45 am]

BILLING CODE 8025–01–P

SMALL BUSINESS ADMINISTRATION

[Declaration of Disaster #3520]

Commonwealth of Kentucky

As a result of the President's major disaster declaration on July 2, 2003, I find that Boyd, Breathitt, Carter, Clay, Elliott, Floyd, Greenup, Harlan, Johnson, Knott, Lawrence, Leslie, Letcher, Lewis, Magoffin, Martin, Owsley, Perry, Pike and Rowan Counties in the Commonwealth of Kentucky constitute a disaster area due to damages caused by severe storms, flooding, mud and rock slides, and tornadoes occurring on June 14, 2003 and continuing. Applications for loans for physical damage as a result of this disaster may be filed until the close of business on September 2, 2003 and for economic injury until the close of business on April 2, 2004 at the address listed below or other locally announced locations: Small Business Administration, Disaster Area 2 Office, One Baltimore Place, Suite 300,Atlanta, GA 30308.

In addition, applications for economic injury loans from small businesses located in the following contiguous counties may be filed until the specified date at the above location: Bath, Bell, Fleming, Jackson, Knox, Laurel, Lee, Mason, Menifee, Morgan and Wolfe in the Commonwealth of Kentucky; Adams, Lawrence and Scioto counties in the State of Ohio; Buchanan, Dickenson, Lee and Wise counties in the Commonwealth of Virginia; and Mingo and Wayne counties in the State of West Virginia.

The interest rates are:

	Percent
For Physical Damage:	
Homeowners With Credit Available Elsewhere	5.625
Homeowners Without Credit Available Elsewhere	2.812
Businesses With Credit Available Elsewhere	5.906
Businesses and Non-Profit Organizations Without Credit Available Elsewhere	2.953
Others (Including Non-Profit Organizations) With Credit Available Elsewhere	5.500
For Economic Injury:	
Businesses and Small Agricultural Cooperatives Without Credit Available Elsewhere	2.953

The number assigned to this disaster for physical damage is 352011. For economic injury the number is 9W2000 for Kentucky; 9W2100 for Ohio; 9W2200 for Virginia; and 9W2300 for West Virginia.

(Catalog of Federal Domestic Assistance Program Nos. 59002 and 59008).

Dated: July 3, 2003.

Allan I. Hoberman,

Acting Associate Administrator for Disaster Assistance.

[FR Doc. 03–17556 Filed 7–10–03; 8:45 am]

BILLING CODE 8025–01–P

SMALL BUSINESS ADMINISTRATION

[Declaration of Disaster #3518]

State of Texas

Webb County and the contiguous counties of Dimmit, Duval, Jim Hogg, La Salle, Maverick, McMullen and Zapata in the State of Texas constitute a disaster area due to severe storms, damaging winds and hail that occurred on June 2, 2003. Applications for loans for physical damage as a result of this disaster may be filed until the close of business on September 2, 2003 and for economic injury until the close of business on April 5, 2004 at the address listed below or other locally announced locations:

U.S. Small Business Administration, Disaster Area 3 Office, 4400 Amon Carter Boulevard, Suite 102, Fort Worth, TX 76155.

The interest rates are:

	Percent
For Physical Damage:	
Homeowners with credit available elsewhere	5.625
Homeowners without credit available elsewhere	2.812
Businesses with credit available elsewhere	5.906
Businesses and non-profit organizations without credit available Elsewhere	2.953
Others (including non-profit organizations) with credit available elsewhere	5.500
For Economic Injury:	
Businesses and small agricultural cooperatives without credit available elsewhere	2.953

The number assigned to this disaster for physical damage is 351811 and for economic injury the number is 9W1800.

(Catalog of Federal Domestic Assistance Program Nos. 59002 and 59008)

Dated: July 3, 2003.

Hector V. Baretto,

Administrator.

[FR Doc. 03–17604 Filed 7–10–03; 8:45 am]

BILLING CODE 8025–01–P

DEPARTMENT OF STATE

[Public Notice 4398]

Determination Related to the Participation of the Magen David Adom Society of Israel in the Activities of the International Red Cross and Red Crescent Movement

Pursuant to the requirements contained in the Foreign Operations, Export Financing, and Related Appropriations, Division E., Title II, of the Consolidated Appropriations Resolution, FY 2003 (Pub. L. 108–7), under the heading of Migration and Refugee Assistance, I hereby determine that the Magen David Adom Society of Israel is not being denied participation in the activities of the International Red Cross and Red Crescent Movement.

This Determination shall be published in the **Federal Register,** and copies shall be provided to the appropriate committees of the Congress.

Dated: June 27, 2003.

Colin L. Powell,

Secretary of State, Department of State.

[FR Doc. 03–17601 Filed 7–10–03; 8:45 am]

BILLING CODE 4710–10–P

OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE

Notice of Meeting of the Industry Sector Advisory Committee on Services (ISAC–13)

AGENCY: Office of the United States Trade Representative.

ACTION: Notice of an partially opened meeting.

SUMMARY: The Industry Sector Advisory Committee on Services (ISAC–13) will hold a meeting on July 22, 2003, from 1:30 p.m. to 4:30 p.m. The meeting will be closed to the public from 2:15 p.m. to 4:30 p.m. and opened to the public from 1:30 p.m. to 2:15 p.m.

DATES: The meeting is scheduled for July 22, 2003, unless otherwise notified.

ADDRESSES: The meeting will be held at the Ronald Reagan Bldg., USA Trade Center, Training Room A.

FOR FURTHER INFORMATION CONTACT: Jennifer Moll, DFO for ISAC–13 at (202) 482–1316, Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC 20230 or Christina Sevilla, Director for Intergovernmental Affairs, on (202) 395–6120.

SUPPLEMENTARY INFORMATION: During the opened portion of the meeting the following agenda item will be discussed.

- Discussion on the International Trade Commission's Recently Released Report: ''Recent Trends in U.S. Services Trade''.
- Report on General Agreement on Trade in Services (GATS) Negotiations.
- Report on Iraq Reconstruction and Related Business Opportunities.

Christopher A. Padilla,

Assistant U.S. Trade Representative for Intergovernmental Affairs and Public Liaison.

[FR Doc. 03–17590 Filed 7–10–03; 8:45 am]

BILLING CODE 3190–01–M

DEPARTMENT OF TRANSPORTATION

Office of the Secretary

Application of Victory Air Transport, Inc. For Certificate Authority

AGENCY: Department of Transportation.

ACTION: Notice of order to show cause (Order 2003–7–7) Dockets OST–02–14027 and OST–02–14028.

SUMMARY: The Department of Transportation is directing all interested persons to show cause why it should not issue an order finding Victory Air Transport, Inc., fit, willing, and able, and awarding it certificates of public convenience and necessity to engage in interstate and foreign charter air transportation of persons, property and mail.

DATES: Persons wishing to file objections should do so no later than July 21, 2003.

ADDRESSES: Objections and answers to objections should be filed in Dockets OST–02–14027 and OST–02–14028 and addressed to the Department of Transportation Dockets (M–30, Room PL–401), U.S. Department of Transportation, 400 Seventh Street SW., Washington, DC 20590, and should be served upon the parties listed in Attachment A to the order.

FOR FURTHER INFORMATION CONTACT: Ms. Delores King, Air Carrier Fitness Division (X–56, Room 6401), U.S. Department of Transportation, 400 Seventh Street, SW., Washington, DC 20590, (202) 366–2343.

Dated: July 7, 2003.

Michael W. Reynolds,

Acting Assistant Secretary for Aviation and International Affairs.

[FR Doc. 03–17600 Filed 7–10–03; 8:45 am]

BILLING CODE 4910–62–P

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

Environmental Impact Statement: Cameron and Willacy Counties, TX

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Notice of Intent.

SUMMARY: The FHWA is issuing this notice to advise the public that an environmental impact statement will be prepared for a proposed second access to South Padre Island, in Cameron or Willacy Counties, Texas.

FOR FURTHER INFORMATION CONTACT: John Mack, District Engineer, Federal Highway Administration, 300 East 8th Street, Austin, Texas, Telephone: (512) 536–5960.

SUPPLEMENTARY INFORMATION: The FHWA, in cooperation with the Texas Department of Transportation, will prepare an environmental impact statement (EIS) proposing to provide a second access to and from South Padre Island. Currently, the Queen Isabella Causeway is the only means of vehicular access to and from the island. The purpose of the proposed project is to provide an alternate route to and from South Padre. Residents and visitors need increased vehicular mobility to enhance their health, safety, and security. This need is heightened during constrained or interrupted traffic flow conditions on the Queen Isabella Causeway resulting from hurricane evacuations, incidents involving the bridge, lane closures associated with bridge repairs and during peak travel periods such as Spring Break and the summer vacation season.

The EIS will examine or evaluate viable alternatives for providing access between the mainland and the island. The project study area includes South Padre Island and the mainland in Cameron and Willacy Counties. Transportation alternatives include taking no action (the no-build alternative), Transportation System Management (TSM), ferrying systems and construction of a second causeway. The environmental study will also include discussions of the social, economic and environmental effects of the proposed project.

A public scoping meeting will be held on August 5, 2003 at 6 p.m. at the South Padre Island Convention Center. This will be the first in a series of meetings to solicit public comments on the proposed action. In addition, a public hearing will be held. Public notice will be given about the time and place of the meetings and hearing. The draft EIS will be available for the public and relevant agencies for comment before the public hearing.

Letters describing the proposed action and soliciting comments will be sent to appropriate Federal, State, and local agencies, and to private organizations and citizens who have previously expressed or are known to have interest in this proposal. A series of public scoping meetings will be held in the area. In addition, a public hearing will be held. Public notice will be given with the time and place of the meetings and hearing. The draft EIS will be available for public and agency review and comment prior to the public hearing.

To ensure that the full range of issues related to this proposed action are addressed and all significant issues identified, comments, and suggestions are invited from all interested parties. Comments or questions concerning this proposed action and the EIS should be directed to the FHWA at the address provided above.

Issued on: June 30, 2003.

(Catalog of Federal Domestic Assistance Program Number 20.205, Highway Planning and Construction. The regulations implementing Executive order 12372 regarding intergovernmental consultation on Federal programs and activities apply to this program.)

John R. Mack,

District Engineer, Austin, Texas.

[FR Doc. 03–17539 Filed 7–10–03; 8:45 am]

BILLING CODE 4910–22–M

DEPARTMENT OF TRANSPORTATION

Surface Transportation Board

[STB Finance Docket No. 34361]

Metro Regional Transit Authority—Acquisition Exemption—Certain Assets of CSX Transportation, Inc.

Metro Regional Transit Authority (METRO) has filed a notice of exemption under 49 CFR 1150.31, *et seq.* to acquire CSX Transportation, Inc.'s (CSXT) right, title and interest in a perpetual freight rail easement over a rail line owned by METRO between approximately milepost 40.42 (valuation station 1856+40) near Howard Street in Akron, OH and approximately milepost 33.70 (valuation station 2206+60) at Krumroy, OH, a distance of approximately 6.72 miles in Summit County, OH.[1]

METRO indicates that it will not operate any freight rail service on the line. METRO further indicates that this transaction is related to STB Finance Docket No. 34362, *Akron Barberton Cluster Railway Company—Lease and Operation Exemption—Metro Regional Transit Authority,* wherein the Akron Barberton Cluster Railway Company has filed a notice of exemption under 1150.41 to lease and operate over the rail line involved here.

Consummation of the transaction was expected to occur on or after June 19, 2003, the effective date of this exemption.

METRO certifies that the projected annual revenues as a result of the transaction will not exceed $5 million, and thus the transaction will not result in the creation of a Class II or Class I rail carrier.

If the verified notice contains false or misleading information, the exemption is void *ab initio.* Petitions to revoke the exemption under 49 U.S.C. 10502(d) may be filed at any time. The filing of a petition to revoke will not automatically stay the transaction.

An original and 10 copies of all pleadings, referring to STB Finance Docket No. 34361, must be filed with the Surface Transportation Board, 1925 K Street, NW., Washington, DC 20423–0001. In addition, a copy of each pleading must be served on Edward J. Fishman, Esq., Kirkpatrick & Lockhart LLP, 1800 Massachusetts Ave., Second Floor, Washington, DC 20036.

Board decisions and notices are available on our Web site at *http://www.stb.dot.gov.*

Decided: July 2, 2003.

By the Board, Joseph H. Dettmar, Acting Director, Office of Proceedings.

Vernon A. Williams,

Secretary.

[FR Doc. 03–17345 Filed 7–10–03; 8:45 am]

BILLING CODE 4915–00–P

DEPARTMENT OF TRANSPORTATION

Surface Transportation Board

[STB Finance Docket No. 34362]

Akron Barberton Cluster Railway Company—Lease and Operation Exemption—Metro Regional Transit Authority

Akron Barberton Cluster Railway Company (ABC), a Class III rail carrier, has filed a verified notice of exemption under 49 CFR 1150.41 *et seq.* to lease, from Metro Regional Transit Authority (METRO), and operate a freight rail easement between approximately milepost 40.42 (valuation station 1856+40) near Howard Street in Akron, OH and approximately milepost 33.70 (valuation station 2206+60) at Krumroy, OH, a distance of approximately 6.72 miles in Summit County, OH.

This transaction is related to STB Finance Docket No. 34361, *Metro Regional Transit Authority—Acquisition Exemption—Certain Assets of CSX*

[1] The freight easement was initially retained by CSXT when CSXT sold the assets comprising the subject line to METRO in *Metro Regional Transit Authority—Acquisition Exemption—CSX Transportation, Inc.,* STB Finance Docket No. 33838 (STB served June 23, 2000).

Transportation, Inc., wherein METRO has filed a notice of exemption under 49 CFR 1150.31 *et seq.* to acquire the rail easement from CSX Transportation, Inc. (CSXT), the current rail carrier on the line involved here. ABC will replace CSXT in providing all rail freight service on the line.

Consummation of the transaction was expected to occur on or shortly after June 20, 2003, the effective date of this exemption.

ABC certifies that the projected annual revenues as a result of the transaction will not exceed $5 million, and thus the transaction will not result in the creation of a Class II or Class I rail carrier.

If the verified notice contains false or misleading information, the exemption is void *ab initio.* Petitions to revoke the exemption under 49 U.S.C. 10502(d) may be filed at any time. The filing of a petition to revoke will not automatically stay the transaction.

An original and 10 copies of all pleadings, referring to STB Finance Docket No. 34362, must be filed with the Surface Transportation Board, 1925 K Street, NW., Washington, DC 20423–0001. In addition, a copy of each pleading must be served on William C. Sippel, Fletcher & Sippel, LLC, Two Prudential Plaza, Suite 3125, 180 North Stetson Ave., Chicago, IL 60601–6721.

Board decisions and notices are available on our Web site at *http://www.stb.dot.gov.*

Decided: July 2, 2003.

By the Board, Joseph H. Dettmar, Acting Director, Office of Proceedings.

Vernon A. Williams,

Secretary.

[FR Doc. 03–17468 Filed 7–10–03; 8:45 am]

BILLING CODE 4915–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Form 3468

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)). Currently, the IRS is soliciting comments concerning Form 3468, Investment Credit.

DATES: Written comments should be received on or before September 9, 2003 to be assured of consideration.

ADDRESSES: Direct all written comments to Glenn Kirkland, Internal Revenue Service, room 6411, 1111 Constitution Avenue, NW., Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the form and instructions should be directed to Larnice Mack at Internal Revenue Service, room 6407, 1111 Constitution Avenue, NW., Washington, DC 20224, or at (202) 622–3179, or through the Internet at *Larnice.Mack@irs.gov*.

SUPPLEMENTARY INFORMATION:

Title: Investment Credit.

OMB Number: 1545–0155.

Form Number: 3468.

Abstract: Taxpayers are allowed a credit against their income taxes for certain expenses they incur for their trades or businesses. Form 3468 is used to compute this investment tax credit. The information collected is used by the IRS to verify that the credit has been correctly computed.

Current Actions: There are no changes being made to the form at this time.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit organizations, individuals or households, farms, and not-for-profit institutions.

Estimated Number of Respondents: 22,573.

Estimated Time Per Response: 20 hours., 26 minutes.

Estimated Total Annual Burden Hours: 461,167.

The following paragraph applies to all of the collections of information covered by this notice:

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. Books or records relating to a collection of information must be retained as long as their contents may become 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.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (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; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: July 8, 2003.

Carol Savage,

Management and Program Analyst.

[FR Doc. 03–17630 Filed 7–10–03; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Form 6478

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)). Currently, the IRS is soliciting comments concerning Form 6478, Credit for Alcohol Used as Fuel.

DATES: Written comments should be received on or before September 9, 2003 to be assured of consideration.

ADDRESSES: Direct all written comments to Glenn Kirkland, Internal Revenue Service, room 6411, 1111 Constitution Avenue, NW., Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the form and instructions should be directed to Larnice Mack at Internal Revenue Service, room 6407, 1111 Constitution Avenue, NW., Washington, DC 20224, or at (202) 622–3179, or through the Internet at *Larnice.Mack@irs.gov*.

SUPPLEMENTARY INFORMATION:

Title: Credit for Alcohol Used as Fuel.

OMB Number: 1545–0231.

Form Number: 6478.

Abstract: IRC section 38(b)(3) allows a nonrefundable income tax credit for businesses that sell or use alcohol mixed with other fuels or sold as straight alcohol. Small ethanol producers are also allowed a nonrefundable credit for production of qualified ethanol. Form 6478 is used to compute the credits.

Current Actions: There are no changes being made to the form at this time.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit organizations.

Estimated Number of Respondents: 1,594.

Estimated Time Per Respondent: 13 hours.

Estimated Total Annual Burden Hours: 20,722.

The following paragraph applies to all of the collections of information covered by this notice:

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. Books or records relating to a collection of information must be retained as long as their contents may become 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.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (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; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: July 8, 2003.

Carol Savage,

Management and Program Analyst.

[FR Doc. 03–17631 Filed 7–10–03; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Open Meeting of the Area 2 Taxpayer Advocacy Panel (Including the States of Delaware, North Carolina, South Carolina, New Jersey, Maryland, Pennsylvania, Virginia and the District of Columbia)

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice.

SUMMARY: An open meeting of the Area 2 Taxpayer Advocacy Panel will be conducted (via teleconference).

DATES: The meeting will be held Tuesday, August 5, 2003.

FOR FURTHER INFORMATION CONTACT: Inez E. De Jesus at 1–888–912–1227, or 954–423–7977.

SUPPLEMENTARY INFORMATION: Notice is hereby given pursuant to section 10(a)(2) of the Federal Advisory Committee Act, 5 U.S.C. App. (1988) that an open meeting of the Area 2 Taxpayer Advocacy Panel will be held Tuesday, August 5, 2003 from 3 p.m. EDT to 4:30 p.m. EDT via a telephone conference call. The Taxpayer Advocacy Panel is soliciting public comments, ideas and suggestions on improving customer service at the Internal Revenue Service. Individual comments will be limited to 5 minutes. If you would like to have the TAP consider a written statement, please call 1–888–912–1227 or 954–423–7977, or write Inez E. De Jesus, TAP Office, 1000 South Pine Island Rd., Suite 340, Plantation, FL 33324. Due to limited conference lines, notification of intent to participate in the telephone conference call meeting must be made with Inez E. De Jesus. Ms. De Jesus can be reached at 1–888–912–1227 or 954–423–7977.

The agenda will include the following: Various IRS issues.

Note: Last minute changes to the agenda are possible and could prevent effective advance notice.

Dated: July 2, 2003.

Tersheia Carter,

Acting Director, Taxpayer Advocacy Panel.

[FR Doc. 03–17632 Filed 7–10–03; 8:45 am]

BILLING CODE 4830–01–P

Corrections

Federal Register

Vol. 68, No. 133

Friday, July 11, 2003

This section of the FEDERAL REGISTER contains editorial corrections of previously published Presidential, Rule, Proposed Rule, and Notice documents. These corrections are prepared by the Office of the Federal Register. Agency prepared corrections are issued as signed documents and appear in the appropriate document categories elsewhere in the issue.

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 9063]

RIN 1545–BB99

Distributions of Interests in a Loss Corporation From Qualified Trusts

Correction

In rule document 03–16229 beginning on page 38177 in the issue of Friday, June 27, 2003 make the following correction:

§1.382–10T [Corrected]

On page 38178, in the second column, in §1.382–10T, in amendatory instruction 3., in the first line, ''1.382.10T'' should read ''1.382–10T''.

[FR Doc. C3–16229 Filed 7–10–03; 8:45 am]

BILLING CODE 1505–01–D

Federal Register

Friday,
July 11, 2003

Part II

Department of Homeland Security

Office of the Secretary

6 CFR Part 25

Regulations Implementing the Support Anti-Terrorism by Fostering Effective Technologies Act of 2002 (the SAFETY Act); Proposed Rule

DEPARTMENT OF HOMELAND SECURITY

Office of the Secretary

6 CFR Part 25

[USCG–2003–15425]

RIN 1601–AA15

Regulations Implementing the Support Anti-Terrorism by Fostering Effective Technologies Act of 2002 (the SAFETY Act)

AGENCY: Office of the Secretary, Homeland Security.

ACTION: Notice of proposed rulemaking.

SUMMARY: This proposed rule would implement Subtitle G of Title VIII of the Homeland Security Act of 2002—the Support of Anti-terrorism by Fostering Effective Technologies Act of 2002 (''the SAFETY Act'' or ''the Act''). As discussed in detail below, the SAFETY Act, through regulations promulgated by the Department of Homeland Security (''the Department''), will provide critical incentives for the development and deployment of anti-terrorism technologies by providing liability protections for Sellers of ''qualified anti-terrorism technologies'' and others.

DATES: Comments and related material must reach the Docket Management Facility on or before August 11, 2003.

ADDRESSES: You may submit comments identified by docket number USCG–2003–15425 to the Docket Management Facility at the U.S. Department of Transportation. To avoid duplication, please use only one of the following methods:

(1) Web site: *http://dms.dot.gov.*

(2) Mail: Docket Management Facility, U.S. Department of Transportation, 400 Seventh Street SW., Washington, DC 20590–0001.

(3) Fax: 202–493–2251.

(4) Delivery: Room PL–401 on the Plaza level of the Nassif Building, 400 Seventh Street SW., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The telephone number is 202–366–9329.

(5) Federal Rulemaking Portal: *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: If you have questions on this proposed rule, call Wendy Howe, Directorate of Science and Technology, Department of Homeland Security, telephone 202–772–9887. If you have questions on viewing or submitting material to the docket, call Dorothy Beard, Chief, Dockets, Department of Transportation, telephone 202–366–5149.

SUPPLEMENTARY INFORMATION

Public Participation and Request for Comments

We encourage you to participate in this rulemaking by submitting comments and related materials. All comments received will be posted, without change, to *http://dms.dot.gov* and will include any personal information you have provided. We have an agreement with the Department of Transportation (DOT) to use the Docket Management Facility. Please see DOT's ''Privacy Act'' paragraph below.

Submitting comments: If you submit a comment, please include your name and address, identify the docket number for this rulemaking (USCG–2003–15425), indicate the specific section of this document to which each comment applies, and give the reason for each comment. You may submit your comments and material by electronic means, mail, fax, or delivery to the Docket Management Facility at the address under **ADDRESSES**; but please submit your comments and material by only one means. If you submit them by mail or delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. If you submit them by mail and would like to know that they reached the Facility, please enclose a stamped, self-addressed postcard or envelope. We will consider all comments and material received during the comment period. We may change this proposed rule in view of them.

Viewing comments and documents: To view comments, as well as documents mentioned in this preamble as being available in the docket, go to *http://dms.dot.gov* at any time and conduct a simple search using the docket number. You may also visit the Docket Management Facility in room PL–401 on the Plaza level of the Nassif Building, 400 Seventh Street SW., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

Privacy Act: Anyone can search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review the Department of Transportation's Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477), or you may visit *http://dms.dot.gov.*

Public Meeting

We do not now plan to hold a public meeting. You may, however, submit a request for one to the Docket Management Facility at the address under **ADDRESSES** explaining why one would be beneficial. If we determine that a public meeting would aid this rulemaking, we will hold one at a time and place announced by a later notice in the **Federal Register**.

Regulatory Background and Analysis

The Department intends to implement the SAFETY Act as quickly as possible. Our twin aims are these:

(1) To produce by regulation as much certainty as possible regarding the application of the liability protections created by the Act;

(2) To provide the Department with sufficient program flexibility to address the specific circumstances of each particular request for SAFETY Act coverage.

The Department does not intend to resolve every conceivable programmatic issue through this proposed rule. Instead, the Department will set out a basic set of regulations and commence the implementation of the SAFETY Act program while considering possible supplemental regulations as experience with the Act grows.

The Department invites comment on all aspects of these proposed regulations and on the policies that underlie them. The initial comment period is relatively brief (30 days) in order to permit the Department to begin implementation of this critical program as soon as possible. After reviewing the comments, the Department may issue an interim final rule and seek additional comment on some or all aspects of the program. In any event, the Department will begin implementation of the SAFETY Act immediately with regard to Federal acquisitions of anti-terrorism technologies and will begin accepting other SAFETY Act applications on September 1, 2003.

Background

As part of the Homeland Security Act of 2002, Public Law 107–296, Congress enacted several liability protections for providers of anti-terrorism technologies. The SAFETY Act provides incentives for the development and deployment of anti-terrorism technologies by creating a system of ''risk management'' and a system of ''litigation management.'' The purpose of the Act is to ensure that the threat of liability does not deter potential manufacturers or Sellers of anti-terrorism technologies from developing and commercializing technologies that could save lives. The Act thus creates certain liability limitations for ''claims arising out of, relating to, or resulting from an act of

terrorism'' where qualified anti-terrorism technologies have been deployed. The Act does not limit liability for harms caused by anti-terrorism technologies when no act of terrorism has occurred.

Together, the risk and litigation management provisions provide the following protections:

- Exclusive jurisdiction in federal court for suits against the Sellers of ''qualified anti-terrorism technologies'' (§ 863(a)(2));
- A limitation on the liability of Sellers of qualified anti-terrorism technologies to an amount of liability insurance coverage specified for each individual technology, provided that Sellers will not be required to obtain any more liability insurance coverage than is reasonably available ''at prices and terms that will not unreasonably distort the sales price'' of the technology (§ 864(a)(2));
- A prohibition on joint and several liability for noneconomic damages, so that Sellers can only be liable for that percentage of noneconomic damages proportionate to their responsibility for the harm (§ 863(b)(2));
- A complete bar on punitive damages and prejudgment interest (§ 863(b)(1));
- A reduction of plaintiffs' recovery by amounts that plaintiffs received from ''collateral sources'', such as insurance benefits or other government benefits (§ 863(c)); and
- A rebuttable presumption that the Seller is entitled to the ''government contractor defense'' (§ 863(d)).

The Act provides that these liability protections are conferred by two separate actions by the Secretary. The Secretary's designation of a technology as a ''qualified anti-terrorism technology'' confers all of the liability protections *except* the rebuttable presumption in favor of the government contractor defense. The presumption in favor of the government contractor defense requires an additional ''approval'' by the Secretary under § 863(d) of the Act. In many cases, however, the designation and the approval can be conferred simultaneously.

Analysis

This preamble to the proposed rule first addresses the two major aspects of the Act—the designation of qualified anti-terrorism technologies and the approval of technologies for purposes of the government contractor defense. Following that discussion, the preamble addresses specific issues regarding the proposed rule and the Department's interpretation of the Act.

Designation of Qualified Anti-Terrorism Technologies

As noted above, the designation of a technology as a qualified anti-terrorism technology confers all of the liability protections provided in the Act, except for the presumption in favor of the government contractor defense. The Act gives the Secretary broad discretion in determining whether to designate a particular technology as a ''qualified anti-terrorism technology,'' although the Act sets forth the following criteria that must be considered to the extent that they are applicable to the technology: (1) Prior United States Government use or demonstrated substantial utility and effectiveness; (2) availability of the technology for immediate deployment; (3) the potential liability of the Seller; (4) the likelihood that the technology will not be deployed unless the SAFETY Act protections are conferred; (5) the risk to the public if the technology is not deployed; (6) evaluation of scientific studies; and (7) the effectiveness of the technology in defending against acts of terrorism. These criteria are not exclusive—the Secretary may consider other factors that he deems appropriate. The Secretary has discretion to give greater weight to some factors over others, and the relative weighting of the various criteria may vary based upon the particular technology at issue and the threats that the technology is designed to address. The Secretary may, in his discretion, determine that failure to meet a particular criterion justifies denial of an application under the SAFETY Act. However, the Secretary is not required to reject an application that fails to meet one or more of the criteria. Rather the Secretary, after considering all of the relevant criteria, may conclude that a particular technology merits designation as a ''qualified anti-terrorism technology'' even if a particular criterion is not satisfied. The Secretary's considerations will also vary with the constantly evolving threats and conditions that give rise to the need for the technologies. The proposed rule provides for designation as a qualified anti-terrorism technology for five to eight years.

The SAFETY Act applies to a very broad range of technologies, including products, services, software, and other forms of intellectual property, as long as the Secretary, as an exercise of discretion and judgment, determines that a technology merits designation under the statutory criteria. Further, as the statutory criteria suggest, a ''qualified anti-terrorism technology'' is not necessarily required to be newly developed—it may have already been employed (*e.g.* ''prior United States government use'') or may be a new application of an existing technology.

The Act also provides that, before designating a ''qualified anti-terrorism technology,'' the Secretary will examine the amount of liability insurance the Seller of the technology proposes to maintain for coverage of the technology at issue. Under Section 864(a), the Secretary must certify that the coverage level is appropriate ''to satisfy otherwise compensable third-party claims arising out of, relating to, or resulting from an act of terrorism when qualified anti-terrorism technologies have been deployed.'' § 864(a)(1). The Act further provides that ''the Seller is not required to obtain liability insurance of more than the maximum amount of liability insurance reasonably available from private sources on the world market at prices and terms that will not unreasonably distort the sales price of Seller's anti-terrorism technologies.'' § 864(a)(2).

The Secretary does not intend to set a ''one-size-fits-all'' numerical requirement regarding required insurance coverage for all technologies. Instead, as the Act suggests, the inquiry will be specific to each application and may involve an examination of several factors, including the following: the amount of insurance the Seller has previously maintained; the amount of insurance maintained by the Seller for other technologies or for the Seller's business as a whole; the amount of insurance typically maintained by sellers of comparable technologies; data and history regarding mass casualty losses; and the particular technology at issue. The Secretary will not require insurance beyond the point at which the cost of coverage would ''unreasonably distort'' the price of the technology. Once the Secretary concludes the analysis regarding the appropriate level of insurance coverage (which might include discussions with the Seller in appropriate cases), the Secretary will identify in a short certification a description of the coverage appropriate for the particular qualified anti-terrorism technology. If, during the term of the designation, the Seller would like to request reconsideration of that insurance certification due to changed circumstances or for other reasons, the Seller may do so. If the Seller fails to maintain coverage at the certified level during that time period, the liability protections of the Act will continue to apply, but the Seller's liability limit will remain at the certified insurance level. Such failure, however, will be regarded as a negative factor in the consideration

of any future application by the Seller for renewal of the applicable designation, and perhaps in any other application by the Seller.

The Department solicits comment on the designation of qualified anti-terrorism technologies, including whether the five to eight year period is an appropriate length of time for such a designation.

Government Contractor Defense

The Act creates a rebuttable presumption that the government contractor defense applies to qualified anti-terrorism technologies ''approved by the Secretary'' in accordance with certain criteria specified in § 863(d)(2). The government contractor defense is an affirmative defense that immunizes Sellers from liability for certain claims brought under § 863(a) of the Act. *See* § 863(d)(1). The presumption of this defense applies to all ''approved'' qualified anti-terrorism technologies for claims brought in a ''product liability or other lawsuit'' and ''arising out of, relating to, or resulting from an act of terrorism when qualified anti-terrorism technologies . . . have been deployed in defense against or response or recovery from such act and such claims result or may result in loss to the Seller.'' *Id.* While the government contractor defense is a judicially-created doctrine, Section 863's express terms supplant many of the requirements in the case law for application of the defense.

First, and most obviously, the Act expressly provides that the government contractor defense is available not only to government contractors, but also to those who sell to state and local governments and the private sector. *See* § 863(d)(1) (''This presumption of the government contractor defense shall apply regardless of whether the claim against the Seller arises from a sale of the product to Federal Government or non-Federal Government customers.'').

Second, Sellers of qualified anti-terrorism technologies need not design their technologies to federal government specifications in order to obtain the government contractor defense under the SAFETY Act. Instead, the Act sets forth criteria for the Department's ''approval'' of technologies. Specifically, the Act provides that during the process of approval for the government contractor defense the Secretary will conduct a ''comprehensive review of the design of such technology and determine whether it will perform as intended, conforms to the Seller's specifications, and is safe for use as intended.'' § 863(d)(2). The Act also provides that the Seller will ''conduct safety and hazard analyses'' and supply such information to the Secretary. *Id.* This express statutory framework thus governs in lieu of the requirements developed in case law for the application of the government contractor defense.

Third, the Act expressly states the limited circumstances in which the applicability of the defense can be rebutted. The Act provides expressly that the presumption can be overcome *only* by evidence showing that the Seller acted fraudulently or with willful misconduct in submitting information to the Secretary during the course of the Secretary's consideration of such technology. *See* § 863(d)(1) (''This presumption shall only be overcome by evidence showing that the Seller acted fraudulently or with willful misconduct in submitting information to the Secretary during the course of the Secretary's consideration of such technology under this subsection.'').

The applicability of the government contractor defense to particular technologies is thus governed by these express provisions of the Act, rather than by the judicially-developed criteria for applicability of the government contractor defense outside the context of the SAFETY Act.

While the Act does not expressly delineate the scope of the defense (*i.e.*, the types of claims that the defense bars), the Act and the legislative history make clear that the scope is broad. For example, it is clear that any Seller of an ''approved'' technology cannot be held liable under the Act for design defects or failure to warn claims, unless the presumption of the defense is rebutted by evidence that the Seller acted fraudulently or with willful misconduct in submitting information to the Secretary during the course of the Secretary's consideration of such technology.

The government contractor defense under *Boyle* and its progeny bars a broad range of claims. The Supreme Court in *Boyle* concluded that ''state law which holds Government contractors liable for design defects'' can present a significant conflict with federal policy (including the discretionary function exception to the Federal Tort Claims Act) and therefore ''must be displaced.'' *Boyle* v. *United Technologies Corp.,* 487 U.S. 500, 512 (1988). The Department believes that Congress incorporated the Supreme Court's *Boyle* line of cases as it existed on the date of enactment of the SAFETY Act, rather than incorporating future developments of the government contractor defense in the courts. Indeed, it is hard to imagine that Congress would have intended a statute designed to provide certainty and protection to Sellers of anti-terrorism technologies to be subject to future developments of a judicially-created doctrine. In fact, there is evidence that Congress rejected such a construction. *See, e.g.*, 148 Cong. Rec. E2080 (November 13, 2001) (statement of Rep. Armey) (''[Companies] will have a government contractor defense as is commonplace *in existing law.*'') (emphasis added).

Procedurally, the presumption of applicability of the government contractor defense is conferred by the Secretary's ''approval'' of a qualified anti-terrorism technology specifically for the purposes of the government contractor defense. This approval is a separate act from the Secretary's ''designation'' of a qualified anti-terrorism technology. Importantly, the Seller may submit applications for both designation as a qualified anti-terrorism technology and approval for purposes of the government contractor defense at the same time, and the Secretary may review and act upon both applications simultaneously. The distinction between the Secretary's two actions is important, however, because the approval process for the government contractor defense includes a level of review that is not required for the designation of a qualified anti-terrorism technology. Specifically, the Act provides that during the process of approval for the government contractor defense the Secretary will conduct a ''comprehensive review of the design of such technology and determine whether it will perform as intended, conforms to the Seller's specifications, and is safe for use as intended.'' § 863(d)(2). The Department believes that certain Sellers will be able to obtain the protections that come with designation as a qualified anti-terrorism technology even if they have not satisfied the requirements for the government contractor defense. Similarly, even if the applicability of the government contractor defense were rebutted under the test set forth in Section 863(d)(1) of the Act, the technology may still retain the designation and protections as a qualified anti-terrorism technology. Fraud or willful misconduct in the submission of information to the Department in connection with an application under the Act may result not only in rebuttal of the presumed application of the government contractor defense, but may also prompt the Department to refer the matter to the Department of Justice for pursuit of criminal or civil penalties.

The Department invites comment regarding the government contractor defense.

Specific Issues Regarding the Act and This Rule

1. *Definition of Anti-Terrorism Technologies.* The Department recognizes that the universe of technologies that can be deployed against terrorism includes far more than physical products. Rather, the defense of the homeland will require deployment of a broad range of technologies that includes services, software, and other forms of intellectual property. Thus, consistent with Section 865 of the Act, Section 25.3(a) of the proposed rule defines qualified anti-terrorism technologies very broadly to include ''any qualifying product, equipment, service (including support services), device, or technology (including information technology)'' that the Secretary, as an exercise of discretion and judgment, determines to merit designation under the statutory criteria.

2. *Development of New Technologies.* The Act's success depends not only upon encouraging Sellers to provide existing anti-terrorism technologies, but also upon encouraging Sellers to develop new and innovative technologies to respond to the ever-changing threats to the American people. The proposed rule is thus designed to allow the Department to assist would-be Sellers during the invention, design, and manufacturing phases in two important respects. First, Section 25.3(h) of the proposal makes clear that the Department, within its discretion and where feasible, may provide feedback to manufacturers regarding whether proposed or developing anti-terrorism technologies might meet the qualification factors under the Act. To be sure, the Department cannot provide advance designation, as some of the factors for the Secretary's consideration cannot be addressed in advance. The Department may, however, provide feedback regarding other factors, with the goal of giving potential Sellers some understanding of whether it might be advantageous to proceed with further development of the technology. Departmental feedback at the design, prototyping, or testing stage of development, to the extent feasible, may provide manufacturers with added incentive to commence and/or complete production of cutting-edge anti-terrorism technology that otherwise might not be produced or deployed in the absence of the risk and litigation management protections in the Act. The Department will perform these consultations with potential Sellers in a manner consistent with the protection of intellectual property and trade secrets, as discussed below.

Second, Section 25.3(g) of the proposal recognizes that Federal agencies will often be the purchasers of anti-terrorism technologies. The Department recognizes that terms on which Sellers are able to provide anti-terrorism technologies to Federal agencies may vary depending on whether the technologies receive SAFETY Act coverage or not. The proposal thus provides that the Department may coordinate SAFETY Act reviews with agency procurements. The Department also intends to review SAFETY Act applications relating to technologies that are the subject of agency procurements on an expedited basis.

The Department requests public comments regarding the best way for the Department to provide feedback to potential Sellers regarding SAFETY Act coverage and the best way for the Department to coordinate SAFETY Act review with agency procurements.

3. *Protection of Intellectual Property and Trade Secrets.* The Department believes that successful implementation of the Act requires that applicants' intellectual property interests and trade secrets remain protected in the application process and beyond. Toward that end, the Department will create an application and review process in which the Department maintains the confidentiality of an applicant's proprietary information. The Department notes that laws mandating disclosure of information submitted to the government generally contain exclusions or exceptions for such information. The Freedom of Information Act, for instance, provides specific exceptions for proprietary information submitted to Federal agencies. The Department seeks further input on this issue.

4. *Evaluation of Scientific Studies; Consultation with Scientific and Technical Experts.* Section 862(b)(6) of the Act provides that, as one of many factors in determining whether to designate a particular technology under the Act, the Secretary shall consider evaluation of all scientific studies ''that can be feasibly conducted'' in order to assess the capability of the technology to substantially reduce the risks of harm. An important part of this provision is that it contemplates review only of such studies as can ''feasibly'' be conducted. The Department believes that the need to protect the American public by facilitating the manufacture and marketing of anti-terrorism technologies might render it infeasible to defer a designation decision until after every conceivable scientific study is completed. In many cases, existing information (whether based on scientific studies, experience with the technology or a related technology, or other factors) might enable the Secretary to perform an appropriate assessment of the capability of the technology to reduce risks of harm. In other cases, even where less information is available about the capability of a technology to reduce risks of harm, the public interest in making the technology available as soon as practicable may render it infeasible to await the conduct of further scientific studies on that issue. In considering whether or to what extent it is feasible to defer a designation decision until additional scientific studies can be conducted, the Department will bring to bear its expertise concerning the protection of the American homeland and will consider the urgency of the need for the technology and other relevant factors and circumstances. The Department invites comment on how the Department should determine what scientific studies ''can be feasibly conducted.''

5. *''Exclusive Federal Jurisdiction'' and ''Scope'' of Insurance Coverage under § 864(a)(3).* The Act creates an exclusive Federal cause of action ''for any claim for loss of property, personal injury, or death arising out of, relating to, or resulting from an act of terrorism when qualified anti-terrorism technologies have been deployed in defense against or response or recovery from such act and such claims result or may result in loss to the Seller.'' § 863(a)(2); *see also* § 863(a)(1). This exclusive ''Federal cause of action shall be brought only for claims for injuries that are proximately caused by sellers that provide qualified anti-terrorism technology.'' § 863(a)(1). The best reading of § 863(a), and the reading the Department is inclined to adopt, is that (1) only one Federal cause of action exists for loss of property, personal injury, or death when a claim relates to performance or non-performance of the Seller's qualified and deployed anti-terrorism technology, and (2) such cause of action may be brought *only against the Seller.*

The exclusive Federal nature of this cause of action is evidenced in large part by the exclusive jurisdiction provision in § 863(a)(2). That subsection states: ''Such appropriate district court of the United States shall have original and exclusive jurisdiction over all actions for any claim for loss of property, personal injury, or death arising out of, relating to, or resulting from an act of terrorism when qualified anti-terrorism technologies have been

deployed in defense against or response or recovery from such act and such claims result or may result in loss to the Seller.'' *Id.* Any presumption of concurrent causes of action (between State and Federal law) is overcome by two basic points. First, Congress would not have created in this Act a Federal cause of action to complement State law causes of action. Not only is the substantive law for decision in the Federal action derived from State law (and thus would be surplusage), but in creating the Act Congress plainly intended to limit rather than increase the liability exposure of Sellers. Second, the granting of exclusive jurisdiction to the Federal district courts provides further evidence that Congress wanted an exclusive Federal cause of action. Indeed, a Federal district court (in the absence of diversity) does not have jurisdiction over state law claims, and the statute makes no mention of diversity claims anywhere in the Act.

Further, it is clear that the Seller is the only appropriate defendant in this exclusive Federal cause of action. First and foremost, the Act unequivocally states that a ''cause of action shall be brought only for claims for injuries that are *proximately caused by sellers* that provide qualified anti-terrorism technology.'' § 863(a)(1) (emphasis added). Second, if the Seller of the qualified anti-terrorism technology at issue was not the only defendant, would-be plaintiffs could, in an effort to circumvent the statute, bring claims (arising out of or relating to the performance or non-performance of the Seller's qualified anti-terrorism technology) against arguably less culpable persons or entities, including but not limited to contractors, subcontractors, suppliers, vendors, and customers of the Seller of the technology. Because the claims in the cause of action would be predicated on the performance or non-performance of the Seller's qualified anti-terrorism technology, those persons or entities, in turn, would file a third-party action against the Seller. In such situations, the claims against non-Sellers thus ''may result in loss to the Seller'' under § 863(a)(2). The Department believes Congress did not intend through the Act to increase rather than decrease the amount of litigation arising out of or related to the deployment of qualified anti-terrorism technology. Rather, Congress balanced the need to provide recovery to plaintiffs against the need to ensure adequate deployment of anti-terrorism technologies by creating a cause of action that provides a certain level of recovery against Sellers, while at the same time protecting others in the supply chain.

The scope of federal preemption of state laws is highly relevant to the Department's implementation of the Act, as the Department will have to determine the amount of insurance that Sellers must obtain. Accordingly, the Department seeks comment on that matter.

6. *Amount of Insurance.* The Act requires that Sellers obtain liability insurance ''of such types and in such amounts'' certified by the Secretary ''to satisfy otherwise compensable third-party claims arising out of, relating to, or resulting from an act of terrorism when qualified anti-terrorism technologies have been deployed.'' § 864(a)(1). However, the Act makes clear that Sellers are *not* required to obtain liability insurance beyond ''the maximum amount of liability insurance reasonably available from private sources on the world market at prices and terms that will not unreasonably distort the sales price of Seller's anti-terrorism technologies.'' § 864(a)(2).

As explained above, the Department eschews any ''one-size-fits-all'' approach to the insurance coverage requirement. Instead, the Department construes the Act as contemplating the examination of several factors. Section 25.4(b) of the proposed rule therefore sets forth a nonexclusive list of several factors that the Department may consider. These include the amount of insurance the Seller has previously maintained; the amount of insurance maintained by the Seller for other technologies or for the Seller's business as a whole; the amount of insurance typically maintained by sellers of comparable technologies; data and history regarding mass casualty losses; information regarding the amount of liability insurance offered on the world market; the particular technology at issue and its intended use; and the point at which the cost of coverage would ''unreasonably distort'' the price of the technology.

In the course of determining the amount of insurance required under the Act for a particular technology, the Department may consult with the Seller, the Seller's insurer, and others. While the decision regarding the amount of insurance required will generally be specific to each Seller or each technology, the Department recognizes that the incentive-based purposes of the Act may be furthered if the Department provides information to potential Sellers regarding the types and amounts of insurance that they will likely be required to obtain. Thus the Secretary may, where appropriate, give guidance to potential Sellers regarding the type and amounts of insurance that may be sufficient under the Act for particular technologies or categories of technologies.

The Department also recognizes that the amount of insurance available at prices that will not unreasonably distort the price of the anti-terrorism technology may vary over time. Thus, the proposed rule is written to give the Department flexibility to address fluctuating insurance prices by providing that, during the term of the designation, the Seller may request reconsideration of the insurance certification due to changed circumstances or other reasons.

The Proposed Rule provides that the Seller shall certify on an annual basis that the Seller has maintained the insurance required by the Under Secretary's certification. It further provides that the Under Secretary may terminate the designation as a qualified anti-terrorism technology if the Seller fails to provide the certification or provides a false certification. Termination of the designation would mean that the Seller would not be able to sell the technology as a qualified anti-terrorism technology after the date of the termination. The Seller's failure to maintain the insurance also may adversely affect the Seller's ability to obtain a renewal of the designation for the technology, and may even adversely affect the Seller's ability to obtain future designations of ''qualified anti-terrorism technologies.'' Finally, a false certification may result in criminal or other penalties under existing laws.

The liability protections of the Act will continue to apply to technologies sold while the SAFETY Act designation was effective, regardless of whether the seller maintains the required insurance. This is necessary because the SAFETY Act protects not only the Seller, but also others in the supply chain. For example, a buyer who purchases the technology while the SAFETY Act designation is still in effect should not be punished for the Seller's failure to maintain the insurance. The Seller, however, will face potential uninsured liability, because the Seller's liability limit will remain at the certified insurance level. This is because subsection (c) of Section 864 makes clear that the Seller's liability is capped at the amount of insurance ''*required*'' to be maintained under Section 864, rather than the amount of coverage actually obtained. The limitation of liability thus relates entirely to the amount of insurance required and makes no reference to whether such insurance is, in fact, maintained by the Seller.

The Department, as part of each certification, will specify the Seller or Sellers of the anti-terrorism technology for purposes of SAFETY Act coverage. The Department may, but need not, specify in the certification the others who are covered by the liability insurance required to be purchased by the Seller.

The Department invites comment regarding the appropriate interpretation of ''prices and terms that will not unreasonably distort sales prices,'' the factors that the Department should consider in determining the appropriate amount of insurance, and the relevance of any other provisions of law, such as the Terrorism Risk Insurance Act of 2002 (''TRIA'').

7. *Use of Standards.* Section 25.3(c) of the proposed rule provides that the Under Secretary may issue safety and effectiveness standards for categories of anti-terrorism technologies, and that the Under Secretary may consider compliance with any such applicable standards in determining whether to grant a designation under the Act. The Department seeks comment on how the Department can best develop standards and implement the SAFETY Act provisions to provide the appropriate market and industry incentives for the development and deployment of anti-terrorism technologies.

8. *Relationship of the SAFETY Act to Indemnification under Public Law 85–804.* The Department recognizes that Congress intended that the SAFETY Act's liability protections would substantially reduce the need for the United States to provide indemnification under Public Law 85–804 to Sellers of anti-terrorism technologies. The strong liability protections of the SAFETY Act should, in most circumstances, make it unnecessary to provide indemnification to Sellers. The Department recognizes, however, that there might be, in some limited circumstances, technologies or services with respect to which both SAFETY Act coverage and indemnification might be warranted. *See* 148 Cong. Rec. E2080 (statement by Rep. Armey) (November 13, 2002) (stating that in some situations the SAFETY Act protections will ''complement other government risk-sharing measures that some contractors can use such as Public Law 85–804'').

In recognition of this close relationship between the SAFETY Act and indemnification authority, in Section 73 of Executive Order 13286 of February 28, 2003, the President recently amended the existing Executive Order on indemnification—Executive Order 10789 of November 14, 1958, as amended. The amendment granted the Department of Homeland Security authority to indemnify under Public Law 85–804. At the same time, it requires that *all* agencies—not just the Department of Homeland Security—follow certain procedures to ensure that the potential applicability of the SAFETY Act is considered before any indemnification is granted for an anti-terrorism technology. Specifically, the amendment provides that federal agencies cannot provide indemnification ''with respect to any matter that has been, or could be, designated by the Secretary of Homeland Security as a qualified anti-terrorism technology'' unless the Secretary of Homeland Security has advised whether SAFETY Act coverage would be appropriate and the Director of the Office of Management and Budget has approved the exercise of indemnification authority. The amendment includes an exception for the Department of Defense where the Secretary of Defense has determined that indemnification is ''necessary for the timely and effective conduct of United States military or intelligence activities.''

Application of Various Laws and Executive Orders to This Rulemaking

Executive Order 12866—Regulatory Planning and Review

The Department has examined the economic implications of this proposed rule as required by Executive Order 12866. Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). Executive Order 12866 classifies a rule as significant if it meets any one of a number of specified conditions, including: Having an annual effect on the economy of $100 million, adversely affecting a sector of the economy in a material way, adversely affecting competition, or adversely affecting jobs. A regulation is also considered a significant regulatory action if it raises novel legal or policy issues.

The Department concludes that this proposed rule is a significant regulatory action under the Executive Order because it will have a positive, material effect on public safety under Section 3(f)(1), and it raises novel legal and policy issues under Section 3(f)(4). The Department tentatively concludes, however, that this proposed rule does not meet the significance threshold of $100 million effect on the economy in any one year under Section 3(f)(1), due to the relatively low estimated burden of applying for this technology program, the unknown number of certifications and designations that the Department will dispense, and the unknown probability of a terrorist attack that would have to occur in order for the protections put in place in this proposed rule to have a large impact on the public. The Department requests comments regarding this determination, and invites commenters to submit any relevant data that will assist the agency in estimating the impact of this rule.

Need for the Regulation and Market Failure

This regulation implements the SAFETY Act and is intended to implement the provisions set forth in that Act. The Department believes the current development of anti-terrorism technologies has been slowed due to the potential liability risks associated with their development and eventual deployment. In a fully functioning insurance market, technology developers would be able to insure themselves against excessive liability risk; however, the terrorism risk insurance market appears to be in disequilibrium. The attacks of September 11 fundamentally changed the landscape of terrorism insurance. Congress, in the findings of TRIA, concluded that temporary financial assistance in the insurance market is needed to ''allow for a transitional period for the private markets to stabilize, resume pricing of such insurance, and build capacity to absorb any future losses.'' TRIA § 101(b)(2). This rulemaking addresses a similar concern, to the extent that potential technology developers are unable to efficiently insure against large losses due to an ongoing reassessment of terrorism issues in insurance markets.

Even after a temporary insurance market adjustment, purely private terrorism risk insurance markets may exhibit negative externalities. Because the risk pool of any single insurer may not be large enough to efficiently spread and therefore insure against the risk of damages from a terrorist attack, and because the potential for excessive liability may render any terrorism insurance prohibitively expensive, society may suffer from less than optimal technological protection against terrorist attacks. The measures set forth in this proposed rule are designed to meet this goal; they will provide certain liability protection from lawsuits and consequently will increase the

likelihood that businesses will pursue important technologies that may not be pursued without this protection.

Costs and Benefits to Technology Development Firms

Since this rulemaking puts in place an additional voluntary option for technology developers, the expected direct net benefits to firms of this rulemaking will be positive; companies presumably will not choose to pursue the designation of ''anti-terrorism technology'' unless they believe it to be a profitable endeavor. The Department cannot predict with certainty the number of applicants for this program. An additional source of uncertainty is the reaction of the insurance market to this designation. As mentioned above, insurance markets appear to currently be adjusting their strategy for terrorism risk, so little market information exists that would inform this estimate. The Department invites comments on these issues.

If a firm chooses to invest effort in pursuing SAFETY Act liability protection, the direct costs to that firm will be the time and money required to submit the required paperwork and other information to the Department. Only companies that choose to request this protection will incur costs. In the preliminary Paperwork Reduction Act analysis, we estimate the reporting burden assuming that each applicant will spend at least 40 hours, and perhaps 200 hours, to prepare the information required by the Department for consideration. For the purposes of this analysis, we assume a loaded labor rate of the personnel preparing the information package of $100 per hour. Consequently, the total cost of the application requirements is estimated to be at least $4,000 per application for a relatively simple application. The Department does not yet have sufficient information to estimate the number of applicants annually. If we assume 1,000 applications annually, the total cost of the application requirement is estimated to range from $4,000,000 to $20,000,000 annually (1,000 applicants $\times$ 40 to 200 hours $\times$ $100 per hour). The regulation further requires that firms conduct safety, effectiveness, utility, and hazard analyses and provide them to the Secretary in the course of applying for this designation. We do not have quantified estimates of the impact of this provision, but we expect that much of the safety, effectiveness, utility, and hazard analysis activity will already take place in the normal course of technology development, since those matters are fundamental characteristics of a product. The Department acknowledges considerable uncertainty in these estimates, but even if the estimates were considerably higher, this does not represent a large investment by firms relative to overall development costs.

The direct benefits to firms include lower potential losses from liability for terrorist attacks, and as a consequence a lower burden from liability insurance for this type of technology. In this assessment, we were careful to only consider benefits and costs specifically due to the proposed rulemaking and not costs that would have been incurred by companies absent the proposed rulemaking. The SAFETY Act requires the sellers of the technology to obtain liability insurance ''of such types and in such amounts'' certified by the Secretary. The entire cost of insurance is not a cost specifically imposed by the proposed rulemaking, as companies in the course of good business practice routinely purchase insurance absent Federal requirements to do so. Any difference in the amount or price of insurance purchased as a result of the SAFETY Act would be a cost or benefit of this rule for firms.

The wording of the SAFETY Act clearly states that sellers are not required to obtain liability insurance beyond the maximum amount of liability insurance reasonably available from private liability sources on the world market at prices and terms that will not unreasonably distort the sales price of the seller's anti-terrorism technologies. We tentatively conclude, however, that this rulemaking will impact both the prices and terms of liability insurance relative to the amount of insurance coverage absent the SAFETY Act. The probable effect of this rule is to lower the quantity of liability coverage needed in order for a firm to protect itself from terrorism liability risks, which would be considered a benefit of this rule to firms. This change will most likely be a shift back in demand that leads to a movement along the supply curve for technology firms already in this market; they probably will buy less liability coverage. This will have the effect of lowering the price per unit of coverage in this market.

The Department also expects, however, that this rulemaking will lead to greater market entry, which will generate surplus for both technology firms and insurers. Again, this market is still in development, and the Department solicits comments on exactly how to predict the effect of this rulemaking on technology development.

Costs and Benefits to Insurers

The Department has little information on the future structure of the terrorism risk insurance market, and how this rulemaking will affect that structure. As stated above, this type of intervention could serve to lower the demand for insurance in the current market, thus the static effect on the profitability of insurers is negative. The benefits of the lower insurance burden to technology firms would be considered a cost to insurers; the static changes to insurance coverage would cause a transfer from insurers to technology firms. On the other hand, this type of intervention should serve to increase the surplus of insurers by making some types of insurance products possible that would have been prohibitive to customers or impossible for insurers to design in the absence of this rulemaking. The Department is interested in public comment on any possible negative or positive impacts to insurers caused by the SAFETY Act and this rulemaking, and whether these impacts would result in transfers within this market or an efficiency change not captured by another party. We encourage commenters to be as specific as possible.

Costs and Benefits to the Public

The benefits to the public of this proposed rulemaking are very difficult to put in dollar value terms since its ultimate objective is the development of new technologies that will help prevent or limit the damage from terrorist attacks. It is not possible to even determine whether these technologies could help prevent large or small scale attacks, as the SAFETY Act applies to a vast range of technologies, including products, services, software, and other forms of intellectual property that could have a widespread impact. In qualitative terms, the SAFETY Act removes a great deal of the risk and uncertainty associated with product liability and in the process creates a powerful incentive that will help fuel the development of critically needed anti-terrorism technologies. Additionally, we expect the SAFETY Act to reduce the research and development costs of these technologies.

The tradeoff, however, may be that a greater number of technologies may be developed and qualify for this program that have a lower average effectiveness against terrorist attacks than technologies currently on the market, or technologies that would be developed in the absence of this rulemaking. The reason for that tradeoff is that, in the absence of this rulemaking, potential

liability might discourage the deployment of anti-terrorism technologies designed to address the most likely and catastrophic scenarios, because profit-maximizing firms will always choose to develop the technologies with the highest demand first. It is the tentative conclusion of the Department that liability discouragement in this market is too strong or prohibitive, for the reasons mentioned above. The Department tentatively concludes that this rule will have positive net benefits to the public, since it serves to strike a better balance between consumer protection and technological development. The Department welcomes comments informing this tradeoff argument, and public input on whether this rulemaking does strike the correct balance.

Regulatory Flexibility Act

The Regulatory Flexibility Act requires the Department to determine whether this proposed rulemaking will have a significant impact on a substantial number of small entities. Although we expect that many of the applicants for SAFETY Act protection are likely to meet the Small Business Administration's criteria for being a small entity, we do not believe this proposed rulemaking will impose a significant financial impact on them. In fact, we believe this proposed rule will be a benefit to technology development businesses, especially small businesses, by presenting them with an attractive, voluntary option of pursuing a potentially profitable investment by reducing the amount of risk and uncertainty of lawsuits associated with developing anti-terrorist technology. The requirements of this proposed rulemaking will only be imposed on such businesses that *voluntarily* seek the liability protection of the SAFETY Act. If a company does not request that protection, the company will bear no cost.

To the extent that demand for insurance falls, however, insurers may be adversely impacted by this rule. The Department believes that eventual new entry into this market and further opportunities to insure against terrorism risk implies that the long-term impact of this rulemaking on insurers is ambiguous but could very well be positive. We also expect that this rulemaking will affect relatively few firms and relatively few insurers either positively or negatively, as this appears to be a specialized industry. Therefore, we preliminarily certify this notice of proposed rulemaking will not have a significant impact on a substantial number of small entities, and we request comments on this certification.

Unfunded Mandates Reform Act of 1995

This rule will not result in the expenditure by State, local and tribal governments, in the aggregate, or by the private sector, of $100 million or more in any one year, and it will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

Paperwork Reduction Act of 1995

The Department will submit the following information collection request to the Office of Management and Budget (OMB) for review in accordance with procedures of the Paperwork Reduction Act of 1995. The proposed information collection will be published to obtain comments from the public and affected agencies.

The Department will request comments on at least the following four points:

(1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

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

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

Overview of This Information Collection

(1) *Type of Information Collection:* New Collection.

(2) *Title of the Form/Collection:* Application for Designation of Qualified Anti-terrorism Technology; Application for Certification as an Approved Product for Homeland Security.

(3) *Agency form numbers and applicable component sponsoring the collection: Form Numbers:* SAFETY–001, SAFETY–002, Directorate of Science and Technology, Department of Homeland Security.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:* Primary: Sellers and potential Sellers of qualified anti-terrorism technology. Abstract: The Application Form for Designation and/or Approval of Qualified Anti-terrorism Technology will be used to provide information to the Under Secretary for Science and Technology of the Department of Homeland Security in determining whether Sellers qualify for risk and litigation management protections under the SAFETY Act.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* 1,000 applicants annually. 40 to 200 hours per application.

(6) *An estimate of the total public burden (in hours) associated with the collection:* 40,000 to 200,000 hours.

If additional information is required, contact: Directorate of Science and Technology, SAFETY Act/room 4320, Department of Homeland Security, Washington, DC 20528.

Small Business Regulatory Fairness Act of 1996

As noted above, the Department has tentatively determined that this proposed rule would not qualify as a ''major rule'' as defined by section 804 of the Small Business and Regulatory Enforcement Act of 1996.

Executive Order 13132—Federalism

The Department of Homeland Security does not believe this proposed rule will have substantial direct effects on the States, on the relationship between the national government and the States, or on distribution of power and responsibilities among the various levels of government. States will, however, benefit from this rule to the extent that they are purchasers of qualified anti-terrorism technologies. The Department requests comment on the federalism impact of this Rule. In particular, the Department seeks comment on whether this proposed rule will raise significant federalism implications and, if so, what is the nature of those implications.

List of Subjects in 6 CFR Part 25

Administrative practice and procedure, Business and industry, Insurance, Science and technology, Security measures.

For the reasons discussed in the preamble, 6 CFR Chapter I is proposed to be amended by adding part 25 to read as follows:

PART 25—REGULATIONS TO SUPPORT ANTI-TERRORISM BY FOSTERING EFFECTIVE TECHNOLOGIES

Sec.

25.1 Purpose.
25.2 Delegation.

25.3 Designation of qualified anti-terrorism technologies.
25.4 Obligations of seller.
25.5 Procedures for designation of qualified anti-terrorism technologies.
25.6 Government contractor defense.
25.7 Procedures for certification of approved products for Homeland Security.
25.8 Confidentiality and protection of intellectual property.
25.9 Definitions.

Authority: Subtitle G of Title VIII of Pub. L. 107–296, 116 Stat. 2238 (6 U.S.C. 441–444).

§ 25.1 Purpose.

This part implements the Support Anti-terrorism by Fostering Effective Technologies Act of 2002, Subtitle G of Title VIII of Public Law 107–296 (''the SAFETY Act'' or ''the Act'').

§ 25.2 Delegation.

All of the Secretary's responsibilities, powers, and functions under the SAFETY Act may be exercised by the Under Secretary for Science and Technology of the Department of Homeland Security (''the Under Secretary'') or the Under Secretary's designees.

§ 25.3 Designation of qualified anti-terrorism technologies.

(a) *General.* The Under Secretary may designate as a qualified anti-terrorism technology for purposes of protections set forth in Subtitle G of Title VIII of Public Law 107–296 any qualifying product, equipment, service (including support services), device, or technology (including information technology) designed, developed, modified, or procured for the specific purpose of preventing, detecting, identifying, or deterring acts of terrorism or limiting the harm such acts might otherwise cause.

(b) *Criteria to be considered.* In determining whether to grant the designation under paragraph (a) of this section (a ''Designation''), the Under Secretary may exercise discretion and judgment in interpreting and weighting the various criteria in each case in determining whether to grant a Designation:

(1) Prior United States Government use or demonstrated substantial utility and effectiveness.

(2) Availability of the technology for immediate deployment in public and private settings.

(3) Existence of extraordinarily large or extraordinarily unquantifiable potential third party liability risk exposure to the Seller or other provider of such anti-terrorism technology.

(4) Substantial likelihood that such anti-terrorism technology will not be deployed unless protections under the system of risk management provided under Subtitle G of Title VIII of Public Law 107–296 are extended.

(5) Magnitude of risk exposure to the public if such anti-terrorism technology is not deployed.

(6) Evaluation of all scientific studies that can be feasibly conducted in order to assess the capability of the technology to substantially reduce risks of harm.

(7) Anti-terrorism technology that would be effective in facilitating the defense against acts of terrorism, including technologies that prevent, defeat or respond to such acts.

(8) Any other factor that the Under Secretary may consider to be relevant to the determination or to the homeland security of the United States.

(c) *Use of standards.* From time to time the Under Secretary may develop, issue, revise, and adopt safety and effectiveness standards for various categories of anti-terrorism technologies. Such standards will be published by the Department at *http://www.dhs.gov,* and copies may also be obtained by mail by sending a request to: Directorate of Science and Technology, SAFETY Act/ room 4320, Department of Homeland Security, Washington, DC 20528. Compliance with any such standards that are applicable to a particular anti-terrorism technology may be considered before any Designation will be granted for such technology under paragraph (a) of this section; in such cases, the Under Secretary may consider test results produced by an independent laboratory or other entity engaged to test or verify the safety, utility, performance, or effectiveness of such technology.

(d) *Consideration of substantial equivalence.* In determining whether a particular technology satisfies the criteria in paragraph (b) of this section and complies with any applicable standards referenced in paragraph (c) of this section, the Under Secretary may take into consideration evidence that the technology is substantially equivalent to other, similar technologies (''predicate technologies'') that have been previously designated as ''qualified anti-terrorism technologies'' under the SAFETY Act. A technology may be deemed to be substantially equivalent to a predicate technology if:

(1) It has the same intended use as the predicate technology; and

(2) It has the same or substantially similar technological characteristics as the predicate technology.

(e) *Duration and depth of review.* Recognizing the urgency of certain security measures, the Under Secretary will make a judgment regarding the duration and depth of review appropriate for a particular technology. This review will include submissions by the applicant for SAFETY Act coverage, along with information that the Under Secretary can feasibly gather from other sources. For technologies with which the Federal Government or other governmental entity already has substantial experience or data (through the procurement process or through prior use or review), the review may rely in part upon that prior experience and, thus, may be expedited. The Under Secretary may consider any scientific studies, testing, field studies, or other experience with the technology that he deems appropriate and that are available or can be feasibly conducted or obtained in order to assess the capability of the technology to substantially reduce risks of harm. Such studies may, in the Under Secretary's discretion, include:

(1) Public source studies;

(2) Classified and otherwise confidential studies;

(3) Studies, tests, or other performance records or data provided by or available to the producer of the specific technology; and

(4) Proprietary studies that are available to the Under Secretary.

In considering whether or the extent to which it is feasible to defer a decision on a Designation until additional scientific studies can be conducted on a particular technology, the Under Secretary will bring to bear his or her expertise concerning the protection of the security of the American homeland and will consider the urgency of the need for the technology.

(f) *Content of designation.* A Designation shall specify the technology and the Seller(s) of the technology. The Designation may, but need not, also specify others who are required to be covered by the liability insurance required to be purchased by the Seller. The Designation shall include the Under Secretary's certification required by § 25.4(h). The Designation may also include such other specifications as the Under Secretary may deem to be appropriate. Failure to specify a covered person or entity in a Designation will not preclude application of the Act's protections to that person or entity.

(g) *Government procurements.* The Under Secretary may coordinate a SAFETY Act review in connection with an agency procurement of an anti-terrorism technology in any manner he or she deems appropriate and consistent with the Act and other applicable laws.

(h) *Pre-application consultations.* To the extent that he or she deems it appropriate, the Under Secretary may consult with potential SAFETY Act

applicants regarding the need for or advisability of particular types of anti-terrorism technologies, although no pre-approval of any particular technology may be given. The confidentiality provisions in § 25.8 shall be applicable to such consultations.

§ 25.4 Obligations of seller.

(a) *Liability insurance required.* Any person or entity that sells or otherwise provides a qualified anti-terrorism technology to Federal and non-Federal Government customers shall obtain liability insurance of such types and in such amounts as shall be required in accordance with this section and certified by the Under Secretary to satisfy otherwise compensable third-party claims arising out of, relating to, or resulting from an act of terrorism when qualified anti-terrorism technologies have been deployed in defense against, response to, or recovery from, such act. The Under Secretary may request at any time (before or after the certification process established under this section) that the Seller or any other provider of qualified anti-terrorism technology submit any information that would:

(1) Assist in determining the amount of liability insurance required; or

(2) Show that the Seller or any other provider of qualified anti-terrorism technology otherwise has met all the requirements of this section.

(b) *Maximum amount.* For the total claims related to one such act of terrorism, the Seller will not be required to obtain liability insurance of more than the maximum amount of liability insurance reasonably available from private sources on the world market at prices and terms that will not unreasonably distort the sales price of the Seller's anti-terrorism technology. The Under Secretary will determine the amount of liability insurance required for each technology, or, to the extent feasible and appropriate, a particular group of technologies. The Under Secretary or his designee may find that—notwithstanding the level of risk exposure for a particular technology, or group of technologies—the maximum amount of liability insurance from private sources on the world market is set at a price or contingent on terms that will unreasonably distort the sales price of a Seller's technology, thereby necessitating liability insurance coverage below the maximum amount available. In determining the amount of liability insurance required, the Under Secretary may consider any factor, including, but not limited to, the following:

(1) The particular technology at issue;

(2) The amount of liability insurance the Seller maintained prior to application;

(3) The amount of liability insurance maintained by the Seller for other technologies or for the Seller's business as a whole;

(4) The amount of liability insurance typically maintained by sellers of comparable technologies;

(5) Information regarding the amount of liability insurance offered on the world market;

(6) Data and history regarding mass casualty losses;

(7) The intended use of the technology;

(8) The possible effects of the cost of insurance on the price of the product, and the possible consequences thereof for development, production, or deployment of the technology; and

(9) In the case of a Seller seeking approval to self-insure, the factors described in 48 CFR 28.308(d).

(c) *Scope of coverage.* Liability insurance obtained pursuant to this section shall, in addition to the Seller, protect the following, to the extent of their potential liability for involvement in the manufacture, qualification, sale, use, or operation of qualified anti-terrorism technologies deployed in defense against, response to, or recovery from, an act of terrorism:

(1) Contractors, subcontractors, suppliers, vendors and customers of the Seller.

(2) Contractors, subcontractors, suppliers, and vendors of the customer.

(d) *Third party claims.* Any liability insurance required to be obtained under this section shall provide coverage against third party claims arising out of, relating to, or resulting from an act of terrorism when the applicable qualified anti-terrorism technologies have been deployed in defense against, response to, or recovery from such act.

(e) *Reciprocal waiver of claims.* The Seller shall enter into a reciprocal waiver of claims with its contractors, subcontractors, suppliers, vendors, and customers, and contractors and subcontractors of the customers, involved in the manufacture, sale, use, or operation of qualified anti-terrorism technologies, under which each party to the waiver agrees to be responsible for losses, including business interruption losses, that it sustains, or for losses sustained by its own employees resulting from an activity resulting from an act of terrorism when qualified anti-terrorism technologies have been deployed in defense against, response to, or recovery from such act.

(f) *Information to be submitted by the seller.* The Seller shall provide a statement, executed by a duly authorized representative of the Seller, of all liability insurance coverage applicable to third-party claims arising out of, relating to, or resulting from an act of terrorism when the Seller's Qualified Anti-terrorism Technology has been deployed in defense against, response to, or recovery from such act, including:

(1) Names of insurance companies, policy numbers, and expiration dates;

(2) A description of the types and nature of such insurance (including the extent to which the Seller is self-insured or intends to self-insure);

(3) Dollar limits per occurrence and annually of such insurance, including any applicable sublimits;

(4) Deductibles or self-insured retentions, if any, that are applicable;

(5) Any relevant exclusions from coverage under such policies;

(6) The price for such insurance, if available, and the per-unit amount or percentage of such price directly related to liability coverage for the Seller's Qualified Anti-terrorism Technology deployed in defense against, or response to, or recovery from an act of terror;

(7) Where applicable, whether the liability insurance, in addition to the Seller, protects contractors, subcontractors, suppliers, vendors and customers of the Seller and contractors, subcontractors, suppliers, vendors and customers of the customer to the extent of their potential liability for involvement in the manufacture, qualification, sale, use or operation of Qualified Anti-terrorism Technologies deployed in defense against, response to, or recovery from an act of terrorism;

(8) Any limitations on such liability insurance; and

(9) In the case of a Seller seeking approval to self-insure, all of the information described in 48 CFR 28.308(a)(1) through (a)(10).

(g) *Seller's continuing obligation.* Within one year after the Under Secretary's certification required by paragraph (h) of this section, and each year thereafter, the Seller shall certify to the Under Secretary that the Seller has maintained the insurance required by the Under Secretary's certification. The Under Secretary may terminate the designation as a qualified anti-terrorism technology for the technology at issue if the Seller fails to provide the certification required by this paragraph or provides a false certification. The Under Secretary may also consider such failure to provide the certification or provision of a false certification when reviewing future applications from the same Seller. The Seller must also notify the Under Secretary of any changes in

types or amounts of liability insurance coverage for any Qualified Anti-terrorism Technology.

(h) *Under Secretary's certification.* For each Qualified Anti-Terrorism Technology, the Under Secretary shall certify the amount of insurance required under Section 864 of the Act. The Under Secretary shall include the certification under this section as a part of the applicable Designation. The certification may specify a period of time for which the certification will apply. The Seller of a Qualified Anti-terrorism Technology may at any time petition the Under Secretary for a revision or termination of the certification under this section. The Under Secretary or his designee may at any time request information from the Seller regarding the insurance maintained by the Seller or the amount of insurance available to the Seller.

§ 25.5 Procedures for designation of qualified anti-terrorism technologies.

(a) *Application procedure.* Any Seller seeking a Designation shall submit all information supporting such request to the Assistant Secretary for Plans, Programs, and Budget of the Department of Homeland Security Directorate of Science and Technology (''the Assistant Secretary''), or such other official of such Directorate as may be designated from time to time by the Under Secretary. The Under Secretary shall make application forms available at *http://www.dhs.gov* and by mail upon request sent to: Directorate of Science and Technology, SAFETY Act/room 4320, Department of Homeland Security, Washington, DC 20528.

(b) *Initial notification.* Within 30 days after receipt of an Application for a Designation, the Assistant Secretary or his or her designee shall notify the applicant in writing that:

(1) The Application is complete and will be reviewed; or

(2) That the Application is incomplete, in which case the missing or incomplete parts will be specified.

(c) *Review process.* The Assistant Secretary or his or her designee will review each complete Application and any included supporting materials. In performing this function, the Assistant Secretary or his or her designee may, but is not required to:

(1) Request additional information from the Seller;

(2) Meet with representatives of the Seller;

(3) Consult with, and rely upon the expertise of, any other federal or nonfederal entity;

(4) Perform studies or analyses of the technology or the insurance market for such technology; and

(5) Seek information from insurers regarding the availability of insurance for such technology.

(d) *Recommendation of the Assistant Secretary.* Within 90 days after receipt of a complete Application for a Designation, the Assistant Secretary shall make one of the following recommendations to the Under Secretary regarding such Application: that the Application be approved and a Designation be issued to the Seller; that the Seller be notified that the technology is potentially eligible for a Designation, but that additional specified information is needed before a decision may be reached; or that the Application be denied. If approval is recommended, the recommendation shall include a recommendation regarding the certification required by § 25.4(h). The Assistant Secretary may extend the time period beyond 90 days upon notice to the Seller; the Assistant Secretary is not required to provide a reason or cause for such extension.

(e) *Action by the Under Secretary.* Within 30 days after receiving a recommendation from the Assistant Secretary pursuant to paragraph (d) of this section, the Under Secretary shall take one of the following actions: approve the Application and issue an appropriate Designation to the Seller, which shall include the certification required by § 25.4(h); notify the Seller in writing that the technology is potentially eligible for a Designation, but that additional specified information is needed before a decision may be reached; or deny the Application, and notify the Seller in writing of such decision. The Under Secretary may extend the time period beyond 30 days upon notice to the Seller; the Under Secretary is not required to provide a reason or cause for such extension. The Under Secretary's decision shall be final and not subject to review, except at the discretion of the Under Secretary.

(f) *Term of designation; renewal.* A Designation shall be valid and effective for a term of five to eight years (as determined by the Under Secretary based upon the technology) commencing on the date of issuance, and the protections conferred by the Designation shall continue in full force and effect indefinitely, after the expiration of the Designation, to all sales of qualified anti-terrorism technologies covered by the Designation that were consummated during such term. At any time after the third anniversary of such issuance, the Seller may apply for renewal of the Designation. The Under Secretary shall make the application form for renewals available at *http://www.dhs.gov* and by mail upon request sent to: Directorate of Science and Technology, SAFETY Act/ room 4320, Department of Homeland Security, Washington, DC 20528.

(g) *Transfer of designation.* Any Designation may be transferred and assigned to any other person or entity to which the Seller transfers and assigns all right, title, and interest in and to the technology covered by the Designation, including the intellectual property rights therein (or, if the Seller is a licensee of the technology, to any person or entity to which such Seller transfers all of its right, title, and interest in and to the applicable license agreement). Such transfer and assignment of a Designation will not be effective unless and until the Under Secretary is notified in writing of the transfer using the ''Application for Transfer of Designation'' form issued by the Under Secretary (the Under Secretary shall make this application form available at *http://www.dhs.gov* and by mail by written request sent to: Directorate of Science and Technology, SAFETY Act/room 4320, Department of Homeland Security, Washington, DC 20528), and the transferee complies with all applicable provisions of the SAFETY Act, this Part, and the relevant Designation as if the transferee were the Seller. Upon the effectiveness of such transfer and assignment, the transferee will be deemed to be a Seller in the place and stead of the transferor with respect to the applicable technology for all purposes under the SAFETY Act, this Part, and the transferred Designation. The transferred Designation will continue to apply to the transferor with respect to all transactions and occurrences that occurred through the time at which the transfer and assignment of the Designation became effective, as specified in the applicable Application for Transfer of Designation.

(h) *Application of designation to licensees.* Any Designation shall apply to any other person or entity to which the Seller licenses (exclusively or nonexclusively) the right to manufacture and sell the technology, in the same manner and to the same extent that such Designation applies to the Seller, effective as of the date of commencement of the license, provided that the Seller notifies the Under Secretary of such license by submitting, within 30 days after such date of commencement, a ''Notice of License of Qualified Anti-terrorism Technology'' form issued by the Under Secretary. The

Under Secretary shall make this form available at *http://www.dhs.gov* and by mail upon request sent to: Directorate of Science and Technology, SAFETY Act/ room 4320, Department of Homeland Security, Washington, DC 20528. Such notification shall not be required for any licensee listed as a Seller on the applicable Designation.

(i) *Termination of designation resulting from substantial modification.* A Designation shall terminate automatically, and have no further force or effect, if the designated Qualified Anti-terrorism Technology is significantly changed or modified. A significant change or modification in the technology is one that could significantly affect the safety or effectiveness of the device. This could include a significant change or modification in design, material, chemical composition, energy source, manufacturing process, or purpose for which it is to be sold. Changes or modifications will be evaluated at a minimum with reference to the description of the technology and its purposes as provided in the Seller's application and with reference to what was designated in the applicable Designation. If a Seller is planning a significant change or modification to a designated technology as defined above, such Seller may apply for a corresponding modification of the applicable Designation in advance of the implementation of such modification. Application for such a modification must be made using the ''Application for Modification of Designation'' form issued by the Under Secretary. The Under Secretary shall make this application form available at *http://www.dhs.gov* and by mail upon request sent to: Directorate of Science and Technology, SAFETY Act/room 4320, Department of Homeland Security, Washington, DC 20528.

§ 25.6 Government contractor defense.

The Under Secretary may certify a qualified anti-terrorism technology as an Approved Product for Homeland Security for purposes of establishing a rebuttable presumption of the applicability of the government contractor defense. In determining whether to grant such certification, the Under Secretary or his or her designee shall conduct a comprehensive review of the design of such technology and determine whether it will perform as intended, conforms to the Seller's specifications, and is safe for use as intended. The Seller shall provide safety and hazard analyses and other relevant data and information regarding such technology to the Department in connection with an application. The Under Secretary or his designee may require that the Seller submit any information that the Under Secretary or his designee considers relevant to the application for approval. The Under Secretary or his designee may consult with, and rely upon the expertise of, any other governmental or non-governmental person or entity, and may consider test results produced by an independent laboratory or other person or entity engaged by the Seller.

§ 25.7 Procedures for certification of approved products for Homeland Security.

(a) *Application procedure.* A Seller seeking certification of anti-terrorism technology as an Approved Product for Homeland Security under § 25.6 (a ''Certification'') shall submit all information supporting such request to the Assistant Secretary. The Under Secretary shall make application forms available at *http://www.dhs.gov*, and copies may also be obtained by mail by sending a request to: Directorate of Science and Technology, SAFETY Act/ room 4320, Department of Homeland Security, Washington, DC 20528. An Application for a Certification may not be filed unless the Seller has also filed an Application for Designation of Qualified Anti-Terrorism Technology for the same technology. The two applications may be filed simultaneously and may be reviewed simultaneously.

(b) *Initial notification.* Within 30 days after receipt of an Application for a Certification, the Assistant Secretary or his or her designee shall notify the applicant in writing that:

(1) The Application is complete and will be reviewed; or

(2) That the Application is incomplete, in which case the missing or incomplete parts will be specified.

(c) *Review process.* The Assistant Secretary or his or her designee will review each complete Application for a Certification and any included supporting materials. In performing this function, the Assistant Secretary or his or her designee may, but is not required to:

(1) Request additional information from the Seller;

(2) Meet with representatives of the Seller;

(3) Consult with, and rely upon the expertise of, any other federal or nonfederal entity; and

(4) Perform or seek studies or analyses of the technology.

(d) *Recommendation of the Assistant Secretary.* Within 90 days after receipt of a complete Application for a Certification, the Assistant Secretary shall make one of the following recommendations to the Under Secretary regarding such Application: that the Application be approved and a Certification be issued to the Seller; that the Seller be notified that the technology is potentially eligible for a Certification, but that additional specified information is needed before a decision may be reached; or that the Application be denied. The Assistant Secretary may extend the time period beyond 90 days upon notice to the Seller; the Assistant Secretary is not required to provide a reason or cause for such extension.

(e) *Action by the Under Secretary.* Within 30 days after receiving a recommendation from the Assistant Secretary pursuant to paragraph (d) of this section, the Under Secretary shall take one of the following actions: approve the Application and issue an appropriate Certification to the Seller; notify the Seller in writing that the technology is potentially eligible for a Certification, but that additional specified information is needed before a decision may be reached; or deny the Application, and notify the Seller in writing of such decision. The Under Secretary may extend the time period beyond 30 days upon notice to the Seller, and the Under Secretary is not required to provide a reason or cause for such extension. The Under Secretary's decision shall be final and not subject to review, except at the discretion of the Under Secretary.

(f) *Designation is a pre-condition.* The Under Secretary may approve an Application for a Certification only if the Under Secretary has also approved an Application for a Designation for the same technology under § 25.3.

(g) *Term of certification; renewal.* A Certification shall be valid and effective for the same period of time for which the related Designation is issued, and shall terminate upon the termination of such related Designation. The Seller may apply for renewal of the Certification in connection with an application for renewal of the related Designation. An application for renewal must be made using the ''Application for Certification of an Approved Product for Homeland Security'' form issued by the Under Secretary.

(h) *Application of certification to licensees.* Any Certification shall apply to any other person or entity to which the Seller licenses (exclusively or nonexclusively) the right to manufacture and sell the technology, in the same manner and to the same extent that such Certification applies to the Seller, effective as of the date of commencement of the license, provided

that the Seller notifies the Under Secretary of such license by submitting, within 30 days after such date of commencement, a ''Notice of License of Approved Anti-terrorism Technology'' form issued by the Under Secretary. The Under Secretary shall make this form available at *http://www.dhs.gov* and by mail upon request sent to: Directorate of Science and Technology, SAFETY Act/ room 4320, Department of Homeland Security, Washington, DC 20528. Such notification shall not be required for any licensee listed as a Seller on the applicable Certification.

(i) *Transfer of certification.* In the event of any permitted transfer and assignment of a Designation, any related Certification for the same anti-terrorism technology shall automatically be deemed to be transferred and assigned to the same transferee to which such Designation is transferred and assigned. The transferred Certification will continue to apply to the transferor with respect to all transactions and occurrences that occurred through the time at which such transfer and assignment of the Certification became effective.

(j) *Issuance of certificate; approved product list.* For anti-terrorism technology reviewed and approved by the Under Secretary and for which a Certification is issued, the Under Secretary shall issue a certificate of conformance to the Seller and place the anti-terrorism technology on an Approved Product List for Homeland Security.

§ 25.8 Confidentiality and protection of intellectual property.

The Secretary, in consultation with the Office of Management and Budget and appropriate Federal law enforcement and intelligence officials, and in a manner consistent with existing protections for sensitive or classified information, shall establish confidentiality protocols for maintenance and use of information submitted to the Department under the SAFETY Act and this Part. Such protocols shall, among other things, ensure that the Department will utilize all appropriate exemptions from the Freedom of Information Act.

§ 25.9 Definitions.

Assistant Secretary—The term ''Assistant Secretary'' means the Assistant Secretary for Plans, Programs, and Budget of the Department of Homeland Security Directorate of Science and Technology, or such other official of such Directorate as may be designated from time to time by the Under Secretary.

Certification—The term ''Certification'' means (unless the context requires otherwise) a certification that a qualified anti-terrorism technology for which a Designation has been issued will perform as intended, conforms to the Seller's specifications, and is safe for use as intended.

Contractor—The term ''contractor'' of a Seller means any person or entity with whom or with which the Seller has entered into a contract relating to the manufacture, sale, use, or operation of anti-terrorism technology for which a Designation is issued (regardless of whether such contract is entered into before or after the issuance of such Designation), including, without limitation, an independent laboratory or other entity engaged in testing or verifying the safety, utility, performance, or effectiveness of such technology, or the conformity of such technology to the Seller's specifications.

Designation—The term ''Designation'' means a designation of a qualified anti-terrorism technology under the SAFETY Act issued by the Under Secretary under authority delegated by the Secretary of Homeland Security.

Loss—The term ''loss'' means death, bodily injury, or loss of or damage to property, including business interruption loss (which is a component of loss of or damage to property).

Physical Harm—The term ''physical harm'' as used in the Act shall mean a physical injury to the body that caused, either temporarily or permanently, partial or total physical disability, incapacity or disfigurement. In no event shall physical harm include mental pain, anguish, or suffering, or fear of injury.

SAFETY Act or Act—The term ''SAFETY Act'' or ''Act'' means the Support Anti-terrorism by Fostering Effective Technologies Act of 2002, enacted as Subtitle G of Title VIII of the Homeland Security Act of 2002, Public Law 107–296.

Seller—The term ''Seller'' means any person or entity that sells or otherwise provides anti-terrorism technology to Federal and non-Federal Government customers for which a Designation has been issued under this Part (unless the context requires otherwise).

Under Secretary—The term ''Under Secretary'' means the Under Secretary for Science and Technology of the Department of Homeland Security.

Dated: July 7, 2003.

Tom Ridge,

Secretary of Homeland Security.

[FR Doc. 03–17561 Filed 7–8–03; 11:58 am]

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Part III

Department of Health and Human Services

Food and Drug Administration

21 CFR Part 101

Food Labeling; Trans Fatty Acids in Nutrition Labeling; Consumer Research to Consider Nutrient Content and Health Claims and Possible Footnote or Disclosure Statements; Final Rule and Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. 94P–0036]

RIN 0910–AB66

Food Labeling: *Trans* Fatty Acids in Nutrition Labeling, Nutrient Content Claims, and Health Claims

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its regulations on nutrition labeling to require that *trans* fatty acids be declared in the nutrition label of conventional foods and dietary supplements on a separate line immediately under the line for the declaration of saturated fatty acids. This action responds, in part, to a citizen petition from the Center for Science in the Public Interest (CSPI). This rule is intended to provide information to assist consumers in maintaining healthy dietary practices. Those sections of the proposed rule pertaining to the definition of nutrient content claims for the ''free'' level of *trans* fatty acids and to limits on the amounts of *trans* fatty acids wherever saturated fatty acid limits are placed on nutrient content claims, health claims, and disclosure and disqualifying levels are being withdrawn. Further, the agency is withdrawing the proposed requirement to include a footnote stating: ''Intake of *trans* fat should be as low as possible.'' Issues related to the possible use of a footnote statement in conjunction with the *trans* fat label declaration or in the context of certain nutrient content and health claims that contain messages about cholesterol-raising fats in the diet are now the subject of an advance notice of proposed rulemaking (ANPRM) which is published elsewhere in this issue of the **Federal Register**.

DATES: This rule is effective January 1, 2006.

FOR FURTHER INFORMATION CONTACT: Julie Schrimpf, Center for Food Safety and Applied Nutrition (HFS–832), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–2373.

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I. Background

A. Nutrition Labeling

The Nutrition Labeling and Education Act of 1990 (the 1990 amendments) (Public Law 101–535) amended the Federal Food, Drug, and Cosmetic Act (the act) to provide, among other things, that certain nutrients and food components be included in nutrition labeling. Section 403(q)(2)(A) and (q)(2)(B) (21 U.S.C. 343(q)(2)(A) and (q)(2)(B)) of the act state that the Secretary of Health and Human Services (the Secretary) (and, by delegation, FDA) can, by regulation, add or delete nutrients included in the food label or labeling if he or she finds such action necessary to assist consumers in maintaining healthy dietary practices.

In response to these provisions, in the **Federal Register** of November 27, 1991 (56 FR 60366), FDA published a proposed rule entitled ''Food Labeling; Reference Daily Intakes and Daily Reference Values; Mandatory Status of Nutrition Labeling and Nutrient Content Revision.'' In that document, the agency proposed to require that foods bear nutrition labeling listing certain nutrients and the amount of those nutrients in a serving of the food. Given the scientific knowledge about *trans* fatty acids at the time, FDA did not propose to require that *trans* fatty acids be listed. However, FDA requested comments on whether the listing of *trans* fatty acids should be voluntary (56 FR 60366 at 60371). (Note: throughout this preamble, FDA has used the term ''*trans* fatty acids'' and ''*trans* fat'' interchangeably; likewise, for the terms ''saturated fatty acids,'' and ''saturated fat'').

In the **Federal Register** of January 6, 1993 (58 FR 2079), FDA issued a final rule implementing the 1990 amendments entitled ''Food Labeling; Mandatory Status of Nutrition Labeling and Nutrient Content Revision, Format for Nutrition Label'' that prescribes how nutrition labeling is to be provided on foods that are regulated by the agency. In that document, the agency required the declaration of total fat and saturated fat in the nutrition label, with the declaration of both monounsaturated fat and polyunsaturated fat (both defined as the *cis* isomers only) required, when claims are made about fatty acids and cholesterol. Based on its review of the comments, the agency stated that it was premature to include *trans* fatty acids in nutrition labeling because of a lack of agreement on the dietary implications of *trans* fatty acid intake. However, the agency acknowledged that it might be necessary to revisit the labeling of *trans* fatty acids in the future (58 FR 2079 at 2090–2092).

FDA received a citizen petition, dated February 14, 1994, from CSPI (docket number 94P–0036/CP1) stating that an increasing body of evidence suggests that dietary *trans* fatty acids raise blood cholesterol levels, thereby increasing the risk of coronary heart disease (CHD). The petitioner argued that the 1993 final rules implementing the 1990 amendments do not adequately reflect the effect of dietary *trans* fatty acids on CHD and that label values for saturated fat underestimate the total amount of ''heart-unhealthy'' fats because *trans* fatty acids are not declared. CSPI requested that FDA amend the definition of saturated fat in

§ 101.9(c)(2)(i) (21 CFR 101.9(c)(2)(i)) to include *trans* fatty acids so that the declaration of saturated fat on the nutrition label would provide consumers with complete information on all ''heart-unhealthy'' fatty acids. In addition, the petitioner requested that all saturated fat claims in § 101.62(c) (21 CFR 101.62(c)), the saturated fat threshold on all cholesterol claims in § 101.62(d), the claims for ''lean'' and ''extra lean'' in § 101.62(e), and disqualification and disclosure levels for health and nutrient content claims be amended to reflect the combined levels of saturated and *trans* fatty acids. Further, CSPI requested that FDA: (1) Limit ''vegetable oil'' claims (e.g., ''made with vegetable oil'') to foods that are low in both saturated and *trans* fatty acids, and (2) require that ''partially hydrogenated'' fat be listed on food labels as ''partially saturated.''

On July 13, 1998, CSPI amended its petition in a way that would maintain the definition of saturated fat in § 101.9(c)(2)(i), yet provide consumers with information on the *trans* fatty acid content of the food. Specifically, CSPI suggested that FDA either: (1) Disclose the sum of *trans* and saturated fats next to the term ''saturated fat*'' with an asterisk at the bottom of the label that states ''contains ___ grams of *trans* fat,'' or (2) disclose the sum of *trans* and saturated fats next to the term ''saturated + *trans* fat'' when *trans* fat was present.

In response to CSPI's petition, FDA issued a proposed rule in the **Federal Register** of November 17, 1999 (64 FR 62746), entitled ''Food Labeling: *Trans* Fatty Acids in Nutrition Labeling, Nutrient Content Claims, and Health Claims'' (hereinafter identified as ''the November 1999 proposal''). In that document, FDA proposed to amend its nutrition labeling regulations to require that the amount of *trans* fatty acids in a food, including dietary supplements, be included in the amount and percent Daily Value (%DV) declared for saturated fatty acids, with a footnote indicating the amount of *trans* fatty acids in a serving of the product, when the product contains 0.5 or more grams (g) *trans* fatty acids per serving. FDA reviewed recent research that showed that consumption of diets containing *trans* fatty acids, like diets containing saturated fats, results in increased serum low-density lipoprotein cholesterol (LDL–C), a major risk factor for CHD. The proposed rule was issued to assist consumers in maintaining healthy dietary practices (64 FR 62746 at 62754).

B. Nutrient Content and Health Claims

In the **Federal Register** of November 27, 1991 (56 FR 60478), FDA also published a proposed rule entitled ''Food Labeling: Definitions of Nutrient Content Claims for the Fat, Fatty Acid, and Cholesterol Content of Food.'' Although the agency proposed definitions for fat, fatty acid, and cholesterol nutrient content claims, it did not propose a definition for the nutrient content claim ''saturated fat free.'' However, the comments in response to that proposal recommended that FDA define the claim ''saturated fat free.''

In the **Federal Register** of January 6, 1993 (58 FR 2302), FDA issued a final rule entitled ''Food Labeling: Nutrient Content Claims, General Principles, Petitions, Definition of Terms; Definition of Nutrient Content Claims for the Fat, Fatty Acid, and Cholesterol Content of Food,'' (hereinafter the ''nutrient content claims final rule''). In that rule, the agency stated that it did not set a *trans* fat criterion for most claims because the evidence suggesting that *trans* fatty acids raise serum cholesterol was inconclusive at that time (58 FR 2302 at 2332 and 2340). However, FDA did set a *trans* fat criterion for the ''saturated fat free'' claim stating that ''because of the uncertainty regarding this issue, the fact that consumers would expect a food bearing a 'saturated fat free' claim to be free of saturated fat and other components that significantly raise serum cholesterol, and the potential importance of a saturated fat free claim, the agency believes that it would be misleading for products that contain measurable amounts of *trans* fatty acids to bear a 'saturated fat free' claim'' (58 FR 2302 at 2332). The *trans* fat criterion for the claim ''saturated fat free'' was set at a level not to exceed 1 percent of total fat in the food (58 FR 2302 at 2419). The agency stated that 1 percent was the appropriate threshold because analytical methods for measuring *trans* fatty acids below that level were not reliable (58 FR 2302 at 2332). This action was taken under the authority of section 403(r)(2)(A)(vi) of the act, which prohibits a claim if it is misleading in light of the level of another nutrient in the food.

Some comments that FDA received after publication of the nutrient content claims final rule objected to the 1 percent criterion for *trans* fatty acids in the definition of ''saturated fat free.'' One comment pointed out that a cookie containing 1.5 g of total fat would be allowed to have only 0.015 g of *trans* fatty acids, an amount that could not be accurately measured. In response to these comments, in the **Federal Register** of August 18, 1993 (58 FR 44020 at 44032), the agency amended the definition of ''saturated fat free'' to require that a food contain less than 0.5 g of *trans* fatty acids in addition to less than 0.5 g of saturated fat per reference amount customarily consumed (hereinafter referred to as ''reference amount'') and per labeled serving to be eligible to bear the claim.

In the November 1999 proposal, FDA concluded that dietary *trans* fatty acids have adverse effects on blood cholesterol measures that are predictive of CHD risk (64 FR 62746 at 62754). Consequently, to avoid misleading claims, the agency proposed that the amount of *trans* fatty acids be limited wherever saturated fat limits are placed on nutrient content claims, health claims, or disclosure and disqualifying levels. In the November 1999 proposal, the agency did not propose to take action requested by CSPI to amend § 101.65(c)(3) (21 CFR 101.65(c)(3)) to state that ''made with vegetable oil'' is an implied claim that the product is low in saturated fat and *trans* fats combined (64 FR 62746 at 62762) because the agency proposed to amend nutrient content claims for saturated fat to include a *trans* fatty acid criterion. The agency stated that the proposed amendments to nutrient content claims and the requirements for implied nutrient content claims in § 101.65(c)(3) adequately addressed the petitioner's request.

In addition, in the November 1999 proposal, FDA requested comment on whether ''*trans* fat free'' claims would help consumers maintain healthy dietary practices and whether they would provide incentive to the food industry to reduce the amount of *trans* fat in the food supply (64 FR 62746 at 62759). FDA proposed a definition for the *trans* fat free claim. FDA concluded that there was no basis for defining ''low *trans* fat'' without quantitative recommendations for daily intake of *trans* fat. Further, FDA did not define a ''reduced *trans* fat'' claim because it was concerned that a reduced *trans* fat claim would detract from educational messages that emphasize lower intakes of saturated fat. Persons who believed that a ''reduced *trans* fat'' claim would be useful were advised to submit a petition under § 101.69 (21 CFR 101.69).

In the November 1999 proposal, FDA proposed to deny CSPI's request that the agency require that ''partially hydrogenated'' fat be listed as ''partially saturated'' fat (64 FR 62746 at 62762). Among other reasons, the agency stated that ''hydrogenated'' and ''partially

hydrogenated'' are not intended to describe the nutritional properties of the fat or oil. It explained that the purpose of the ingredient statement is to identify the ingredients in a food by listing the common or usual names of each ingredient (64 FR 62746 at 62762–62763).

Comments to the November 1999 proposal requested that the final rule define the nutrient content claim ''reduced *trans* fat.'' Other comments suggested a ''reduced saturated fat'' claim that would be defined as a reduction of saturated and *trans* fats combined. The agency considered these comments and determined that all interested parties should have an opportunity to comment on whether the final rule should define claims that address reduced levels of *trans* fat. Therefore, FDA reopened the comment period for the November 1999 proposal on December 5, 2000, for a period of 45 days (65 FR 75887) stating that it would consider only comments that addressed ''reduced *trans* fat'' and ''reduced saturated and *trans* fat'' claims.

Subsequent to FDA's November 1999 proposal, the Institute of Medicine of the National Academy of Sciences (IOM/NAS) issued a report entitled ''Dietary Reference Intakes for Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein and Amino Acids'' (the IOM/NAS macronutrient report) (Ref. 140) and found, similar to the effect of saturated fat, ''a positive linear trend'' between *trans* fatty acid intake and total and LDL–C concentrations, and therefore increased risk of CHD. Because *trans* fats are unavoidable in ordinary diets, the IOM/NAS report recommended that ''*trans* fat consumption be as low as possible while consuming a nutritionally adequate diet.'' Likewise, the conclusions in two other scientific reports, which became available subsequent to the November 1999 proposal, i.e., the Dietary Guidelines for Americans, 2000 (Ref. 88) and guidelines from the National Cholesterol Education Program (NCEP) (Ref. 89), were similar with recommendations to limit *trans* fat intake in the diet. Although the IOM/NAS report (Ref. 140) underscored the relationship between the intake of *trans* fat and the increased risk for heart disease and emphasized that consumers need to limit *trans* fat in their diets, it did not provide a Dietary Reference Intake (DRI) value for *trans* fat or information that FDA believes is sufficient to support the agency's establishing a Daily Reference Value (DRV) or other information on the label, such as a %DV, for *trans* fat.

In response to the recommendations of the new scientific reports to limit the intake of *trans* fat and to provide consumers with label information that may better assist them in understanding the quantitative declaration of *trans* fat in the context of a total daily diet, FDA reopened the comment period of the November 1999 proposal for a period of 30 days (67 FR 69171, November 15, 2002). In that document the agency proposed to require an asterisk (or other symbol) in the %DV column for *trans* fat, when it is listed, that is tied to a similar symbol at the bottom of the Nutrition Facts box that is followed by the statement ''Intake of *trans* fat should be as low as possible.'' The agency stated that the statement is taken from the IOM/NAS macronutrient report and is consistent with the dietary guidance in the other recent scientific reports identified in that document (67 FR 69171 at 69172).

In the November 15, 2002, **Federal Register** document to reopen the comment period the agency also stated that it would consider the exercise of its enforcement discretion for those manufacturers who wanted to begin labeling the *trans* fat content of food products prior to publication of the final rule (67 FR 69171 at 69172). The agency cautioned manufacturers that the *trans* fat final rule may differ from what was being proposed in the November 15, 2002, document to reopen the comment period and that manufacturers would then be required to change their labels to conform to the final rule.

C. Comments

FDA received over 1,650 letters in response to the November 1999 proposal, over 45 letters in response to the December 5, 2000, notice reopening the comment period, and over 25 letters in response to the November 15, 2002, proposal and notice to reopen the comment period. Each of these letters contained one or more comments. Responses were received from industry, trade associations, consumers, consumer advocacy organizations, academia, health care professionals, professional societies, city and State governments, other Federal agencies, and other countries. Some of the comments supported the proposal generally or supported aspects of the proposal. Other comments objected to specific provisions and requested revisions. Some comments requested that the proposal be withdrawn or reproposed. A few comments addressed issues outside the scope of the proposal and will not be discussed here. On September 18, 2001, the Office of Information and Regulatory Affairs (OIRA), Office of Management and Budget, sent to the Secretary of the Health and Human Services (the Secretary) a letter requesting that the Secretary and FDA consider giving greater priority to the November 1999 proposal (Ref. 156) in light of the growing body of scientific evidence suggesting that consumption of *trans* fatty acids in foods increases the consumer's risk of developing CHD. The estimated public health benefits from increased consumer awareness of *trans* fat content in foods that were described in FDA's preliminary Regulatory Impact Analysis in the November 1999 proposal, and the subsequent evidence found in more recent studies, strongly support the interests of the Government to lower the incidence of and economic burden of CHD in the United States. This final rule summarizes the relevant comments that were received in response to the November 1999 proposal and provides the agency's conclusions regarding the labeling of *trans* fat on the Nutrition Facts panel.

A summary of the relevant comments that pertain to nutrition labeling of *trans* fat, the agency's responses to the comments, and a discussion of the agency's conclusions follow.

II. Highlights of the Final Rule

In this final rule and given the current state of scientific knowledge, FDA is requiring the mandatory declaration in the nutrition label of the amount of *trans* fatty acids present in foods, including dietary supplements. The declaration of this nutrient must be on a separate line immediately under the declaration for saturated fat but it will not include a %DV that is required for some of the other mandatory nutrients, such as saturated fat. In addition, the agency is withdrawing those sections of the proposed rule pertaining to the definition of nutrient content claims for ''free'' and for ''reduced'' levels of *trans* fatty acids, and limits on the amounts of *trans* fatty acids, wherever saturated fatty acid limits are placed on nutrient content claims, health claims, and disclosure and disqualifying levels. Further, the agency is withdrawing the proposed requirement to include a footnote stating: ''Intake of *trans* fat should be as low as possible.''

The action the agency is taking in this final rule is based on its evaluation of comments received in response to the November 1999 proposal, the reopening of the comment period on November 15, 2002, and on scientific evidence that shows that consumption of *trans* fatty acids increases LDL–C, a primary risk factor for CHD. The scientific evidence includes current authoritative reports,

such as Dietary Guidelines 2000 (Ref. 87), that recommend that Americans cut back on *trans* fats when reducing fat intake. The agency concludes that the declaration of this nutrient on a separate line, will help consumers understand that *trans* fat is chemically distinct from saturated fat and will assist them in maintaining healthy dietary practices. The agency intends to promote consumer awareness and understanding of the health effects of *trans* fat as part of an educational program. FDA is issuing an ANPRM elsewhere in this issue of the **Federal Register** that will solicit comment and additional consumer research that potentially could be used to establish new nutrient content claims about *trans* fat, to establish qualifying criteria for *trans* fat in certain nutrient content claims and health claims, and to establish disclosure and disqualifying criteria for *trans* fat. In addition, the ANPRM is soliciting comment on whether it should consider statements about *trans* fat, either alone or in combination with saturated fat and cholesterol, as a footnote in the Nutrition Facts panel or as a disclosure statement in conjunction with claims to enhance consumer's understanding about cholesterol-raising lipids.

III. Legal Authority

General Comments

FDA received a number of comments from trade associations and others in industry asserting that FDA did not meet its burden under the first amendment in proposing to mandate nutrition labeling of *trans* fat. Further, the comments asserted that FDA did not meet its first amendment burden for establishing restrictions on specific claims by virtue of how FDA defined nutrient content claims or established disqualifying and disclosure levels, including the effects that those actions would have on restricting certain health claims on food. In addition, comments raised questions about whether the agency's proposed action was consistent with the Administrative Procedure Act (APA) and whether the agency was acting consistent with its authority under the act.

As stated in section VI of this document, FDA is withdrawing those sections of the rule pertaining to the definition for nutrient content claims that were proposed, and to limits on the amounts of *trans* fatty acids wherever saturated fatty acid limits are placed on nutrient content claims, health claims, and disclosure and disqualifying levels. Further, the agency is withdrawing the proposed requirement to include a footnote stating ''Intake of *trans* fat should be as low as possible.'' The agency provides an overview of comments received on these withdrawn sections in section VI of this document, and therefore, is not addressing those comments here. Thus, the agency is addressing only those comments that pertain to legal issues about the agency's action to require mandatory *trans* fat labeling.

A. Statutory Authority

Several comments question whether the agency's proposed requirement for mandatory *trans* fat labeling would prevent consumer deception or would assist consumers in maintaining healthy dietary practices. The comments suggest that the data do not support mandatory *trans* fat labeling, unless the label contains a nutrient content or health claim related to fat or cholesterol or unless polyunsaturated fat or monounsaturated fat is voluntarily declared on the label. Specifically, the comments assert that mandatory *trans* fat labeling in the absence of claims, or statements about other fats, would not assist consumers in following healthy dietary practices or would not prevent consumer deception.

A few comments suggest that there was no basis for concluding any health benefit can be expected from disclosure of *trans* fat levels on foods when present in amounts that have not been clinically shown to have a material impact on human health or disclosure on foods with a trivial contribution of fat.

Another comment argues that the agency could only require mandatory labeling of *trans* fat under the statute where the absence of such labeling constitutes the omission of a material fact under section 201(n) of the act (21 U.S.C. 321(n)), such as when nutrient content claims are made about cholesterol or fatty acids, or when polyunsaturated and monounsaturated fats are voluntary listed. A related comment suggests that *trans* fat labeling would be appropriate where the declaration of ''total fat'' and ''saturated fat,'' that did not explicitly include *trans* fat, were established as misleading under section 201(n) of the act (without *trans* fat listed). The comment seems to suggest that the declaration of ''total fat'' and ''saturated fat'' in that situation would be misleading if the actual nutrition contribution from *trans* fat that such products make to the diet was greater in comparison to other products. In addition, one comment suggests that mandatory nutrition labeling of *trans* fat can only be ''material'' where there is sufficient *trans* fat present in the food to significantly impact the overall fatty acid contribution that the food makes to the diet, such that only having total fat and saturated fat on the label would misrepresent the nutritional value of the product in a material way.

FDA believes it has adequate authority to adopt this rule. FDA's authority under the act to require *trans* fat labeling includes sections 201(n), 403(a)(1) and (q), and 701(a) of the act (21 U.S.C. 371(a)). FDA has authority under section 701(a) of the act to issue regulations for the efficient enforcement of the act. FDA can require labeling of certain facts that are material in light of representations made in the labeling or with respect to consequences which may result from the use of the article in order for a product not to be misbranded under sections 201(n) and 403(a) of the act. Further, under section 403(q)(2)(A) of the act, the Secretary (and FDA, by delegation) may require that information relating to a nutrient be in the labeling of food for the purpose of ''providing information regarding the nutritional value of such food that will assist consumers in maintaining healthy dietary practices.''

The agency believes that the data in the record supports mandatory *trans* fat labeling to ensure that consumers are not misled and are adequately informed about the product's attributes. Accordingly, FDA believes that mandatory *trans* fat labeling is necessary for foods not to be misbranded under section 403(a) of the act. The absence of information about the content of *trans* fat in foods that are subject to mandatory labeling would constitute an omission of a material fact under section 201(n) of the act.

Under the act, the agency has the mandate to ensure that labeling provides truthful and nonmisleading information to consumers. Thus, the law provides the agency with authority to require specific label statements when needed for reasons other than to ensure the safe use of food. Under section 403(a)(1) of the act, a food is misbranded if its labeling is false or misleading in any particular. Section 201(n) of the act amplifies what is meant by ''misleading'' in section 403(a)(1) of the act. Section 201(n) of the act states that, in determining whether labeling is misleading, the agency shall take into account not only representations made about the product, but also the extent to which the labeling fails to reveal facts material in light of such representations made or suggested in the labeling or material with respect to consequences which may result from use of the article to which the labeling relates under the conditions of use prescribed in the labeling or under such

conditions of use as are customary or usual (see § 1.21 (21 CFR 1.21)). Thus, the omission of certain material facts from the label or labeling of a food causes the product to be misbranded within the meaning of 21 U.S.C. 343(a)(1) and 321(n).

In general, the agency believes the concept of ''material fact'' is one that must be applied on a case-by-case basis. The agency has required special labeling in cases where information is necessary to ensure that consumers are aware of special health risks associated with consumption of a particular product. For example, although protein products intended for use in weight reduction are not inherently unsafe, FDA requires a warning statement for such products that states, in part, that very low calorie protein diets may cause serious illness or death. Another example of required information is the use of the term ''milk derivative'' following the ingredient declaration of sodium caseinate when used in a product labeled ''non dairy'' (21 CFR 101.4(d)).[1]

Consumption of *trans* fat results in consequences to the consumer. Consumers may increase or decrease their risk of CHD based on the level of *trans* fat in their diets. Thus, the presence or absence of *trans* fat in a food product is a material fact under section 201(n) of the act.

Consumers must know—and the agency believes is material information that the reasonable consumer should know—the amount of *trans* fat in food products that they select as part of their total daily diet to choose products that would allow them to reduce their intake of *trans* fat, and thus, reduce the risk of CHD. Section IV of this document discusses the scientific evidence for why *trans* fat consumption places consumers at risk for CHD. Absent mandatory labeling, consumers would not be able to understand the relative contribution that foods make to their total daily intake of *trans* fat. First, because polyunsaturated and monounsaturated fats are not subject to mandatory labeling, simply including *trans* fat as part of the total fat contribution would not allow consumers to calculate the *trans* fat content by finding the difference between the sum total of all the mandatory fats listed on the label and the total fat content. Second, even if all component fats were required to be listed, it would not be realistic to expect consumers to do such calculations on each product to compare the relative *trans* fat contribution of each. Further, the fact that an individual food product may contain zero gram *trans* fat is still a ''material fact'' for that food. In the context of mandatory labeling of nutrients in a nutrition facts panel, the relative contribution of various food products to the total day's consumption of a heart unhealthy fat is important for consumers ''to readily observe and comprehend the information and to understand the relative significance of that information in the context of the total daily diet'' (section 2(b)(1)(A) of Public Law 101–535). Further, foods in which *trans* fat has replaced saturated fat would appear to be heart healthy based on the saturated fat grams listed on the nutrition facts panel, when, in fact, such foods may not be heart healthy due to the large contribution of *trans* fat to the total fat content. Consumers would be misled without having *trans* fat information available on the label. Thus, for the reasons set forth previously, FDA concludes that it is acting within its statutory authority under the act to require *trans* fat labeling.

Moreover, Congress provided the agency with the express authority to add to the list of nutrients on the label under section 403(q)(2)(A) of the act. As stated in section V.A of this document, section 403(q)(2)(A) gives FDA the authority to require that information on additional nutrients be included in nutrition labels if FDA determines that providing such information will assist consumers to maintain healthy dietary practices. Section IV of this document provides ample evidence of the heart unhealthy effects from consumption of *trans* fat over a range of intakes, information the agency believes is material information that the reasonable consumer should know. When scientific evidence supports such labeling, the agency has discretion to determine whether to require the addition of a particular nutrient to the label of food products. Thus, the agency is well within its statutory authority for requiring mandatory labeling of *trans* fat and is not limited to requiring such information only when certain claims are made or only when other fats are listed on the label.

Further, the agency disagrees with the comments that assert that mandatory *trans* fat labeling would not assist consumers to maintain healthy dietary practices, unless the label also carries a nutrient content or health claim or information about other fats. The agency also disagrees with comments suggesting that there is no basis for concluding any health benefit can be expected from disclosure of *trans* fat if foods contain a trivial amount of *trans* fat or if *trans* fat is not present in amounts that have not been clinically shown to adversely affect human health.

The agency is exercising the discretion that Congress gave it in the 1990 amendments to include *trans* fat as a mandatory nutrient in food labeling, based on the state of the scientific evidence on the increased LDL–C levels from intake of *trans* fat (see section IV of this document). The scheme that Congress established would require all mandatory nutrients be listed on the food label, including those that the agency determines are necessary under section 403(q)(2)(A) of the act. Congress wanted one uniform statutory scheme for food labeling and discussed the importance of maintaining consistency in the format and content of the food label to ''help all consumers to better understand and improve their eating habits by providing uniform information in a coherent and understandable format.'' (136 Cong. Rec. S 16607 at 16609 (statement of Senator Metzenbaum)). The statute does not require other mandatory nutrients to be listed, for example, saturated fat, only when monounsaturated and polyunsaturated fat are voluntarily listed. Mandatory nutrients are listed for each food that bears a nutrition facts panel. Food that bears a nutrition label must contain certain required nutrients as part of that label to not be misbranded.

Further, section 403(q)(2)(A) provides that mandatory labeling would be appropriate when information about a nutrient would assist consumers to maintain healthy dietary practices. Information on the *trans* fat content of food would assist consumers in this way. Consumers need the information on *trans* fat content of all foods that they consume so that they can reduce their intake of *trans* fat. The fact that a food may have no *trans* fat or a small amount of *trans* fat is useful information to the consumer so that food choices can be made and the consumer can put that product, along with many other products consumed as part of the daily diet, into the context of the total daily diet to maintain healthy dietary practices. Consumers would have information on the amount of *trans* fat in a product, along with other information about the amount of saturated fat and cholesterol. Consumers could use information about all three fats, not just saturated fat and

[1] FDA's regulation regarding the failure to reveal material facts (§ 1.21) states that ''affirmative disclosure of material facts * * * may be required, among other appropriate regulatory procedures, by * * * regulations in this chapter promulgated pursuant to section 701(a) of the act; or direct court enforcement action (emphasis added).'' Thus, establishing a requirement for mandatory *trans* fat labeling is consistent with § 1.21.

cholesterol, to incorporate nutrition education information about recommended contributions for all three fats to the diet when making healthier food choices. There is ample discussion in section IV of this document about the heart unhealthy effects of consuming *trans* fat and there is a new and strong consensus among the scientific community for reducing *trans* fat intake. Thus, the agency believes it is within the bounds of its statutory authority under section 403(q)(2)(A) of the act to require the listing of *trans* fat on the food label, which listing is not dependent on the presence of claims or other voluntary fat information.

B. The First Amendment

Several general comments were received asserting that the agency's action to mandate labeling is subject to review under the first amendment. The comments assert that mandatory labeling of *trans* fat is commercial speech, and thus, such speech is entitled to the full range of first amendment protections as all commercial speech (citing to *Pearson* v. *Shalala*, 164 F.3d 650 (D.C. Cir. 1999)). The comments further assert that ''compelled speech'' is entitled to the same protections as speech ''bans,'' (citing to *Central Hudson Gas & Elec. Corp.* v. *Public Service Comm'n of New York*, 477 U.S. 557 at 566 (1980)). One comment explained that the court in *Pearson* emphasized that the first amendment does not allow FDA to restrict truthful, nonmisleading information as a ''paternalistic'' means of directing consumer food choices (164 F.3d at 656 (citing *Bates* v. *State Bar of Arizona*, 433 U.S. 350 at 377(1977) (''[W]e view as dubious any justification that is based on the benefits of public ignorance.'')); *44 Liquormart, Inc.* v. *Rhode Island*, 517 U.S. 484, 503 (1996) (opinion of Stevens, J. joined by Kennedy, J., and Ginsburg, J.) (''The First Amendment directs us to be especially skeptical of regulations that seek to keep people in the dark for what the government perceives to be their own good.''). The comment further cited several cases for the proposition that the government cannot compel speech when disclosures are not necessary to materially alleviate real consumer harm (citing to *IDFA* v. *Amestoy*, 92 F.3d 67, 73 (2nd Cir. 1996); *Ibanez* v. *Florida Dep't of Business and Prof'l Regulation*, 512 U.S. 136 (1994); and *Edenfield* v. *Fane*, 507 U.S. 761 (1993)). Another comment suggests that the agency needed to consider the limitations imposed by the first amendment to avoid unjustified burdens and costs on food labeling where there is no genuine public health benefit from a rule that does not materially alleviate a genuine harm of potential consumer deception.

Some comments assert that FDA's proposal to mandate *trans* fat labeling does not remedy a concrete harm as required by the first amendment. One comment suggests that a *trans* fat labeling rule could be supported if carefully crafted to remedy consumer deception but not where risk of consumer deception cannot be established as a genuine harm. Other comments state that FDA did not tailor its approach to labeling and would be requiring mandatory labeling of *trans* fat for foods containing as little as 0.5 g *trans* fat, which would not alleviate a genuine harm. The comment seems to further suggest that including *trans* fat in the total fat content on the label would be sufficiently tailored to alleviate a genuine harm. Another comment states that there is mere speculation in the record that providing information on *trans* fat would assist consumers to maintain healthy dietary practices, and thus, is not narrowly tailored to materially alleviate a genuine harm.

A few comments state that treating *trans* fats the same as saturated fat on labeling would be the same as proposing to require false information on labels. Such an outcome, the comments state, would be indefensible on Constitutional grounds. One comment states that mandatory declaration of *trans* fat can only be justified under constitutional provisions when the absence of such declaration would constitute an omission of a material fact.

FDA believes that this regulation is consistent with the first amendment. As noted previously, the failure to disclose the amount of *trans* fat in a product is an omission of material fact. When a manufacturer makes explicit or implicit health claims, the failure to provide *trans* fat information is likely to mislead the consumer. Moreover, the reasonable consumer would expect that the information on the label would give them the most important nutrition information relative to the healthfulness of a product. Yet the omission of *trans* fat runs counter to that expectation, impeding rational consumer choice. As the agency has explained earlier, consumers need information about *trans* fat on all foods, not just those that contain a certain threshold level of *trans* fat, to reduce overall intake of *trans* fat in the diet. Consumers can use that information to compare products and make selections that can reduce their risk of CHD.

Accordingly, FDA believes that this final rule passes muster under the four-part test in *Central Hudson* primarily because, as discussed previously, requiring the factual information on the amount of *trans* fat in labeling ensures that the label is not false or misleading. Under the first prong of *Central Hudson*, commercial speech must be related to lawful activity and not be misleading. Speech that is false or misleading is not protected and may be prohibited (*Central Hudson*, 447 U.S. 557 at 563–564).[2]

Given this determination, arguably the agency need not address the other three parts of the *Central Hudson* test at all. Nonetheless, and particularly in light of FDA's showing that such information is important to ensuring that consumers are adequately informed about the products they are buying, the proposed requirement satisfies the next three prongs. Turning to the second prong, the asserted governmental interest must be substantial. FDA's interest is clearly substantial, for at least two reasons. As noted previously, the FDA has a substantial interest in protecting and promoting public health and in preventing consumer deception by ensuring the accuracy and completeness of *trans* fat information in labeling. (See *Pearson*, 164 F.3d at 656.) The food labeling regulations seek to ensure that consumers have access to information about food that is scientifically valid, truthful, reliable, and not misleading. (58 Fed. Reg. 2478, 2526 (1993)). Consumers have a first amendment interest in obtaining information on which to base a decision, particularly one that has health consequences, regarding whether to buy a product, and this interest is ''served by insuring that the information is not false or deceptive.'' (*National Comm'n on Egg Nutrition* v. *FTC*, 570 F.2d 157, 162 (7th Cir. 1977), *cert. denied*, 439 U.S. 821 (1978)).

Moreover, FDA has a substantial governmental interest in assisting consumers to maintain healthy dietary practices. Such interest is consistent with the purpose of section 403(q)(2)(A) of the act; to provide information to consumers on nutrients (*trans* fat content of food) when such information is of public health importance. The government is not confined to asserting a substantial government interest in preventing consumer deception for a regulation before that regulation can sustain a first amendment review (*Rubin* v. *Coors Brewing Co.*, 514 U.S.476, 484–

[2] The agency does not need to address the comments that asserted that proposing to treat *trans* fat the same as saturated fat in the November 1999 proposal would be the same as requiring false labeling. Since the agency is requiring separate line labeling in this final rule, those comments are moot.

85 (1995) (finding that the protection of the health, safety, and welfare of citizens is a substantial government interest)). In fact, FDA's interest in this rule includes an interest in ensuring consumers have information they need to help them maintain healthy dietary practices by providing factual information to consumers on food labels so that they can reduce CHD risk.

Under the third prong of *Central Hudson*, the regulation must directly advance the government's interest asserted (*Central Hudson* 447 U.S. 557 at 566). Requiring mandatory *trans* fat labeling on food products directly advances the government interest. As stated in section V.A of this document, analyses of survey data show that consumers rely on the Nutrition Facts label as a guide to choosing foods that meet their dietary objectives. The most frequently reported label use and the one that increased the most following the implementation of the 1990 amendments was to see how high the food was in nutrients such as fat. Mandatory *trans* fat labeling would help consumers maintain healthy dietary practices because it would provide needed information about the amount of *trans* fat in a given product so that consumers could plan a daily diet in a way that would reduce their intake of *trans* fat. Further, as stated in section V.A of this document, consumers need to be able to see the *trans* fat content of all foods subject to mandatory labeling so that they can compare the relative contribution of *trans* fat from each and make purchasing decisions accordingly.

Finally, under the fourth prong of *Central Hudson*, the regulation must be no more extensive than necessary to serve the government interest (*Central Hudson* 447 U.S. 557 at 566). That is the case here. Given, as stated in section V.A, that consumers need to understand the relative contribution of *trans* fat from all foods subject to mandatory labeling to make choices among products that will reduce their intake of *trans* fat, there are not ''numerous and obvious less-burdensome alternatives'' (*Cincinnati* v. *Discovery Network*, 507 U.S. 410, 418 n.13 (1993)) than the requirement imposed here. Imparting truthful, factual, noncontroversial information about the presence or absence and amount of *trans* fat in food products on the label will provide consumers with information to help them to reduce their risk of CHD. Thus, the agency's action to require factual information be imparted to consumers about *trans* fat content of foods by requiring such information in labeling is sufficiently narrowly tailored to meet the fourth prong of *Central Hudson*. The ''government is not required to employ the least restrictive means conceivable'' rather it is required to have '''a fit that is not necessarily perfect, but reasonable; that represents not necessarily the single best disposition but one whose scope is in proportion to the interest served''' (*Greater New Orleans Broadcasting Ass'n, Inc.* v. *U.S.*, 527 U.S. 173 at 177 (citing *Board of Trustees of State Univ. of N.Y.* v. *Fox*, 492 U.S. 469, 480 (1989))). Requiring disclosure of *trans* fat content would assist consumers to maintain healthy dietary practices, provide complete, factual information on a food label to help them to reduce *trans* fat intake and thereby reduce their risk of CHD. Further, it would prevent them from being misled by providing information on *trans* fat that can help them make product comparisons and choose products that are heart healthy.

The agency disagrees with the suggestion that narrow tailoring under the fourth prong of *Central Hudson* requires that *trans* fat content be included in the figure for total fat content. Such an approach would not provide consumers with labeling information on the amount of *trans* fat in a product. To provide consumers with a way to calculate the amount of *trans* fat in a product, all other fats (including monounsaturated and polyunsaturated fats) would be required to be on the label. The comment provided no basis for why monounsaturated fat and polyunsaturated fat should be made mandatory, why it would make sense for consumers to have to calculate the value for *trans* fat content from each label under the statutory scheme in section 403(q)(2)(A) of the act, and why such an approach would be less burdensome under the fourth prong of *Central Hudson* to support its assertion.

Moreover, there is a substantial argument that the agency need not satisfy the *Central Hudson* test because that test applies to prohibitions on speech, and not compelled commercial speech, which is at issue here. Although consumer curiosity alone is an insufficient interest to compel factual speech (*International Dairy Foods Ass'n* v. *Amestoy*, 92 F. 3d 67, 74 (2nd Cir. 1996)), the government can compel manufacturers to disclose information that ''bears on a reasonable concern for human health or safety or some other sufficiently substantial government concern.'' Id. FDA's rule to require mandatory *trans* fat labeling is one that would require manufacturers to disclose such information.

Further, the U.S. Court of Appeals for the second circuit upheld a regulation compelling speech where the goal of the statute was to reduce the amount of mercury released into the environment; a goal that was ''inextricably intertwined with the goal of increasing consumer awareness of the presence of mercury in a variety of products'' (*National Electrical Manufacturer's Ass'n* v. *Sorrell*, 272 F. 3d 104, 115 (2d Cir. 2001)). FDA is providing information that will assist consumers to maintain healthy dietary practices and prevent consumers from being misled if incomplete nutrition information on *trans* fat were provided on the food label, i.e., information that did not include the presence or amount of *trans* fat in foods. Similar to the goal the State of Vermont has in increasing awareness of consumers to prevent the harmful consequences of mercury containing products entering the environment, FDA wants to prevent the harmful consequences (increased risk of CHD) to consumers from *trans* fats. Thus, the agency's action to require *trans* fat labeling in this rule comports with similar actions in other compelled commercial speech cases which have been upheld under the first amendment.

For all of the foregoing reasons, the agency believes it has complied with its burdens under the first amendment to support mandatory disclosure of the amount of *trans* fat in food labeling. The information that FDA is requiring in food labeling for *trans* fat, i.e., the amount of *trans* fat listed in grams or an optional footnote stating ''Not a significant source of *trans* fat'' if zero grams are present, is purely factual information. FDA's action to compel *trans* fat labeling does not ''prescribe what shall be orthodox in politics, nationalism, religion, or other matters of opinion or force citizens to confess by word or act their faith therein.'' Rather, it simply provides for factual and uncontroversial information that can be supported if such labeling is reasonably related to FDA's government interests (*Zauderer*, 471 U.S. at 650–51 (distinguishing between the level of review necessary under the first amendment where factual and uncontroversial information is required and recognizing that the constitutionally protected interest in not providing such information is minimal); see also *Glickman* v. *Wileman Brothers & Elliott, Inc.*, 521 U.S. 457, 472 (1997) (distinguishing compelled financial contributions that promote speech to encourage consumer purchases from speech in which the content of the message focuses on political or ideological differences). FDA's interests in requiring mandatory *trans* fat labeling

is to protect the public health by providing consumers with information that will assist them in maintaining healthy dietary practices and by preventing misleading labeling by providing factual, truthful, and noncontroversial information.

Providing information to consumers about the *trans* fat content of foods on food labeling is reasonably related to the agency's interest of assisting consumers to maintain healthy dietary practices. As explained in section IV of this document, there is a relationship between the level of *trans* fat in the diet and risk of CHD. To reduce this risk, consumers need information about the level of *trans* fat in food products. The agency has evidence that consumers refer to product labels when purchasing food products and use labels to determine how much fat is in a product (Ref. 96). Thus, by requiring that *trans* fat information be on a food label, the agency will be assisting consumers in making food purchasing decisions that can result in a reduction in *trans* fat intake so that they can reduce their risk of CHD. Moreover, because the presence or absence of *trans* fat is a material fact under section 201(n) of the act, as explained earlier, mandatory labeling that provides information about the presence or absence of *trans* fat, and if present, at what levels, is a reasonable means for imparting full, factual information to consumers so that they will not be misled in purchasing decisions because they have no information about *trans* fat content and may not even be able to calculate it based on information on other fats on the label.

The agency has carefully considered the limitations imposed by the first amendment to avoid unjustified burdens and costs of food labeling where there is no genuine public health benefit from the rule that does not alleviate a harm of potential consumer deception. The agency did carefully calculate the costs and benefits of food labeling (see section IX of this document) and determined that the scope of mandatory *trans* fat labeling was in proportion to the government interest served. *Cincinnati* v. *Discovery Network, Inc.*, 507 U.S. 410 (1993) (stating that a regulation ''should indicate that its proponent 'carefully calculated' the costs and benefits associated with the burden on speech imposed by its prohibition'' (quoting *Fox*, 492 U.S. at 480)). Moreover, the agency has documented that there is a public health benefit to the final rule. To the extent that those who commented ''believe that their money is not being well spent, 'does not mean that they have first amendment complaint.''' *Glickman*, 521 U.S. at 472.

Administrative Procedure Act

One comment asserts that FDA must adopt regulations that are supported by the rulemaking record and that are not otherwise arbitrary and capricious in light of the statutory limitations on the agency's authority. This comment and another assert that the data do not support a basis for treating *trans* fat and saturated fat the same either chemically or for purposes of one's health, and that therefore, FDA is proposing to require food labels that provide false information. One comment said that to equate *trans* fat and saturated fat on the existing body of evidence would be arbitrary and capricious in violation of the APA. Another comment asserts that FDA did not account for legal and policy considerations that are necessary to construct an appropriate *trans* fat regulatory framework and thus, does not have a rulemaking record that satisfies the agency's burden of proof under the APA. The comment seemed to relate deficiencies in the record necessary to satisfy first amendment requirements to a failure to satisfy APA requirements. One comment asserts that the rulemaking record for FDA's proposal does not support the expansive scope of the mandatory *trans* fat labeling proposal, and therefore, fails to satisfy the requirements of the APA. The comment states that the body of scientific evidence did not establish a genuine ''harm'' from *trans* fat consumed at ordinary intake levels from foods that would be subject to the mandatory labeling requirements.

To the extent that comments were raising concerns about the agency going to a final rule based on including *trans* fat in the amount and % DV for saturated fat and that doing so would be the same as requiring false information on labels, those comments are now moot since the agency is requiring a separate line for labeling *trans* fat. FDA disagrees with the comment that suggests that FDA did not account for legal and policy considerations necessary to construct an appropriate *trans* fat regulatory framework, and that the rulemaking record does not support the scope of this rule. As stated previously, the agency is using the statutory framework that Congress provided in section 403(q)(2)(A) of the act to require mandatory *trans* fat labeling. Further, the agency has explained its rationale, based on the science, for why it believes that it is necessary for consumers to have information on the *trans* fat content of foods to maintain healthy dietary practices. To the extent that the comments assert that the body of scientific evidence did not establish a ''harm'' from *trans* fat consumed at ordinary intake levels from foods, and thus, would preclude the agency from requiring mandatory *trans* fat labeling under the APA, the agency disagrees. The science supports adverse health effects from consumption of *trans* fat among a range of intakes that includes intakes at average intake levels among the U.S. population (see section IV of this document). That said, mandating the disclosure of this information does not require FDA to find that *trans* fatty acids actually cause CHD. In mandating the disclosure of this information, FDA need not meet the standard of proof required to establish causation in a private tort action (*Glastetter* v. *Novartis Pharmaceutical Corp.*, 252 F.3d 986, 991 (8th Cir. 2001)).

> ''The distinction between avoidance of risk through regulation and compensation for injuries after the fact is a fundamental one. In the former, risk assessments may lead to control of a toxic substance even though the probability of harm to any individual is small and the studies necessary to assess the risk are incomplete; society as a whole is willing to pay the price as a matter of policy. In the latter, a far higher probability (greater than 50 percent) is required since the law believes it is unfair to require an individual to pay for another's tragedy unless it is shown that it is more likely than not that he caused it * * *.''

In re ''Agent Orange'' Product Liability Litigation, 597 F. Supp. 740, 781 (E.D.N.Y.) 1984), *aff'd* 818 F. 2d 145 (2d. Cir. 1987). In making its decision, the agency follows ''the preventive perspective that agencies adopt in order to reduce public exposure to harmful substances.'' *Glastetter*, 252 F. 3d at 991, quoting *Hollander* v. *Sandoz Pharmaceuticals Corp.*, 95 F. Supp. 2d 1230, 1234 n.9 (W.D. Okla. 2000). Accordingly, so long as we conclude that the consumer would reasonably expect this information to be disclosed and that it is scientifically justifiable to require its disclosure, we are justified in taking this action.

The agency has determined, based on this scientific evidence, that consumers need this information to maintain healthy dietary practices. Thus, the agency is not precluded under the APA, as the comment suggests, from issuing this final rule. In addition, the agency has discussed why it believes that this final rule comports with the first amendment, and thus, disagrees with the comment that suggests that because it did not meet its burdens under the first amendment, it did not satisfy the APA requirements.

IV. Review of the Science

A. Reviews by the Federal Government and the Institute of Medicine (IOM)/ National Academy of Sciences (NAS)

In the November 1999 proposal, FDA reviewed reports published by the U.S. Federal government and the IOM/NAS. These reports, which were published between 1988 and 1995, showed that conclusions about the role of *trans* fat in raising LDL–C, the primary risk factor for CHD, and dietary recommendations were evolving as results from new studies became available (64 FR 62746 at 62749). For example, the 1988 Surgeon General's Report (Ref. 2) and the 1989 IOM/NAS Report (Ref. 4) found no adverse effects of *trans* fat. Later, the 1993 publication from the NCEP stated that ''*trans* fatty acids raise LDL–C levels nearly as much as do cholesterol-raising saturated fatty acids'' (Ref. 5). The fourth edition of Dietary Guidelines for Americans, a joint 1995 publication from the U.S. Department of Health and Human Services and the U.S. Department of Agriculture (USDA) stated that, ''Partially hydrogenated vegetable oils, such as those used in many margarines and shortenings, contain a particular form of unsaturated fat known as *trans*-fatty acids that may raise blood cholesterol levels, although not as much as saturated fat'' (Ref. 6).

Subsequent to the November 1999 proposal, new expert panels have been convened to update, in light of new scientific evidence, the conclusions and recommendations in the reports discussed previously. FDA has reviewed these new reports to evaluate whether their updated conclusions reversed or significantly altered its earlier conclusions.

The Dietary Guidelines 2000 (Ref. 87) makes the following statements regarding *trans* fatty acids and food sources of *trans* fat:

> Foods high in *trans* fatty acids tend to raise blood cholesterol. These foods include those high in partially hydrogenated vegetable oils, such as many hard margarines and shortenings. Foods with a high amount of these ingredients include some commercially fried foods and some bakery goods. (Ref. 87, p. 28);
>
> Aim for a total fat intake of no more than 30 percent of calories, as recommended in previous editions of the Guidelines. If you need to reduce your fat intake to achieve this level, do so primarily by cutting back on saturated and *trans* fats. (Ref. 87, p. 30);
>
> Limit use of solid fats, such as ... hard margarines, ... and partially hydrogenated shortenings. Use vegetable oil as a substitute. (Ref. 87, p. 30).

In the report describing the basis for its recommendations, the Advisory Committee on Dietary Guidelines 2000 (Ref. 88) suggested that information be provided to help the reader of the Dietary Guidelines 2000 distinguish among the different kinds of fats—saturated, *trans*, and unsaturated. The advisory committee summarized the scientific evidence on *trans* fatty acids as follows:

> *Trans* fatty acids are included because a definitive body of recent experimental evidence indicates that *trans* fatty acids raise the concentration of the most dangerous form of serum cholesterol (LDL-cholesterol).

The advisory committee further states:

> *Trans* fatty acids also tend to lower a protective form of serum cholesterol (HDL-cholesterol). Prospective epidemiological studies further note that higher intakes of *trans* fatty acids are associated with a higher incidence of coronary heart disease. (Ref. 88, p. 37).

Recent guidelines from the National Cholesterol Education Program (NCEP) (Ref. 89) provide an update to the 1993 NCEP report (Ref. 5). The 2001 NCEP report is an evidence-based report that extensively references the scientific literature. The expert panel concluded that:

> *Trans* fatty acids raise serum LDL-cholesterol levels. Through this mechanism, higher intakes of *trans* fatty acids thus should increase risk for CHD. Prospective studies support an association between higher intakes of *trans* fatty acids and CHD incidence. (Ref. 89, p. V–15).

Based on these conclusions, the Expert Panel recommended for individuals at increased risk for CHD that:

> Intakes of *trans* fatty acids should be kept low. The use of liquid vegetable oil, soft margarine, and *trans* fatty acid-free margarine are encouraged instead of butter, stick margarine, and shortening. (Ref. 89, p. V–15).

Lastly, a recent report of the IOM/NAS found ''a positive linear trend between *trans* fatty acid intake and LDL cholesterol concentration, and therefore increased risk of CHD'' (Ref. 140). The report summarized that this would suggest a Tolerable Upper Intake Level (UL) of zero, but because *trans* fats are unavoidable in ordinary diets and achieving such a UL would require extraordinary changes in dietary intake patterns that might introduce other undesirable effects and unknown health risks, a UL was not proposed. Instead, the report recommended ''that *trans* fat consumption be as low as possible while consuming a nutritionally adequate diet.''

In summary, the recently updated Dietary Guidelines (Ref. 87), NCEP (Ref. 89), and IOM/NAS (Ref. 140) reports, based on current scientific evidence, consistently find that *trans* fatty acids are associated with increased LDL–C levels and, therefore, that lower intakes of both saturated and *trans* fatty acids are important dietary factors in reducing the risk of CHD in the general population and for those at increased risk for CHD. In addition, these new reports (Refs. 87, 89, and 140) either reversed previous scientific conclusions of no deleterious effects of *trans* fatty acids (Refs. 2 and 4), or strengthened previous scientific conclusions of an adverse effect of *trans* fat intakes on CHD risk (Refs. 5 and 6). Thus, based on the current body of scientific evidence, there is strong agreement among the expert panels that the available evidence is sufficiently compelling to conclude that *trans* fat intakes increase CHD risk. Accordingly, these expert panels recommended, in addition to their longstanding recommendations that Americans consume diets limited in saturated fat, that consumers also select food products that are low in *trans* fat. Although the expert panels' primary emphases remain on limiting intakes of saturated fat (which contributes on average about 11–12 percent of calories in U.S. diets), they also have recommended limiting intakes of *trans* fats (which contribute, on average, about 3 percent of calories in U.S. diets). These recommendations are made for the general population (Refs. 87 and 140) and persons at increased risk for CHD whose LDL–C is above goal levels (Ref. 89).

(Comment 1) Several comments on the November 1999 proposal questioned whether the conclusions regarding *trans* fat would be supported by pending scientific reviews. Some of these comments recommended that FDA not issue a final rule until after publication of Dietary Guidelines 2000. Other comments recommended waiting until the IOM/NAS completes work on a review of dietary reference values for macronutrients.

The Dietary Guidelines 2000 have been published (Refs. 87 and 88). While they do not mention *trans* fat in its broad guideline, ''Choose a diet that is low in saturated fat and cholesterol and moderate in total fat,'' the recommendations from the Dietary Guidelines 2000 and the accompanying advisory committee review clearly state that foods high in *trans* fatty acids tend to raise blood LDL–C which increases the risk of CHD. Reductions in intakes of both saturated and *trans* fats are suggested for maintaining total fat to no more than 30 percent of calories. Substitutions of foods low in *trans* and saturated fatty acids (e.g., vegetable oils) for foods with higher levels of *trans* fatty acids (e.g., hard margarines, partially hydrogenated shortenings) are also recommended. Thus, in the Dietary Guidelines 2000, the recommendations to reduce *trans* fat intake are definitive,

not tentative. Additionally, the recommendations in the Dietary Guidelines 2000 are reinforced by similar findings and recommendations from other recent expert panels (Refs. 89 through 91, and 140), including those of the IOM/NAS report on macronutrients (Ref. 140), which has also been published. The IOM/NAS report recommends that ''*trans* fat consumption be as low as possible while consuming a nutritionally adequate diet.''

(Comment 2) One comment suggested that *trans* fat is a healthier choice than saturated fat, quoting 1994 and 1998 statements that it attributed to the American Heart Association (AHA) recommending that margarine be used instead of butter and that *trans* fats displace saturated fats in the diet. The comment suggested that, if AHA or others in the scientific community recommend margarine be used instead of butter, this establishes that hydrogenated vegetable oils and *trans* fat have health benefits, at least in comparison to saturated fatty acids. Several other comments stated that *trans* fats displace saturated fats in the diet, thus implying that they are healthful alternatives to saturated fats.

FDA disagrees with the comments' conclusions that the recommendations of the AHA and other scientific bodies that margarine be substituted for butter provides a basis for concluding that *trans* fat has health benefits or is a healthier choice than saturated fats. The recently updated 2000 AHA Guidelines (Ref. 91) recommend that intakes of foods with a high content of cholesterol-raising fatty acids (i.e., *trans* and saturated fats) be limited because both raise serum LDL–C levels, and consequently, increase CHD risk. Specifically, the AHA recommends limiting the intake of: (1) Foods rich in saturated fatty acids (e.g., full-fat dairy products, fatty meats, tropical oils), and (2) *trans*-fatty acids, the major contributor of which is hydrogenated fat (Ref. 91). Relative to *trans* fat, the 2000 AHA guidelines state that, ''It has been established that dietary *trans*-unsaturated fatty acids can increase LDL cholesterol and reduce HDL cholesterol'' (Ref. 91). Moreover, the AHA recommendations are consistent with the recommendations of the other scientific bodies described earlier in this document. All of these reports recommend substituting vegetable oils for animal fats; and, within the vegetable oil category, recommend selecting those products that are lower in or free of *trans* fat (e.g., liquid vegetable oils, soft margarines, and *trans*-free margarines) in place of more hydrogenated oil products (e.g., stick margarines and shortenings). More recently, the IOM/NAS concluded that there is no evidence of health benefits associated with *trans* fat intakes, but that *trans* fat does increase LDL–C and, therefore, the risk of CHD (Ref. 140). Thus, the comment's premise that the current recommendations of the AHA and other scientific bodies support the conclusion that *trans* fat is a healthful alternative to butter and animal fats is not consistent with, nor supported by, the full context and intent of recommendations by the AHA and other scientific bodies.

Those comments that said *trans* fat is a healthful alternative to saturated fat also are not consistent with the recommendations of the AHA and other scientific bodies. These expert bodies all concluded that both *trans* and saturated fatty acids increase the risk of CHD by increasing serum LDL–C levels and, therefore, they recommended limiting intakes of both *trans* and saturated fatty acids.

It should be noted that recommendations to consume margarine instead of butter are based on the fact that the combined amount of cholesterol-raising lipids (*trans* and saturated fats) are lower in margarines than in butter (Ref. 92). Additionally, butter, unlike margarine, contains dietary cholesterol which also has cholesterol-raising effects (Ref. 139).

B. Published Studies

To evaluate the evidence that dietary *trans* fat increases the risk of CHD, FDA reviewed the scientific evidence cited in the petition and recent human studies from its own literature search. In the November 1999 proposal, FDA summarized its review of the findings of intervention and observational studies on the relationship between intakes of *trans* fatty acids and CHD (64 FR 62746 at 62749–62754). FDA considered the findings from human studies to constitute evidence that is more directly relevant and persuasive than findings from animal studies. FDA gave greater weight to results from dietary intervention studies than to observational (epidemiological) studies because of an intervention study's ability to provide evidence for a cause-effect relationship. FDA regarded results from observational studies as indirect evidence for a relationship between *trans* fatty acid intake and CHD risk. FDA also reviewed estimates of dietary intakes of *trans* fatty acids in the U.S. population (64 FR 62746 at 62752–62753).

In the November 1999 proposal, FDA evaluated results of 12 dietary intervention studies (Refs. 7 through 15, 34, 36, and 82). FDA focused on the physiological measures of serum and plasma LDL–C concentrations to evaluate whether *trans* fatty acid intakes influence the risk of CHD because such measures are recognized as valid predictors of increased risk for CHD (Ref. 5). FDA concluded that controlled intervention studies, in different population groups in the United States and other countries, consistently indicate that consumption of diets containing *trans* fatty acids, like diets containing saturated fats, results in increased serum LDL–C (a major risk factor for CHD) compared with consumption of diets containing *cis*-monounsaturated or *cis*-polyunsaturated fat sources (64 FR 62746 at 62753). The agency also compiled reports of changes in serum total and high density lipoprotein cholesterol (HDL–C) and serum lipoproteins to present a more complete picture of serum lipid changes (64 FR 62746 at 62799–62821).

In the November 1999 proposal, FDA also reviewed nine publications that examined associations between *trans* fatty acids, serum lipids and CHD endpoints: Four publications describing three prospective cohort studies (Refs. 19 through 21 and 38), one publication describing an inter-cohort study (Ref. 22), three publications describing case control studies (Refs. 16 through 18), and one publication describing a cross-sectional study (Ref. 23). FDA stated that these epidemiological investigations of associations between dietary *trans* fatty acids and risk of CHD must be interpreted cautiously because of the imprecision associated with the dietary collection methodologies used, the difficulty of eliminating confounding factors, and because no dose-response relationship has been demonstrated in the studies (64 FR 62746 at 62752). FDA also stated that despite these generally recognized deficiencies in the observational studies, the repeated and consistent findings from these studies show that consumption of *trans* fatty acids is associated with adverse effects on CHD risk in humans, which supports the findings from intervention studies (64 FR 62746 at 62752).

Thus, in the November 1999 proposal, FDA concluded that controlled intervention studies in different population groups in the United States and other countries consistently indicate that consumption of diets containing *trans* fatty acids, like diets containing saturated fats, results in increased serum LDL–C compared with consumption of diets containing *cis*-monounsaturated or *cis*-polyunsaturated

fat sources (64 FR 62746 at 62753). FDA also concluded that these findings are consonant with findings from observational studies among free-living persons in the United States and other countries (64 FR 62746 at 62753).

In the November 1999 proposal, FDA also summarized the results of estimates of dietary intake of *trans* fatty acids in the U.S. population (64 FR 62746 at 62752). FDA noted that estimates of mean consumption of *trans* fatty acids in the United States ranged from about 3 g/day to about 13 g/day. Based on national food disappearance data, estimated mean values for the daily per capita consumption of total *trans* fatty acids were variable: 12.8 g/day (Ref. 24), 10.2 g/day (Ref. 39), and 8.1 g/day (Ref. 25). Based on a nationally representative sample of the U.S. population, the estimated mean intake of *trans* fatty acids was 5.3 g/day (2.6 percent of calories) and the 90th percentile intake was 9.4 g/day for individuals 3 years of age and older in the U.S. population (Ref. 12). Estimates of mean *trans* fatty acids intake were 4.4 g/day for men and 3.6 g/day for women in one observational study in the United States (Ref. 18) and 3.4 g/day for men in another (Ref. 23). Some studies presented mean or median intakes for quintiles of the population studied. Median intakes were 3.1 g/day for men and 3.0 g/day for women in the lowest quintile and 6.7 g/day for men and 6.8 g/day for women in the highest quintile (Ref. 18). Another study reported intakes of 1.5 g/day and 5.3 g/day, respectively, for the lowest and highest quintiles of male health professionals (Ref. 19). For female nurses in the United States, mean energy-adjusted intakes of *trans* fatty acids were 2.4 and 5.7 g/day, respectively for the lowest and highest quintiles of *trans* fatty acid intakes (Ref. 21). FDA concluded that, overall, the estimates of mean *trans* fatty acids intakes are similar to intakes of *trans* fatty acids in the U.S. intervention studies (the selected intervention studies used in this comparison were those in which *trans* fatty acid contents were determined by chemical analysis of duplicate portions of the diets and for which statistically significant increases in serum LDL–C were reported compared to diets containing *cis*-polyunsaturated fatty acids (Refs. 13, 34, and 82) or *cis*-monounsaturated fatty acids (Ref. 12)). The intakes of *trans* fatty acids for which the increases in serum LDL–C were statistically significant in the intervention studies ranged from 7.6 g/day to 13 g/day (Refs. 12, 13, 34, and 82). FDA stated that these levels are very similar to the estimated intakes of the many individuals in the United States whose *trans* fatty acid intake is greater than the mean of 5.3 g/day (64 FR 62746 at 62753).

Subsequent to the November 1999 proposal, additional studies on the topic of *trans* fatty acid intakes and CHD risk have been published (Refs. 98 through 102). FDA reviewed the findings from these new studies to evaluate whether they differ significantly from the findings of studies included in the proposed rule. In general, the results from these recently published intervention and prospective studies are consistent with the results from the studies included in the November 1999 proposal in that they also found that diets containing *trans* fat increased LDL–C, and therefore, CHD risk (Refs. 98 to 101) and that, in free-living populations, consumption of *trans* fat was associated with increased risk of heart attack and death from CHD (Ref. 102). In addition, a cross-sectional observational study has been published (Ref. 93). This study, which was the subject of several comments, suggests no relationship between current intakes of *trans* fat in European countries and CHD risk. FDA has addressed this study in Comment 4 of this document.

(Comment 3) Many comments discussed the strength of the scientific evidence for establishing whether *trans* fatty acids adversely affect CHD risk by raising LDL–C levels. A number of comments found the evidence to be strong and supportive of *trans* fatty acid labeling on foods. Other comments questioned whether there was sufficient evidence to warrant labeling of *trans* fat content. Several comments stated that the health impact of the intake levels reported in population-based surveys and observational studies was minimal.

A few comments to the November 15, 2002, proposal to reopen the *trans* fat comment period questioned the scientific validity of the IOM/NAS report based on the underlying science and regression equations relied upon. The comments argued that one of the articles relied upon (Ref. 83) was an opinion essay and was not peer-reviewed by the *New England Journal of Medicine* (NEJM) where it was published.

Based on an evaluation of the scientific evidence, FDA concludes that the scientific evidence is sufficient to require nutrition labeling of *trans* fat. In the November 1999 proposal, FDA systematically summarized and reviewed the available individual human studies (64 FR at 62749–62754 and 62798 to 62821). In re-examining this review in light of the comments, FDA finds no basis to alter its earlier conclusion that, in general, there is consistency in finding adverse effects of *trans* fat on CHD risk. Controlled intervention studies in different population groups in the United States and other countries consistently indicated that consumption of diets containing *trans* fat results in elevations of LDL–C, and therefore, increased risk of CHD (Refs. 7 to 15, 34, 36, and 82). In addition, positive statistical associations are consistently reported in observational studies between estimated *trans* fat intake in free-living populations and incidence of CHD manifested as heart attack or death from CHD (Refs. 16 to 22, and 38) or increased risk of CHD as assessed by higher levels of LDL–C (Ref. 23) (64 FR 62751 to 62753). Thus, FDA continues to find that a large body of the most persuasive types of evidence (i.e., intervention trials and prospective cohort observational studies) consistently show that *trans* fat intakes adversely affect CHD risk under both controlled trial conditions and in free-living populations following their usual dietary patterns. This consistency was seen across studies done: (1) In the United States and several European countries, (2) using a variety of test and control products and study designs, (3) using a range of intake levels for *trans* fatty acids (less than (<) 1 percent to 7 percent of calories), (4) by different investigators and research groups, (5) with different populations and selection/exclusion criteria, and (6) within different total dietary contexts. This relationship was also consistently found in comparisons of high vs. low consumers of *trans* fats in free-living U.S. populations consuming their normal diets. Thus, whether controlled intervention trials or among free-living U.S. populations consuming their usual diets, the adverse effects of *trans* fat intakes on CHD risk were consistently observed.

Moreover, FDA's conclusions were consistent with those of independent Federal Government expert panels that published dietary recommendations for U.S. population groups subsequent to publication of the November 1999 proposal (Refs. 87 and 89 through 91) that were cited in the **Federal Register** to reopen the comment period on November 15, 2002. These expert panels, reviewing the same scientific evidence as FDA described in the proposed rule, and given their knowledge of U.S. dietary patterns, consistently concluded that *trans* fat intakes are associated with increased CHD risk and recommended that U.S.

consumers and those who need to lower their LDL–C level minimize their intakes of *trans* fat to reduce their risk of CHD. For example, the IOM/NAS noted ''a positive linear trend between *trans* fatty acid intake and total and LDL–C concentrations, and therefore, increased risk of CHD, thus suggesting an upper limit of zero'' (Ref. 90). However, they further stated that, because *trans* fatty acids are unavoidable in ordinary diets, a complete avoidance of these fats is not possible without extraordinary changes in patterns of dietary intake. Such extraordinary adjustments may introduce other undesirable effects (e.g., elimination of foods such as diary products and meats that contain *trans* fatty acids may result in inadequate intakes of protein and certain micronutrients). For these reasons, the IOM/NAS recommended that *trans* fatty acid consumption be as low as possible while consuming a nutritionally adequate diet. In response to the comments about the scientific validity of an article used in the IOM/NAS report, FDA notes that the paper by Ascherio and coworkers (Ref. 83) is not the only information that the IOM/NAS relied on to conclude that *trans* fatty acid consumption should be as low as possible relative to CHD risk. Moreover, FDA did not find the LDL/HDL cholesterol ratio used in the Ascherio et al. analysis to be a useful endpoint for purposes of the *trans* fatty acid rule-making (see Comment 10). Additionally, FDA's independent evaluation of the scientific evidence concluded that there is consistency in finding adverse effects of *trans* fat on risk of CHD. Therefore, even though the independent reviews of FDA and the other expert panels differed to some degree in how they used the available scientific evidence, the resultant consistency of the conclusions across these reviews provides strong credence to the finding that *trans* fatty acid consumption increases CHD risk via increases in LDL–C.

In summary, based on the consistent results across a number of the most persuasive types of study designs (i.e., intervention trials and prospective cohort studies) that were conducted using a range of test conditions and across different geographical regions and populations, the agency now agrees with the comments that stated that the available evidence for an adverse relationship between *trans* fat intakes and CHD risk is strong. FDA also finds the results from the large prospective cohort studies among free-living U.S. population groups to be persuasive evidence that the *trans* fat intakes associated with U.S. dietary patterns can have a significant adverse effect on CHD risk for U.S. consumers. The scientific agreement for this relationship among the various expert groups and consensus among these expert groups in recommending that U.S. consumers limit their intakes of saturated and *trans* fats now provide further evidence of the strength of the science and the public health importance of lowering *trans* fat intakes for U.S. consumers. Therefore, the comments do not persuade FDA to change its position in the proposed rule that labeling of *trans* fatty acids is warranted based on: (1) The scientific evidence; and (2) the public health importance of the guidelines recommending that consumers limit their intakes of both of the LDL–C-raising fats: *trans* and saturated fats. Thus, FDA concludes that its tentative conclusion in the proposed rule that ''under conditions of use in the United States, consumption of *trans* fatty acids contributes to increased serum LDL–C levels, which increases the risk of CHD'' (64 FR 62746 at 62754) is no longer tentative. FDA continues to find the overall weight of scientific evidence in support of this conclusion to be sufficiently compelling to now warrant *trans* fatty acid labeling.

(Comment 4) Several comments stated that a new observational study by van de Vijver et al., ''Association between *trans* fatty acid intake and cardiovascular risk factors in Europe: The *trans*FAIR Study'' (Ref. 93) showed no association between average total *trans* fat intake in Europe and LDL–C or HDL–C so that average *trans* fat intake in the United States is probably not detrimental to human health.

FDA disagrees with the comments. The *trans*FAIR study had a cross-sectional design, measuring *trans* fatty acid intake and serum lipids in 327 men and 299 women, ages 50 to 65 years, in 8 European countries from approximately 1997 to 1999. The study reported no statistically significant association between total *trans* fat intake and serum LDL–C. The habitual intake of *trans* fat was estimated to be about 2 g/day (e.g., approximately 1 percent of calories).

FDA notes that cross-sectional designs, such as the one used by van de Vijver et al., are relatively weak designs for showing associations between diet and serum lipids (Ref. 93). As an observational study, they are generally considered to be less persuasive than intervention trials. Moreover, compared with other types of observational studies (e.g., prospective (cohort) observational studies and retrospective (case-control) studies), they are considered particularly weak. Considering the weaknesses of the cross-sectional design used in the *trans*FAIR study compared with the much larger body of evidence from more persuasive types of studies (i.e., intervention trials and prospective observational studies) that consistently demonstrate an adverse effect of *trans* fat intakes on LDL–C, FDA does not find the *trans*FAIR study to be sufficiently compelling to override the overall weight of the scientific evidence reviewed in the November 1999 proposal or to override the independent conclusions of recent expert panels convened by the Federal Government (Refs. 87 and 89), the IOM/NAS (Ref. 90), and the AHA (Ref. 91).

For the reasons cited previously, FDA disagrees with the comments that a lack of association between *trans* fat intake and serum lipids in the European *trans*FAIR study indicates that average *trans* fat intake in the United States is probably not detrimental to human health.

(Comment 5) Many comments emphasized the inadequacies in the assessment of intakes of *trans* fatty acids by the U.S. population and noted that the current data are insufficient in regard to the *trans* fatty acid content of foods. One comment noted that USDA's data for the *trans* fatty acid content of foods are limited to a few foods with a small number of samples. Thus, the comment concluded that extrapolation of *trans* fatty acid content from a few foods must be used to estimate the content of *trans* fat in the large number of foods that make up the total diets of the U.S. population. This extrapolation results in intake estimate errors with unknown effects. Some comments assert that the data are an over-estimate of the U.S. population's *trans* fatty acid intake and other comments assert that the data are an under-estimate.

FDA agrees that estimates of dietary intakes of *trans* fat, as with all intake estimates based on participant reports and limitations in compositional data bases, are subject to multiple sources of error. In the November 1999 proposal, the agency reviewed intake estimates from three different types of data: (1) National food consumption survey, (2) national disappearance data, and (3) observational studies done in U.S. population groups. By examining results from multiple methods of estimating intakes, the agency was able to assess some, but not all, of the uncertainties in current intake estimates. In discussing these data, FDA noted the very limited composition data available for the *trans* fatty acid composition of foods and the difficulties in determining the accuracy

of reported *trans* intakes with current knowledge and methods (64 FR at 62752–62753).

In the November 1999 proposal, FDA reviewed an analysis that used the results of the 1989–1991 Continuing Survey of Food Intakes by Individuals (CSFII), a national food consumption survey of the U.S. population conducted by the USDA (Ref. 26). This study reported a mean *trans* fatty acid intake of 5.3 g/day (2.6 percent of calories) for persons 3 years and older. One way to evaluate the accuracy of survey intake estimates is to compare the reported caloric intakes to known requirements, or to levels from intervention trials that have been shown to maintain body weight for some period of time. The authors of this study stated that these reported caloric intakes were 20–40 percent below known physiologic requirements, suggesting significant under-reporting of intakes (Ref. 26). The reported caloric intakes in the CSFII were also approximately 265 to 1,000 calories/day below levels required to maintain body weights for U.S. subjects in intervention trials (Ref. 26). Therefore, the estimates of intakes from the CSFII survey data are likely significantly under-reported, particularly when expressed on a gram per day basis.

The second type of *trans* fatty acid intake estimate considered in the November 1999 proposal was derived from estimates of *trans* fatty acids available in the U.S. food supply calculated from USDA-Economic Research Service fats and oils production figures and food disappearance data for fats and oils. Three studies provided daily per capita estimates of *trans* fatty intakes of 12.8 g, 10.2 g, and 8.1 g. (Refs. 24, 39, and 25, respectively). Although all three estimates were ''corrected'' for losses due to waste in processing and use, per capita intake estimates based on disappearance data generally overestimate intakes (Ref. 4).

Finally, observational studies conducted in U.S. populations also can provide intake estimates. In the November 1999 proposal, FDA reviewed several observational studies, including several prospective cohort studies conducted in U.S. populations who were healthy at the time of enrollment (Refs. 19, 21, and 38). Estimates of daily *trans* intakes ranged from 1.3 to 3.2 percent of calories and from 1.5 to 6.4 g/day for adult participants in these studies. These ranges of intake estimates are somewhat lower than those in the CSFII survey so are therefore also likely underestimated. However, even with these relatively low intake estimates, these studies found that among free-living adults, those adults consuming *trans* fatty acids at the highest quintiles of intake had increased relative risk of CHD as compared to adults consuming *trans* fatty acids at the lowest quintiles of intake.

In summary, the different types of studies, and different studies within a study type, estimated different intake levels for the U.S. population. The estimates from the food disappearance data are likely overestimated. The estimates from the observational studies and the national food consumption survey are likely underestimated. All estimates used the same compositional data base which, as noted above, has very limited data on the *trans* fat content of foods. Although we have no external ''gold standard'' against which to determine which estimate is most accurate, the available intake estimates suggest that average intakes of U.S. consumers probably fall within the range of 1.3 g to 12.8 g/day.

Because of the multiple sources of uncertainty in intake estimates, caution must be exercised to avoid over-interpretation of the available dietary intake estimates and their relationship to the *trans* fat levels used in the intervention trials. It is important to note, however, that the agency's determination of the scientific basis for and public health importance of *trans* fat labeling was based on the totality of the scientific evidence. In this evaluation, FDA weighted the results of the intervention trials most heavily. The intervention trials clearly demonstrate, in a cause and effect manner, an adverse effect of *trans* fat intakes on LDL–C levels, and therefore on CHD risk, across a broad range of intakes (less than 1 percent to 7 percent of calories), dietary patterns, and population groups. For the purposes of determining that the scientific evidence was sufficient to conclude that *trans* fat labeling was warranted from a public health perspective, FDA finds that the intervention and observational studies provided strong evidence of both a causal relationship between *trans* fat intake and risk of CHD and applicability to the general U.S. population. Therefore, FDA does not need to rely solely on dietary intake estimates to make this determination.

Because of the serious public health consequences of CHD in the U.S. population, prudent public health dictates that we help consumers control those risk factors which they can alter directly through their own behavior. Heart-healthy diets that limit the intakes of both saturated and *trans* fats can serve this purpose as is evidenced by recommendations in the recent expert panel reports (Refs. 87, 89 through 91, and 140).

(Comment 6) Many comments addressed the issue of the relevance of intervention study intakes to usual conditions of use in the United States. Some comments expressed concern that FDA's conclusions relied on intervention studies in which the intakes of *trans* fatty acids were very high and not representative of U.S. intakes of about 5.3 g/day (3 percent of calories).

FDA disagrees with the comments that it relied heavily on intervention trials with high *trans* fat intake. A range of fatty acid intakes was included in the dietary intervention assessments. For example, the four U.S. research investigations with chemical analyses of the diets included a total of 15 study diets (Refs. 12, 13, 34, and 82). These studies included diets with little or no *trans* fat (e.g., 0.4 to 0.6 percent of calories), diets that contained moderate levels of *trans* fat (e.g., 3 to 4 percent of calories), as well as diets with a higher intake of *trans* fat (e.g., 6 to 7 percent of calories). FDA relied on the totality of the evidence, i.e., intervention studies that had *trans* fat intakes that ranged from very low levels (less than 1 percent of calories) to intakes up to 6 to 7 percent of calories and on findings from observational studies that showed an adverse relationship between *trans* fat intakes and CHD risk among U.S. population groups consuming their usual diets.

Thus, in the aggregate, the U.S. intervention studies included an assessment of the effect of a wide range of *trans* fatty acid levels that overlap the range of intake estimates for the U.S. population. As noted in FDA's response to Comment 5, the relevance of the findings from the intervention studies for the U.S. population are shown by the consistent findings of an adverse relationship between *trans* fat and CHD risk in the prospective studies of free-living U.S. population groups. Thus, the relevance of the *trans* intakes used in the intervention studies for the U.S. population was confirmed by the consistent findings in the prospective studies that showed an adverse association between *trans* intake and CHD risk among free-living U.S. population groups. The recommendations of recent expert panels that Americans limit their intakes of *trans* fat shows that a broad-based scientific agreement exists as to the public health merits of *trans* fat labeling for the U.S. population within the context of current dietary intakes.

(Comment 7) Other comments suggested that the study populations were not representative of the U.S. population. For example, one comment said that the intervention studies included individuals at high risk with serum cholesterol levels greater than (>) 320 milligrams (mg)/deciliter (dL) or LDL–C > 130 mg/dL. Another comment stated that the agency failed to reflect that relative risk will depend on the base risk of the population used for comparisons with the U.S. general population.

FDA disagrees with these comments. Of the 512 subjects included in the dietary intervention studies cited in the November 1999 proposal, 48 percent of the dietary intervention population had an LDL–C level of 100 to 120 mg/dL that is categorized as near or above optimal level according to the NCEP lipid classification scheme (Ref. 89). Thirty-eight percent had an LDL–C of 130 to 159 mg/dL, categorized as borderline high; and 14 percent had a LDL–C of greater than or equal to (≥)160 mg/dL, categorized as high. Only 5 percent of the participants had a low HDL–C level, < 40 mg/dL; and another 7 percent had a high HDL–C level, ≥60 mg/dL. Most (88 percent) had mean HDL–C levels in the range of 41 to 59 mg/dL. Also, 73 percent of the population was in the age group where the CHD risk is lower, e.g., men <45 years of age and women <55 years of age. The study populations were described as participants who had normal cardiac, kidney and liver function, and were not taking medications that affect lipid levels. Many participants had near or optimal LDL–C levels and most had HDL–C levels that were neither high nor low by the NCEP criteria. The data that FDA relied on included a dietary intervention population that is representative of the U.S. general population.

(Comment 8) Some comments suggested that the test products were not representative of available commercial products in the U.S. marketplace. One comment suggested that several studies were designed to study the effects of different food oil sources and not designed to specifically study the effect of *trans* fat on blood lipid levels.

FDA disagrees with these comments. In general, the test products used in studies done by U.S. research groups were either commercially available products or were produced specifically for a study by U.S. manufacturers using oil sources commonly used in the U.S. market (Refs. 12 through 15, 34, and 82). However, regardless of whether studies used products typical of those commercially available in other countries, products commercially available in the United States, or products developed specifically for the study at hand, results were generally consistent across all these studies and consistent with the larger body of evidence that included studies done in Europe and with European oils. That is, there was consistency across studies in finding that higher intakes of *trans* fat resulted in increased levels of LDL–C and, therefore, in increased risk of CHD. Moreover, the observational studies in U.S. populations, where participants were consuming products commercially available in the U.S. marketplace, also consistently showed that higher intakes of *trans* fat were associated with adverse effects on CHD risk (Refs. 19, 21, and 38).

FDA also recognizes that the intervention studies were designed with a variety of objectives in mind. Some were designed to compare two different sources of hydrogenated oils (e.g., Refs. 9, 14, 15, and 36). Many were designed to compare the effects of different types of fatty acids by varying the source oils to achieve the desired fatty acid types and levels (e.g., Refs. 7, 8, 10, 11 through 13, and 34). The study designs also varied significantly in how they identified controls for the comparisons of interest. Despite these differences in objectives and study design, the general consistency across studies in finding that *trans* intakes are adversely related to CHD risk provides evidence that the relationship is likely real and not simply an artifact of a particular type of study design (Ref. 94).

Thus, most of the intervention trials provide enough information about test products, study population, and study diets to evaluate their relevance to the U.S. general population. The wide range of *trans* fatty acid intakes, products, and population characteristics in these studies overlaps with those found for U.S. consumers in the general population. Important, however, is that there is remarkable consistency across the intervention studies, regardless of population, products and diets used, in finding that higher intakes of *trans* fatty acids are associated with increased levels of serum LDL–C, a major risk factor for CHD. Thus, the available intervention studies show consistent results across a broad range of use conditions and population characteristics. FDA, therefore, disagrees with comments that suggest that the test products used in intervention studies are not applicable to the U.S. marketplace, or the study designs are not applicable to evaluating the relationship of *trans* fat to CHD risk in the U.S. population.

(Comment 9) Many comments questioned whether the scientific evidence shows that the physiological effects of *trans* fat on CHD risk are equivalent to, greater than, or less than those of saturated fat on a gram-for-gram basis. Some comments noted that the intervention studies show that the increase in LDL–C levels associated with *trans* fat is greater than that from unsaturated fats but less than that from saturated fat. Some comments noted that in the review of science for the November 1999 proposal, FDA concluded that the available studies do not provide a definitive answer to the question of whether *trans* fatty acids have an effect on LDL–C and CHD risk equivalent to saturated fats on a gram-for-gram basis, but in the preliminary regulatory impact analysis, FDA estimated that the effects of saturated and *trans* fatty acids on LDL–C levels are about equivalent.

FDA notes that the intervention studies demonstrate that the net physiologic effect of a particular fatty acid or category of fatty acids is dependent upon the composition of both the intervention diet and the comparison diet. In the dietary intervention research reviewed, the study investigators used a variety of study designs to assess the effect of a defined quantity of *trans* fatty acids (provided by food sources of hydrogenated oil) on levels of serum or plasma lipids. The best study designs controlled the variation in the ranges of protein, fat, cholesterol, and carbohydrate with particular attention given to the fatty acids. The effect of *trans* fat study diets were compared by replacement with food sources of: (1) *Cis*-unsaturated fatty acids, (2) monounsaturated (oleic) fatty acids, and (3) saturated fatty acids. As FDA stated in the November 1999 proposal (64 FR 62745 at 62750), the intervention study data showed the following: (1) *Trans* fatty acids increased LDL–C in comparison with *cis*-polyunsaturated fatty acids (Refs. 8, 13, 15, and 82); (2) *trans* fatty acids increased LDL–C levels in comparison with *cis*-monounsaturated fatty acids (Refs. 7, 11 and 12); and (3) *trans* fatty acids increased LDL–C, or there was no significant difference, in comparison with saturated fatty acids (Refs. 7 through 12). Based on these results, FDA concluded in the science review section of the November 1999 proposal that the available studies do not provide a definitive answer to the question of whether *trans* fatty acids have an effect on LDL–C and CHD risk equivalent to

saturated fats on a gram-for-gram basis. However, FDA also stated that the studies that compared a saturated fat diet with a diet in which some of the saturated fat was replaced with *trans* fat showed that *trans* fat, like saturated fat, increases LDL–C.

For purposes of its regulatory impact analysis in the proposal, FDA needed a basis for quantifying its estimates of the compliance costs and benefits associated with given changes in *trans* fat intakes and the associated changes in CHD risk. The available evidence always presents some uncertainty for these types of analyses, as there is with other inputs into regulatory decisions. Given these caveats, FDA, in order to develop the tools required for a quantitative evaluation of benefits and costs, reviewed a meta analysis of five intervention trials that included six levels of *trans* fat intakes (Refs. 62 and 69). Using multiple regression to statistically control for differences in other fatty acids between *trans*-enriched diets and reference diets, the authors projected linear increases in LDL–C as a function of level of increasing *trans* fat intake. According to the regression equations, each additional percent of energy from *trans* fat, when substituted for the same percent of calories from *cis*-monounsaturated fatty acids, was predicted to increase LDL–C by 1.5 mg/dL. This relationship was then used as the basis for estimating the benefits and costs of the proposed rule and not for purposes of establishing whether there is a gram-for-gram relationship between *trans* and saturated fatty acids on LDL–C levels and CHD risk. FDA notes that, in rulemaking to implement the 1990 amendments, the agency also found it necessary to use coefficients derived from regression equations to estimate the benefits and costs of various regulations (56 FR 60856, November 27, 1991; 58 FR 2927, January 6, 1993). In one such analysis, FDA used the equation of Hegsted and Keys to predict how changes in total serum cholesterol would be affected by projected changes in saturated fat intake (56 FR 60856 at 60869, November 27, 1991). Because the Hegsted and Keys equations did not include coefficients for *trans* fat or information on components of total cholesterol (e.g., LDL–C), FDA found it necessary to find regression equations that included *trans* fat intakes and LDL–C levels. The equations of Katan et al. and Zock et al. (Refs. 62 and 69), together with the equations of Mensink and Katan (Ref. 65), which summarized the results of 27 clinical trials, were available to meet this need for a quantitative basis on which to estimate the benefits and costs of the proposed rule.

In estimating the benefits and costs, FDA also recognized that the type of macronutrient substituted for *trans* fat in the diet would affect the magnitude and nature of the changes in LDL–C in response to decreases in *trans* fatty acid intakes. Thus, FDA also estimated how the benefits and costs would be altered if saturated fat, *cis*-polyunsaturated fat or carbohydrate, rather than *cis*-monounsaturated fat, were used to replace some of the *trans* fat in the diet. In this analysis an intermediate step in the calculation showed that when saturated fat was substituted for *cis*-monounsaturated fat, LDL–C was raised by 1.52 mg/dL, an amount similar to that found when *trans* fat was substituted for *cis*-monounsaturated fat (1.50 mg/dL).

Regardless of whether FDA reviewed the effects of saturated fat and *trans* fat on LDL–C and CHD risk for the science section or the regulatory impact section, the conclusion about those effects is the same. That is, both *trans* fatty acids and saturated fatty acids raise LDL–C levels, a major risk factor for CHD risk. Consumers need to minimize their intakes of both types of fatty acids within a moderate fat intake to implement dietary guidelines for healthful diets. These conclusions are consistent with those reached independently by expert panels (Refs. 87, 89, 90 and 91).

(Comment 10) Many comments addressed the issue of the potential adverse effects of *trans* fat on HDL–C levels. Some comments suggested that *trans* fat has more adverse health effects than saturated fat because *trans* fat, in addition to raising LDL–C, also lowers HDL–C, the so-called ''good'' cholesterol, whereas saturated fat raises HDL–C. Some comments noted that *trans* fat raises the LDL/HDL ratio approximately twice as much as saturated fat. Other comments stated that, in the prospective studies, the risk of CHD associated with *trans* fat intake was much greater than the risk associated with saturated fat, and much greater than would be predicted based on the effect on serum lipids. In contrast, one comment stated that it is premature to conclude that *trans* fat intake lowers HDL–C because many intervention studies showed that *trans* fat intake causes only a small decrease or has no effect on HDL–C.

Based on the recommendations of the 1993 NCEP Expert Panel (Ref. 5), in the November 1999 proposal, FDA concluded that an examination of the effects of *trans* fatty acids on serum LDL–C would provide the strongest evidence, and should be the primary criterion, to evaluate whether *trans* fatty acids influence CHD risk. In the November 1999 proposal, FDA tentatively concluded that the available evidence demonstrated that under conditions of use in the United States, consumption of *trans* fatty acids contributes to increased serum LDL–C levels, which increases the risk of CHD. The evidence for this relationship alone was sufficient for the agency to tentatively conclude that addressing *trans* fatty acids in nutrition labeling is important to public health.

FDA's review of the intervention trials showed that HDL–C decreased when *trans* fats replaced saturated fats. Further, Federal Government advisory groups (Refs. 88 through 90, and 140) and an advisory group of health professionals (Ref. 91) have stated that substitution of *trans* fat for saturated fat lowers HDL–C.

To date, lowered HDL–C levels have been shown to be a useful predictor of heart disease risk because of its correlation with CHD risk. However, it is not known whether lowering HDL–C is related to CHD risk in a cause and effect manner. Until this relationship is confirmed by appropriate study designs, the use of HDL–C as a surrogate biomarker for CHD risk must be done with caution and clear recognition of the uncertainty surrounding this use. For example, FDA notes that the NCEP 2001 Report (Ref. 89) makes several statements that both recognize and qualify the relationship between *trans* fatty acids, HDL–C, and CHD risk. While the NCEP Report states that a low HDL–C level is strongly and inversely associated with risk for CHD, the NCEP Report also states that, because of the association of low HDL levels with other atherogenic factors, a low HDL–C is not as strongly independent in its prediction as suggested by usual multivariate analysis.

Therefore, while FDA did not place primary reliance upon the relationships among *trans* fat intakes and adverse effects on HDL–C and CHD risk in deciding that nutrition labeling was warranted, FDA also recognizes this possible relationship, so concerns about possible adverse effects cannot be ignored (64 FR 62746 at 62798 to 62821). For this reason, FDA included information on the effects of *trans* fatty acids on HDL–C levels when reviewing the available human studies in the science review section. Additionally, because of the possibility of an adverse effect on HDL–C levels from *trans* fat intake and a correlation between such an effect with CHD risk, the possible impact on HDL–C levels from *trans* fat

intake was used in the regulatory impact section as one of several possible approaches for determining cost benefit ratios of *trans* fat labeling. The agency would have been remiss in evaluating the full range of possible cost/benefit relationships if it had failed to include this potential adverse effect from *trans* fatty acid intakes to CHD risk in these analyses.

The question of interpretation of LDL/HDL ratios is more difficult. For example, concurrent small changes in both LDL–C and HDL–C could result in a similar LDL/HDL ratio as would concurrent large changes in both LDL–C and HDL–C assuming the changes are in the same direction. Or, large changes in HDL–C with moderate changes in LDL–C could give similar LDL/HDL ratios as would moderate changes in HDL and small changes in LDL. However, it is likely that the magnitude of the change in the individual blood cholesterol levels is as, or more, important than is a change in the ratio of the two. Thus, interpretation of the LDL/HDL ratio is unclear and until there is evidence by which its meaning can be more precisely defined, use of this ratio requires considerable caution. However, even with these caveats, regardless of whether results are expressed as increased levels of LDL–C or as increases in LDL/HDL ratios, the conclusion is the same: *trans* fat intakes increase CHD risk.

(Comment 11) A number of comments emphasized that, in addition to HDL–C, *trans* fat has other adverse effects that may contribute to CHD risk but saturated fat does not. The comments mentioned that *trans* fat has adverse effects on various CHD risk factors including serum lipoprotein(a), serum triglycerides, insulin resistance and diabetes risk. These comments also stated that *trans* fat has adverse effects on aspects of lipid metabolism that may cause increased CHD risk, such as interference with metabolism of omega–3 fatty acids, interference with enzymes such as delta–6–desaturase, promotion of essential fatty acid insufficiency, and increase in free radical formation. Several of the comments argued that some of these CHD risk factors represent additional biological mechanisms related to *trans* fat that could account for the amount of CHD risk observed in prospective studies beyond that explained by changes in LDL–C and HDL–C.

Some comments stated that *trans* fat may have adverse effects on other health conditions, besides CHD. One of these comments requested that, in order to provide the full picture of health issues involved with *trans* fats, FDA review *trans* fat effects on cancer, obesity, immunity, reproduction, development, and diabetes when publishing the final rule. Another comment characterized *trans* fatty acids as being atypical fatty acids with an insidious nature in disrupting lipid metabolism. Some comments identified potential adverse effects of *trans* fat on lowered birth weights and decreased visual acuity in infants exposed to high levels of *trans* fatty acids in utero or via breast milk. The comments suggested that FDA advise pregnant and lactating women to limit their *trans* fat intake.

FDA recognizes that the relationship of biomarkers, other than LDL–C, and to a lesser degree, HDL–C, with CHD risk is less well established and difficult to interpret. Moreover, at this time, the findings suggesting effects of *trans* fat on non-heart disease risks are preliminary. Therefore, FDA finds that its focus on LDL–C provides a sufficient basis for concluding that the labeling of *trans* fat levels in food products is warranted.

V. Nutrition Labeling of *Trans* Fats

In the November 1999 proposal, FDA proposed that when *trans* fats are present in a food, including dietary supplements, the declaration of saturated fat must include the combined quantitative amount by weight of both saturated and *trans* fats. Further, FDA proposed that when 0.5 or more grams per serving of *trans* fats are present, the declaration be followed by a symbol that refers to a footnote at the bottom of the nutrition label stating the number of grams of *trans* fat present in a serving of the product, i.e., ''Includes ___ g *trans* fat.'' The agency also had discussed, in addition to the one proposed, several other options for declaring *trans* fat in the Nutrition Facts panel. These included: (1) Declaring the combined amount of both saturated fat and *trans* fat as ''Saturated fat'' without identifying the amount of *trans* fat, (2) declaring the combined amount of both saturated fat and *trans* fat as ''Saturated + *trans* fats'' without identifying the amount of *trans* fat, (3) declaring the combined amount of both saturated fat and *trans* fat as ''Saturated + *trans* fats'' with an explanatory footnote stating the amount of each fat separately, and (4) declaring the amount of *trans* fat as a separate line item under saturated fat. The agency proposed that with all of these options the term ''*trans* fatty acids'' and ''*trans* fat'' could be used interchangeably.

A. Voluntary v. Mandatory Declaration of Trans Fatty Acids in Nutrition Labeling

(Comment 12) The majority of the comments supported the November 1999 proposal, which required the mandatory declaration of *trans* fat in nutrition labeling when it is present in a food, including dietary supplements. An overwhelming majority of comments supporting the mandatory declaration of *trans* fat did so because of public health concerns. Some comments stated that the scientific evidence clearly demonstrates that consumption of *trans* fat contributes to increased LDL–C and, hence, increased risk of CHD. Several comments noted that consumers are increasingly aware of the relationship between dietary fat and chronic disease, especially CHD, and look to the nutrition label for information about ''heart-unhealthy'' fat. A few comments noted that another benefit of mandatory labeling of *trans* fat is that it may provide an incentive to manufacturers to reduce the *trans* fat content of their foods.

A few comments stated that mandatory labeling of *trans* fat was not warranted because the scientific data linking *trans* fat to CHD is weak and because the average intake of *trans* fat, estimated as 2.91 percent of energy in the proposal, is minimal. Other comments also opposed mandatory labeling stating that the effect of *trans* fat on LDL–C or CHD risk was not sufficient to establish public health risk at ordinary levels of intake.

Some comments stated that, although mandatory labeling of *trans* fat was not warranted, a requirement for label declaration of *trans* fat could be justified in certain circumstances. Several of these comments stated that required label declaration of *trans* fat was justified if it was needed to prevent the label from being misleading because of the level of *trans* fat in light of other information on the label about total fat or fatty acids. Several comments that opposed mandatory declaration of *trans* fat suggested that, in order to prevent consumer deception, *trans* fat declaration should be required when nutrient content claims or health claims are made about fatty acids or dietary cholesterol or when there is label declaration of monounsaturated and polyunsaturated fats. One comment stated that there is no evidence that *trans* fat declaration would assist consumers in following healthy dietary practices unless certain claims are made or unless monounsaturated and polyunsaturated fats are declared on the label. One comment stated that the

amount of *trans* fat is ''material'' only when *trans* fat is present at greater than 1 g per serving because it would then significantly impact the overall fatty acid contribution to the diet. Another comment stated that *trans* fat declaration should be required only when *trans* fat is present at greater than 2 g per serving because that threshold would capture the food categories that contribute the vast majority of *trans* fat to the diet but would exclude products that contain only a trivial amount of *trans* fat. This comment stated that mandatory *trans* fat labeling of products with 2 g *trans* fat or less per serving would have a significant labeling burden although the foods make little overall contribution to *trans* fat in a mixed diet and have not been shown to have any public health impact. Another comment suggested that, if no claims are made, *trans* fat declaration should be voluntary if *trans* fat is present at 0.5 g or less per serving. One comment suggested that, if there are no claims about fatty acids or cholesterol, *trans* fat declaration should not be required when the food is ''low'' in total fat. The comment stated that a food ''low'' in total fat conforms with dietary recommendations; that no material improvement in food choices can be made from knowledge of the specific *trans* fat level in a ''low fat'' food; and that the level of *trans* fat in a ''low fat'' food is not enough to have any adverse impact on public health.

One comment stated that *trans* fat declaration should be optional because consumers prefer simplicity and clarity in nutrition labeling and consumers are unlikely to benefit from added verbiage about a nutrient that is not familiar to them. One comment suggested that *trans* fat declaration should be voluntary, but should be required under the same conditions that declaration of monounsaturated and polyunsaturated fat is required. The comment stated that *trans* fat declaration would then be required when fatty acid or cholesterol claims are made, and this would be the case for important food sources of *trans* fat, such as margarines, which often make such claims. According to the comment, although not all foods would choose or be required to disclose *trans* fat, the foods that are predicted to reformulate and that generate the expected health benefits of *trans* fat labeling would do so. After the initial disclosure of *trans* fat by these foods, additional foods would disclose *trans* fat due to competitive pressure (described by the comment as ''the unfolding principle''). The comment stated that market incentives and facilitation of information flow, rather than mandatory disclosure, are the best ways to achieve *trans* fat disclosure.

FDA disagrees with comments opposed to mandatory declaration of *trans* fat. The 1990 amendments mandated nutrition labeling on most foods to provide consumers with information about specified nutrients that would help them maintain healthy dietary practices, as well as to create an incentive to food companies to improve the nutritional qualities of their products. Section 403(a) requires that food be adequately labeled and that material facts about a food's characteristics be disclosed to consumers. Section 403(q)(2)(A) of the act gives the Secretary (as delegated to FDA in § 5.10 (21 CFR 5.10)) the authority to require that information on additional nutrients be included in nutrition labels, if the Secretary determines that providing such information will assist consumers to maintain healthy dietary practices. In the legislative history of the 1990 amendments, Congress noted that ''Scientific evidence has clearly linked dietary habits to good health. For this reason, it is important for FDA to provide consumers with better information about the foods they eat.'' (Ref. 141). As described in section IV of this document, scientific studies have demonstrated consistently that consumption of *trans* fat increases LDL–C, a major risk factor for CHD.

New studies and recent expert reports (Refs. 87, 90, 95, and 140) have been published and confirm the relationship between *trans* fat intake and risk of CHD. These studies' reports corroborate the agency's earlier finding in the proposed rule that information on *trans* fat on the nutrition label will assist consumers to maintain healthy dietary practices. Dietary Guidelines 2000 cautions consumers that foods high in *trans* fatty acids tend to raise blood cholesterol and gives examples of food sources of *trans* fat (Ref. 87). The Guidelines advise Americans who need to reduce fat intake to ''do so primarily by cutting back on saturated and *trans* fats'' (Ref. 87). Likewise, the Executive Summary of the NCEP 2001 report urges primary prevention of CHD in the United States through lifestyle changes (Ref. 95). The NCEP's Therapeutic Lifestyle Changes Diet recommends that those who wish to lower their LDL–C level reduce their intake of saturated fat and keep consumption of *trans* fat low (Ref. 89). Similarly, the IOM/NAS report recommends ''that *trans* fat consumption be as low as possible while consuming a nutritionally adequate diet'' (Ref. 90). It is clear that persons interested in following these recommendations and maintaining optimal LDL–C levels must be able to determine levels of both saturated and *trans* fats in individual food products. This information provides consumers with the ability to maintain healthy dietary practices. Information on saturated fat content is already available in Nutrition Facts panels on food labels. The practical way to inform consumers of the level of *trans* fat in individual food products is for the information also to be included in the Nutrition Facts panel.

Government and industry surveys consistently find that a majority of American consumers report looking at the nutrition label the first time they purchase a food product (e.g., about 75 percent according to FDA surveys (Ref. 96) and 51 percent according to a 1997 industry survey (Ref. 97). According to the FDA surveys, the most frequently reported label use and the one which increased most following the implementation of the 1990 amendments was ''to see how high or low the food is in things like calories, salt, vitamins, fat, etc.'' (70 percent in 1995, up 12 percent from 1994) (Ref. 96, table 16.1).

These survey data show that consumers rely on the Nutrition Facts label as a guide to choosing foods that meet their dietary objectives. As consumers learn more about the dietary significance of *trans* fat and the dietary advice to limit its consumption, the Nutrition Facts panel is where label users will expect and want to find this information. If they cannot find information on *trans* fat content there or if it is only there when claims are made about fatty acids or cholesterol, they will be hampered in their ability to implement the most recent dietary guidance, and are likely to be misled about a food's basic characteristics.

Therefore, FDA, as delegated by the Secretary, has concluded that *trans* fat is a material fact which cannot be omitted from the label. In addition, information on the *trans* fat content of food will assist consumers in maintaining healthy dietary practices. As such, FDA is acting in accordance with section 403(a) and (q)(2)(A) of the act to require that information on *trans* fat content be included in nutrition labeling. Including *trans* fat as a mandatory component of nutrition labeling will allow consumers to choose foods that will reduce their intake of *trans* fat, along with saturated fat, within the recommended intake level for total fat in a manner that is consistent with the most recent dietary guidance.

FDA disagrees with the comments that stated that mandatory labeling of *trans* fat is not warranted because average *trans* fat intake is minimal or because *trans* fat consumption is not a matter of public health risk at ordinary levels of intake. As described in section IV of this document, subjects in intervention studies showing that *trans* fat intake raises LDL–C levels had a wide range of *trans* fat intake levels, including levels that overlap the range of intake estimates for the U.S. population. The findings from intervention studies are supported by findings of a positive association between *trans* fat intake and increased CHD risk in the prospective observational studies, among free-living subjects consuming ordinary diets. Taken together, these studies demonstrate that *trans* fat consumption in the United States is a matter of public health concern at ordinary levels of intake.

FDA disagrees with the comments that suggested that the nutrition label would not be misleading if grams of *trans* fat were not listed, except where claims about fatty acids or cholesterol were made, monounsaturated fats and polyunsaturated fats were declared, or where *trans* fats were present at less than 2 g, 1g or 0.5 g per serving. The agency believes that the absence of information of the amount of *trans* fat in a product, when labeling of *trans* fat as a mandatory nutrient is required, even where *trans* fat is present at less than 0.5 g, would be misleading. The presence or absence of *trans* fat in a product is a material fact as to the consequences that may result from the use of the product. Consumers need to know when a product contains less than 0.5 g *trans* fat just as much as they need to know when a product contains 1, 2, or more grams of *trans* fat in order to understand how each product impacts their overall dietary intake of *trans* fat. Such need is not based solely on the presence or absence of claims, levels of other fats, or declaration of other fats on the label. Consumers need to understand how each product contributes to their overall intake of *trans* fat in order to maintain healthy dietary practices which call for reducing *trans* fat intake as low as possible while consuming a nutritionally adequate diet. Consumption of several foods, each with 0.5 to 1 g *trans* fat per serving, over the course of a day may result in a significant overall *trans* fat intake for the day. The association between the intake of *trans* fat over a range of intakes and the risk of CHD are discussed in section IV of this document. Because low levels of *trans* fats may have significant impacts on increased CHD risk, there are important public health reasons for excluding foods high in *trans* fat intake and for including foods lower in *trans* fat intake. Consumers need the *trans* fat information on products in order to determine how each product fits into their individual health goal for reducing *trans* fat intake in the context of their total daily diet. Thus, the agency is requiring *trans* fat labeling, regardless of whether claims are made or the levels of other fats are declared, to prevent products from being misleading under sections 403(a)(1) and 201(n) of the act. Therefore, as described in section III of this document, in this rulemaking FDA is relying on its authority under those sections as well as its authority under section 403(q)(2)(A) of the act to require that information on *trans* fat be included in nutrition labeling to assist consumers in maintaining healthy dietary practices. Requiring such information on labels, whether or not voluntary nutrients are listed or claims are made about fatty acids or cholesterol, is consistent with statutory directives for nutrition labeling in section 403(q)(1) of the act, where amounts of nutrients of public health significance are required to be listed, regardless of other information on the label. FDA also disagrees with the comments that stated that *trans* fat declaration would assist consumers in maintaining healthy dietary practices only under certain circumstances, such as when certain claims are made, when monounsaturated and polyunsaturated fats are declared on the label, when *trans* fat is present at greater than 0.5 g, 1 or 2 g per serving or when the food is not ''low'' in total fat (i.e., more than 3 g fat/reference amount). As described previously, consumers need information on both saturated and *trans* fats in individual food products so that they can follow current dietary recommendations and maintain optimal LDL levels. It is the provision of *trans* fat information on foods consumed throughout the day that can assist consumers in maintaining healthy dietary practices, and the usefulness of this information is not limited to foods with certain nutritional characteristics. In addition, the consumption of several foods with 0.5 or 1 g of *trans* fat per day that may provide a total of 8 g of *trans* fat to the diet would be expected to have the same effect on LDL–C levels as consumption of one food with 8 g *trans* fat. Requiring *trans* fat to be declared only when present at a specified level would be inconsistent with statutory directives for nutrition labeling in section 403(q)(1) of the act, where amounts of nutrients of public health significance are required to be listed, regardless of the amount present.

Similarly, tying mandatory declaration of *trans* fat to the declaration of monounsaturated and polyunsaturated fats overlooks the difference in health effects of these fatty acids and the basic premise of section 403(q) of the act that requires the listing of nutrient information necessary to assist consumers in maintaining healthy dietary practices. Unlike information on *trans* fat, FDA has not determined that information on monounsaturated and polyunsaturated fat is necessary to assist consumers in maintaining healthy dietary practices. Accordingly, the declaration of those fatty acids is not mandatory. Rather, unless claims are made about fatty acids or cholesterol, the agency provides that their listing is voluntary (§ 101.9(c)(2)(ii), (c)(2)(iii), and (c)(3)), consistent with the authority in section 2(b)(1)(C) of the 1990 amendments that stipulates that regulations shall ''permit the label or labeling of food to include nutrition information which is in addition to the information required by such section 403(q) and which is of the type described in subparagraph (1) or (2) of such section * * *.''

Regarding the comment that consumers prefer simplicity and clarity in labels, FDA does not agree that providing a listing of the amount of *trans* fat on a label is not simple or clear nor did the comment provide any rationale for its assertion. Further, FDA does not agree that *trans* fat listing on a label would be ''added verbiage'' about an unfamiliar nutrient that likely will not benefit consumers. The comment presented no information to support its assertion. The addition of *trans* fat as a mandatory nutrient on a separate line will not significantly change the appearance of the nutrition information that consumers are already familiar with. Having consistent information about *trans* fat present on all food labels will facilitate consumer education efforts about *trans* fat, as discussed later in this document (see Comment 28).

FDA is not persuaded by the comment that it is not necessary to make *trans* fat labeling mandatory because, after an initial disclosure of *trans* fat by certain foods, additional foods would disclose *trans* fat due to competitive pressure (unfolding principle). Although some disclosure of *trans* fat under competitive pressure might occur, the overall extent of such voluntary disclosure is not certain. Before the 1990 amendments

were enacted, provision of nutrition labeling information was voluntary except in certain circumstances. At the time when nutrition labeling was voluntary, many foods did not provide nutrition labeling, demonstrating that the disclosure suggested by the ''unfolding principle'' was incomplete. To remedy this situation, Congress enacted the 1990 amendments, mandating that nutrients of public health significance be declared on food labels under section 403(q) of the act.

As mentioned earlier, section 403(q)(2)(A) of the act provides for the inclusion of an additional nutrient(s) if the Secretary (as delegated to FDA in § 5.10) determines that it should be included in nutrition labeling to assist consumers in maintaining healthy dietary practices. FDA is not asserting, as its basis for mandatory *trans* fat nutrition labeling, a rationale that is different from that which Congress declared by statute for such mandatory labeling. Lacking any congressional direction to do otherwise, the agency considers it implicit that any such added nutrients would be listed in a similar manner to those specified in section 403(q)(1) of the act. Accordingly, the agency is amending § 101.9 *Nutrition Labeling of Food*, to add *trans* fat as a mandatory component of nutrition labeling on all foods in accordance with section 403(q)(2)(A) of the act.

B. Format, Including Percent of Daily Value (% DV), for Nutrition Labeling of Trans Fat

FDA received many comments regarding the proposed option for nutrition labeling of *trans* fatty acids and other options discussed in the preamble. In addition, comments were received suggesting that *trans* fat be listed in conjunction with the listing of total fat.

The agency did not receive comments supporting either of the two options that would declare only the combined amount of saturated fat and *trans* fat rather than the individual amounts present. In light of the lack of support for these two options and the fact that these options do not allow consumers to determine the individual amounts of saturated fat and *trans* fat, the agency is not considering them further.

FDA also received a few comments that supported the proposed footnote statement ''Intake of *trans* fat should be as low as possible'' or a modification of it. However, the overwhelming majority of comments opposed the use of the footnote.

1. Proposed Option

(Comment 13) Many comments supported the proposed option of having the amount of *trans* fat included in the amount declared for ''Saturated Fat'' and in the calculation of the corresponding % DV with a footnote stating ''Includes ___ g *trans* fat'' when the food contains *trans* fat. Comments stated that combining both saturated and *trans* fat in the declaration of saturated fat maintains a consistent public health message and provides consumers with a less confusing means to identify ''heart-unhealthy'' fats in one place on the label. Comments suggested that, to assist consumers, *trans* fat should be included with saturated fat because saturated and *trans* fats have similar physiological and functional properties and because there is no DV for *trans* fat. Comments suggested that combining saturated and *trans* fats will decrease the likelihood that consumers would look only at the declared level for *trans* fat and choose a food because it has little or no *trans* fat, even though it contains a high amount of saturated fat. Furthermore, the comments suggested that combining *trans* with saturated fats would create an incentive for manufacturers to decrease ''heart-unhealthy'' fats in foods.

Comments supporting inclusion of *trans* fat in the calculation of the % DV for saturated fat stated that such action is reasonable for purposes of consumer information. One of these comments argued that *trans* fats are already included in recommendations to limit total fat to 30 percent of calories, a number that should not be increased, and are excluded from definitions of unsaturated fats for labeling purposes (i.e., § 101.9(c)(2)(ii) and (c)(2)(iii)). This comment acknowledged that including *trans* fat would in effect lower the reference value for saturated fat. The comment argued that this would help Americans reduce their risk of heart disease, quoting from the IOM/NAS report ''Diet and Health'' which states that ''saturated fatty acid intake [should] be maintained at less than 10 percent of total calories by individuals,'' but that ''further reduction, to 8 or 7 percent of calories or lower, would confer greater health benefits.'' The comment said that including *trans* fat in the % DV would help Americans follow this advice.

However, many comments opposed this option of including *trans* fat with saturated fat, arguing that including *trans* fat with saturated fat is scientifically inaccurate and misleading because *trans* and saturated fats are chemically, functionally, and physiologically different. Comments pointed out that chemically *trans* fats are unsaturated fatty acids that contain one or more double bonds in a *trans* configuration while saturated fats do not contain double bonds. Moreover, comments stated that *trans* fatty acids do not have the same functional characteristics as saturated fats because their melting and crystallization kinetics are quite different. Comments also pointed out that *trans* fat is physiologically distinct from saturated fat, stating that *trans* fat decreases HDL–C levels and that saturated fat does not. In addition, there were comments suggesting that *trans* fat adversely affects other factors that contribute to CHD, such as lipoprotein(a), and may cause adverse effects unrelated to CHD. For these reasons, the comments were adamant that *trans* fat should not be treated as though it is ''bioequivalent'' to saturated fat and, consequently, the listing of *trans* fat should be disassociated from the listing of saturated fat.

In addition, several comments objected to combining both *trans* and saturated fats on the grounds that it is inconsistent with FDA's regulatory precedent of classifying nutrients based on their chemical definition or structure, rather than their physiological effect. Specifically, the comments cited FDA's decision when implementing the 1990 amendments to establish a chemical definition for saturated fat rather than a physiological definition (58 FR 2079 at 2089).

A few comments expressed concern that by including *trans* fat with saturated fat, FDA is creating a category of ''bad'' or ''cholesterol-raising'' fat that is inconsistent with the current nutrition label, which provides consumers with information about the nutrient profile of a product rather than providing information about perceived health effects. Other comments stated that FDA's proposal to combine *trans* fat and saturated fat may mislead consumers, albeit misleading them for their own good, by causing them to misclassify *trans* fats as saturated fats or causing them to assume that the DV for saturated fat has been reduced (the effect of combining the quantitative amounts of *trans* and saturated fats and determining the % DV using the established DV for saturated fat). Further, several comments stated that adding *trans* fat to the amount of saturated fat declared may mislead and confuse consumers by leading them to incorrectly conclude that the amount of saturated fat has increased.

Other comments stated that, because of the magnitude of CHD risk in the prospective studies, *trans* fat should be

labeled more prominently than proposed in the November 1999 proposal. These comments argued that listing the amount of *trans* fat in a footnote is more confusing and implies that it is unimportant. In addition, comments stated that footnotes, which can use smaller type size, are more difficult to read. One comment stated that it was not surprising that consumers were unfamiliar with the term since it was not allowed to appear on Nutrition Facts labels. This comment suggested that consumer knowledge about *trans* fat would improve as more dietary recommendations are made for limiting *trans* fats and as they are listed in food labeling.

Other comments objected to including *trans* fats when calculating the % DV for saturated fat stating that the effects of *trans* fat on LDL–C have not been proven to equal the effects of saturated fat on LDL–C, so they should not be held to the same standard. These comments argued that including *trans* fat in the calculation of % DV assumes that *trans* fat is equivalent to saturated fat on a gram-for-gram basis, whereas the agency admitted in the proposal that available studies do not allow for such a conclusion. The comments stated that no authoritative bodies have recommended that *trans* fat be considered as a part of the dietary recommendation for saturated fat. Also, they stated that including *trans* fat, in effect, lowers the DRV for saturated fat and there is no new data on saturated fat that supports this action, i.e., that there is no basis for concluding that saturated fats are now sufficiently worse than previously believed to justify an apparent reduction in recommended intakes. One comment also argued that if the declaration of % DV changed on a product as a result of including *trans* fat with saturated fat, consumers may incorrectly assume a change has been made which made the product less healthy when, in fact, no such change had occurred.

One comment said that FDA should not include *trans* fat in the calculation of % DV unless the DRV for saturated fat is increased to 22 g since the agency had actually rounded down the DRV for saturated fat from 22.2 g (equivalent to 10 percent of calories from a 2,000 calorie diet) to 20 g when implementing the 1990 amendments (see 58 FR 2206 at 2219). Another comment objected to the idea of increasing the DRV for saturated fat because products that do not contain *trans* fat would appear healthier (i.e., have a lower % DV) even though the amount of saturated fat in the product would remain the same.

Based on comments received, FDA is persuaded that there are inherent weaknesses and inconsistencies in its proposed option. Therefore, the agency has reconsidered its proposal to include *trans* fats in the declaration of saturated fat with a footnote indicating the amount of *trans* fat. The agency acknowledges that declaring the amount of saturated fat and *trans* fat together, even with the proposed footnote, could lead some consumers to believe that the two types of fatty acids are chemically and physiologically the same. Clearly, *trans* fats contain double bonds and thus, are chemically distinct from saturated fat. Likewise, although both saturated and *trans* fats do raise LDL–C levels, physiologic distinctions between the two types of fatty acids do exist as discussed previously in Comments 10 and 11. While findings on some of these distinctions are preliminary, they do not support the position which the agency took in the November 1999 proposal that the two fatty acids should be declared as one combined entity because of similar physiological effects.

The agency re-evaluated its position, noted in the final rules implementing the 1990 amendments, that there is insufficient knowledge about the physiological effects of particular fatty acids to use anything other than a chemical definition for saturated fats (58 FR 2079 at 2089). In that rulemaking, FDA reconsidered its regulatory position in place since 1973 (38 FR 2132 at 2134, January 19, 1973) of linking the definition of saturated fatty acids to effects of particular fatty acids on blood total and LDL–C and determined that a chemical definition was a more appropriate approach. The agency stated that a chemical definition avoids much of the controversy regarding blood cholesterol effects of short to medium and certain very long chain fatty acids because the definition is not subject to changes in knowledge about the physiological effects of a particular fatty acid. In addition, the agency stated that a chemical definition approach to labeling fatty acids avoids the uncertainty about physiological effects other than those related to CHD (58 FR 2079 at 2089). Based on its re-review of the position noted in the final rules implementing the 1990 amendments, the comments received on proposed rule opposing a contrary position, and current science on *trans* fat, the agency is persuaded that it would be important to approach *trans* fat labeling on the basis of using a chemical definition and not based on physiological effects. Accordingly, the agency concludes that it is necessary to disassociate saturated and *trans* fats on the nutrition label so that consumers do not misinterpret the declaration of saturated fat by thinking that *trans* fats are included in that definition.

The agency also acknowledges the concerns expressed in comments about the prominence given to the information on *trans* fat. Current food labeling regulations do allow for a smaller type size for footnotes (§ 101.9(d)(1)(iii)) and limit the declaration of amounts in footnotes to statements saying that the food is not a significant source of specified nutrients (e.g., § 101.9(c)(3)). Consequently, consumers may overlook quantitative information on *trans* fat content placed there.

In the November 1999 proposal, FDA expressed concern that consumers may not yet know what *trans* fats are or know about their impact on health (64 FR 62746 at 62755). The agency agrees with the comment that suggested that consumer knowledge would improve as more dietary recommendations are made for limiting *trans* fats and as they are listed in nutrition labeling. In addition, the agency notes that media attention to *trans* fat has been widespread since publication of the November 1999 proposal. For example, public awareness about *trans* fats was increased as reports of the IOM/NAS report on *trans* fatty acids were issued (Ref. 140), as consumer and health groups issue press releases and reports about *trans* fats (Refs. 147 and 148), as food manufacturers add information about the *trans* fat content of products to labels, and as industry announcements are made about the *trans* fat content of packaged and restaurant foods (Refs. 149 and 150). In addition, the agency is planning a consumer education program discussed later in Comment 28 to further heighten consumers' knowledge of what *trans* fats are and their impact on health. Thus, the agency no longer believes that its prior reasoning, i.e., that *trans* fat would need to be included in the declaration of saturated fats in order for consumers to understand that *trans* fats are heart unhealthy is necessarily true. Consumers should be more aware of *trans* fat based on the public exposure to information on *trans* fat over the past years and FDA efforts before the rule becomes effective.

In the November 1999 proposal, FDA tentatively concluded that, in the absence of dietary recommendations for *trans* fats, it was reasonable to include *trans* fats in the % DV for saturated fat (46 FR 62746 at 62756). Consequently, FDA proposed that the % DV be calculated by combining the amount of

saturated fat and *trans* fat in a food and dividing by the DRV for saturated fat (20 g). In effect, this is equivalent to having a combined DRV for saturated and *trans* fat of 20 g. FDA agrees with the comments that suggest that this approach is problematic in that by displacing the DV for saturated fat with *trans* fat, the DV, in essence, is lowered for saturated fat. However, the DV for saturated fat has not changed. Therefore, it would be scientifically more accurate to keep the DV for saturated fat intact, without displacing it with *trans* fat. This approach would be consistent with the recent IOM/NAS macronutrient report (Ref. 140) that does not treat saturated and *trans* fats together. FDA concludes that there is an insufficient scientific basis at this time for combining the declared amounts of *trans* and saturated fats and calculating the % DV. Additionally, FDA is persuaded by the arguments discussed previously that point to the differences between saturated fat and *trans* fat that it is inappropriate to do so.

Accordingly, the agency concludes that other options that disassociate *trans* fat from the listing of saturated fat would be preferable to the proposed option. The other options identified in the proposal and those suggested in comments are discussed later.

2. Option to List Saturated and *Trans* Fat on Same Line

(Comment 14) Several comments preferred the option identified in the November 1999 proposal that would list ''Saturated + *trans* fat'' with the amount in grams and the % DV based on the combined value, and the individual amounts of both saturated and *trans* fats in a footnote. One comment suggested that the footnote declare the specific amount of *trans* fat only, while another suggested that the individual amounts be listed in separate lines immediately below the combined amount rather than in a footnote. These comments stated that this type of declaration shows that: (1) There are two different fatty acid categories, thereby maintaining the chemical definitions of *trans* fat and saturated fat and indicating equal importance to health; (2) gives them equal prominence with poly- and monounsaturated fats; (3) suggests to consumers that *trans* fats have similar cholesterol-raising properties as saturated fats; and (4) provides an easy method for comparing the ''heart-unhealthy'' fat content of foods. The comments also argued that this type of declaration indicates the combined total amount of saturated and *trans* fats, a number that would stay constant when saturated and *trans* fats are substituted for each other, and it was therefore clearer to declare the sum of both.

Alternatively, a few comments recommended declaring the individual amounts for saturated fat and *trans* fat on one line in the nutrition label, i.e.,. ''Saturated fat __g + *trans* fat __g.'' These comments pointed out that declaring saturated and *trans* fats in this way would be consistent with the chemical definitions for each type of fatty acid and would help consumers see that *trans* fats are different from saturated fats. The comments argued that research may elucidate new properties or biological effects of both saturated and *trans* fatty acids, warranting this distinction between them. From a consumer perspective, one of the comments also argued that, if FDA begins to mandate the placement of nutrient content information in locations other than the current nutrient list, consumers may become increasingly confused about where on the food label to locate information that they need.

Two comments urged the agency to harmonize its *trans* fat labeling policy internationally, noting that this format, i.e., ''Saturated fat _ g + *trans* fat _g,'' was proposed by Canada in June 2001, for use in mandatory nutrition labeling in that country (Ref. 103).

Other comments did not favor listing saturated and *trans* fats on the same line as ''Saturated + *trans* fat'' for the same reasons expressed in opposition to the proposed option, namely because *trans* and saturated fats are chemically different, because they have different effects on HDL–C, and because, according to preliminary data, *trans* fat may have effects on non-heart disease risks that saturated fats are not reported to have. In addition to concerns about the chemical and physiological differences between *trans* and saturated fats, some comments expressed opposition to labeling the two on the same line because public health and scientific organizations that are instrumental in establishing daily reference intake values have not yet established a DV for *trans* fat. Many other comments objected to having saturated and *trans* fats on one line, in any manner, if it resulted in *trans* fat being included in the calculation of the % DV for saturated fat. Specific arguments against including *trans* fat when calculating the % DV for saturated fat are discussed in the preceding comment.

The agency is not persuaded by comments supporting this option. While this option does indicate more clearly than the proposed rule that saturated and *trans* fats represent two different categories of fat, it would still necessitate a displacement of the % DV for saturated fat by *trans* fat and would not disassociate the two fats in terms of potential physiologic effects. Based on the reasons set forth in response to Comment 13, we believe that it would be scientifically more accurate to not displace the % DV for saturated fat with *trans* fat. In addition, this option would not be consistent with our rationale, as explained in the response to Comment 13, for why a chemical definition approach to labeling is preferred. Such an approach avoids the uncertainty about physiological effects now or in the future. While the two fatty acids do both lead to increased LDL–C, advisory groups (as noted in comment 10 of this document) have stated that substitution of *trans* fat for saturated fat lowers HDL–C. Low levels of HDL–C can be a predictor of CHD. While evidence concerning the differing effects of saturated fat and *trans* fat on other disease risk factors is preliminary, FDA is convinced by comments that it is preferable to disassociate the two fatty acids and maintain a chemical definition approach to labeling. Accordingly, the agency finds this option unacceptable.

Those comments stating that saturated and *trans* fat are substituted for each other recognized that the two types of fats have some functional similarities. However, comments were not unanimous in stating that the combined total amount of saturated and *trans* fats would stay constant when one of the two fatty acids was raised or lowered. Some comments indicated that *trans* fats could be reduced significantly with a smaller concomitant increase in saturated fat. In addition, FDA points out that the intent of this rulemaking is not to make such substitutions easier from a labeling perspective but to encourage the reduction of both types of fats to assist consumers in maintaining healthy dietary practices.

FDA recognizes that Canada has issued final rules on nutrition labeling that declare saturated fat and *trans* fat on one line. However, FDA has determined, based on comments to this final rule, that such declaration would not be an appropriate approach for the agency at this time. Such an option would not account for the chemical and physiological differences between saturated and *trans* fat, and thus, would be inconsistent with the agency's past approach to labeling that is based on chemical differences. Further, there are additional differences between Canada's new nutrition labeling rule and existing U.S. regulations, under § 101.9, that will need to be reviewed by both countries.

After further review and discussion, the United States and Canada can consider the possibility of mutual recognition of nutrition labels.

3. Option to Include *Trans* Fat as a Part of Total Fat

(Comment 15) Several comments recommended a new option that would place an asterisk (or other symbol) after the declaration of total fat (i.e., ''Total Fat*'') that references a footnote stating the number of grams of *trans* fat included in the total fat declaration (e.g., ''*Includes___g *trans* fat''). A few comments proposed an alternative to this option that would declare *trans* fat in a parenthetical statement on the same line with ''total fat'' (i.e., ''Total Fat __ g (includes__ g *trans* fat)'').

Some of these comments suggested that declaring *trans* fat as a part of total fat alleviates many of the concerns voiced about the proposed option. The comments stated that this option discloses the amount of *trans* fat in scientifically accurate terms and is consistent with current regulations that include the quantity of *trans* fat within the amount declared for total fat. A comment said that this option should be used until a DRV is established for *trans* fat. Another comment suggested that the DRV for total fat should be increased to accommodate *trans* fat. Other comments stated that current dietary guidelines recommend monitoring both total fat and saturated fat intake, especially for consumers concerned about their heart health, and that the AHA recommends focusing on the total amount of fat consumed to address concerns about *trans* fat consumption.

The comments stated that placing the asterisk beside ''total fat'' has advantages for consumers. At least one comment stated that this type of listing may be more readily seen by consumers since it gives greater prominence to the *trans* fat information. Other comments stated that including *trans* fat as a part of total fat avoids the confusion that consumers would experience with FDA's proposed option when amounts declared for saturated fat would appear to have increased.

The agency disagrees with those comments suggesting that concerns about *trans* fat consumption can be addressed by focusing on the total amount of fat consumed. FDA agrees that *trans* fats are chemically a component of total fat; however, that is also true for saturated, polyunsaturated, and monounsaturated fatty acids that are listed as subcomponents of total fat in many food labels. Therefore, the agency does not agree that *trans* fatty acids should be listed only as a part of total fat until there is an established DRV for *trans* fatty acids, particularly since DRVs also have not been established for poly- or monounsaturated fatty acids. The agency also points out that the current DRV for total fat includes all fatty acids, so does not need to be increased to accommodate *trans* fatty acids.

Further, placing an asterisk after ''Total Fat'' on the label with a footnote stating the grams of *trans* fat, or a statement of the grams of *trans* fat beside the total fat on the label likely would lead to the same types of objections that were raised when that approach was considered for saturated fat. Moreover, previous comments in comment 13 raised concerns about consumers overlooking quantitative information in a footnote. Further, comments raised concern about not maintaining the chemical distinction for individual fatty acids, as has been the past agency practice. Placing *trans* fat on the same line of total fat may raise questions about how *trans* fat is to fit within the % DV for total fat. The agency is not persuaded by any the comments that the problems with this option would be any different than those with the option to label *trans* fat on the same line as saturated fat. Thus, the agency is not persuaded that the nutrition label should identify levels of *trans* fat in the total fat declaration through the addition of a footnote or parenthetical listing.

Moreover, while total fat in the diet is important, the composition of that total fat intake is at least equally, if not more, important. Recent recommendations from the Dietary Guidelines 2000 (Ref. 87) and the Dietary Guidelines Advisory Committee (Ref. 88) have emphasized reducing intake of both saturated and *trans* fats while placing less emphasis on reducing total fat intake. For example, while the 1995 edition of the Dietary Guidelines recommended that Americans choose a diet ''low'' in fat and saturated fat (Ref. 6), the 2000 edition now recommends ''moderate'' total fat (Ref. 87) with guidance that consumers needing to reduce their total fat intake do so by cutting back on saturated and *trans* fats. Similarly, the 2000 AHA Guidelines specifically recommend limiting ''intake of foods with high content of cholesterol-raising fatty acids'' (i.e., saturated and *trans* fatty acids) rather than total fat (Ref. 91). The 2001 NCEP report increased the recommendation for individuals with elevated LDL–C for total fat intake from 30 to 35 percent of calories provided that saturated and *trans* fats be kept low (Ref. 89).

The comments suggesting that *trans* fat information would have greater prominence and be more readily seen when related to total fat rather than saturated fat did not provide any data to support this position. While doing so would move *trans* fat up one line in the Nutrition Facts label, FDA has no basis to conclude that this would make it more prominent to consumers.

The agency acknowledges that the options of using an asterisk next to total fat with a footnote listing *trans* fat or listing *trans* fat parenthetically next to total fat would avoid any possible confusion experienced by consumers as a result of the proposed option if levels of saturated fat appeared to have increased when, instead, amounts of *trans* fat were added to the amount of saturated fat. However, other options, such as the option of declaring *trans* fat on a separate line would also avoid the possibility of such confusion and, at the same time, would more clearly identify *trans* fat as a separate subcomponent of total fat, in a manner similar to the other subcomponents, i.e., saturated, poly- and monounsaturated fats.

For the reasons noted previously, the agency is not persuaded that the nutrition label should identify levels of *trans* fat in the total fat declaration through the addition of a footnote or parenthetical listing.

4. Option to Include a Separate Line for *Trans* Fats

(Comment 16) Many comments recommended that *trans* fat content be declared on a separate line on the Nutrition Facts panel because of the problems ascribed to the proposed option. In general, these comments stated that there is no scientific evidence to support FDA's proposal to combine saturated and *trans* fatty acids because both of these fatty acids have different chemical structures and physiological effects. They asserted that a separate line on the nutrition label for *trans* fats would fully inform consumers about the kind of fats that are in the foods they select and consume. These comments urged the agency to list *trans* fat in the same way as other subcomponents of total fat, i.e., saturated and poly- and monounsaturated fats. They stated that doing so would clarify the chemical differences between the fatty acids, including saturated fatty acids, and would be easier for consumers to understand since it eliminates the need for a footnote. Comments also noted that adding a separate line for *trans* fat would be consistent with FDA's regulatory precedent, which was established with the 1993 mandatory

nutrition labeling regulations, of classifying nutrients based on their chemical definition or structure, rather than their physiological effect (58 FR 2079 at 2089). Moreover, the comments argued that listing *trans* fat on a separate line now would avoid having to do it later if future scientific research shows that the effects of *trans* fat consumption are significantly different from the effects of saturated fat consumption.

Several comments argued that by providing a separate line for *trans* fat, consumers can be educated more easily about the health effects of *trans* fatty acids. These comments disagreed with FDA's position in its November 1999 proposal that *trans* fat should be combined with saturated fat because consumers lack knowledge about *trans* fat information and do not understand the term *trans* fat. Also, some comments stated that FDA's rationale for not listing *trans* fat more prominently (i.e., that consumers are not familiar with the term ''*trans* fat'') is not justified since consumers do not generally know much about mono- or polyunsaturated fats yet quantitative information may be provided for them in nutrition labeling and must be provided when claims are made about fatty acids or cholesterol. A few comments also stated that creating a separate line for *trans* fat establishes a basis for current and future consumer education about the health risks and benefits of a variety of fatty acids that affect LDL–C and HDL–C levels.

A few comments in favor of a separate line for *trans* fat in nutrition labeling specifically addressed the need to establish a DRV for *trans* fat. One comment stated that FDA could establish a DRV for *trans* fat based on international recommendations for *trans* fat consumption. Another comment indicated that a DRV for *trans* fat could be established at a level equal to or below the average daily intake of *trans* fat. One other comment stated that the only basis for establishing a daily value would be the amount of naturally-occurring *trans* fat in ruminant (dairy) products since they have not been shown to be associated with increased risk of CHD; otherwise, the DRV for *trans* fats formed through partial hydrogenation should be zero. However, the majority of those commenting stated that scientific evidence is not sufficient to support the establishment of a DRV for *trans* fat because no public health or scientific organization has proposed guidelines for dietary intake levels of *trans* fat at this time. Some of these comments said that *trans* fat should be treated in a manner consistent with poly- and monounsaturated fats, i.e., without a % DV, until such time as there is a basis for establishing a DRV for *trans* fat. A few comments suggested waiting until the IOM/NAS completes its report on DRIs for macronutrients. A few comments noted that listing *trans* fat on a separate line with no % DV would be less useful to consumers because they would not be able to determine if the amount were high or low in the context of the daily diet. One comment stated that if there is enough scientific evidence to require the mandatory labeling of *trans* fat, the agency should provide the information that will help consumers to interpret the magnitude of the amount in the food. Additionally, other comments stressed the importance in helping consumers understand the relevance of the nutrient amount in the context of the total diet.

One comment objected to the option of having a separate line for *trans* fat on the basis of consumer confusion. It said that adding a fourth line of fatty acid information would confuse consumers because they would have to look at several separate values when comparing food products. This comment also was concerned that the use of a separate line would not encourage the food industry to reduce ''heart-unhealthy'' fat in the food product.

FDA agrees with comments that point out that there are chemical differences between saturated and *trans* fatty acids. The agency noted these differences in its November 1999 proposal when it proposed to include the amount of *trans* fat in the declaration of saturated fat. The intent was to assist consumers in understanding the cholesterol-raising properties of the food by declaring the two fatty acids under the name ''saturated fat'' without changing the definition of saturated fat, but FDA acknowledged that this action ''may confuse consumers and lead some to misclassify *trans* fatty acids as saturated fats'' (64 FR at 62746 62755). The agency is persuaded by the large number of comments on this issue that the proposed action was, in fact, interpreted by many as incorrectly classifying the two different fatty acids as ''saturated fat'' and that it is necessary to disassociate *trans* fat from saturated fat to prevent misleading consumers in this way.

FDA also acknowledges that while the two types of fatty acids have similar effects on LDL–C, there are other physiological distinctions between them. Because the overall weight of scientific evidence in support of the finding that consumption of *trans* fat, like saturated fat, contributes to increased LDL–C levels increasing the risk of CHD, was sufficiently compelling to warrant *trans* fat labeling, the agency did not focus on other physiological effects of *trans* fat. While studies on a variety of physiological effects of *trans* fat are ongoing and results preliminary, the agency is persuaded by comments that the declaration of *trans* fat on a separate line will best accommodate future scientific development. This will be helpful if future research more clearly elucidates the physiological mechanisms of each and confirms that *trans* fat does have adverse effects on other CHD risk factors or health conditions that differ significantly from saturated fat.

As pointed out by comments, doing so has the advantage of being consistent with: (1) The format used to list the other subcomponents of total fat, namely saturated, polyunsaturated and monounsaturated fats; (2) the declaration of quantitative amounts contiguous to the listing of the nutrient rather than in a footnote; and (3) the agency's regulatory precedent of classifying nutrients based on their chemical definition or structure. Consistency with the existing format can be expected to assist consumers in recognizing *trans* fat as a subcomponent of total fat. It will also be responsive to consumer interest in knowing the full breakout of fatty acids since, when poly- and monounsaturated fats are declared, the amounts for saturated, *trans*, polyunsaturated, and monounsaturated fats will add up to the amount of total fat except for minor deviations that may result from application of rounding rules in § 101.9(c)(2).

The agency agrees with the majority of the comments that the scientific evidence is not sufficient to support the establishment of a DRV for *trans* fat at this time. The comments that attempted to suggest a basis for doing so did not suggest particular values or submit scientific evidence to justify the establishment of such values. FDA emphasizes that existing DRVs are based on quantitative dietary intake recommendations developed from extensive scientific evidence that establishes values that will promote public health (58 FR 2206 at 2217). DRVs have not been based on international recommendations, which may not be germane in the United States, or on average dietary intake levels, which may not represent healthy dietary consumption patterns. The FDA is not aware of any international recommendations that it could rely on, nor did the comment provide any such specific recommendations. The agency has relied extensively on reports from the IOM/NAS in developing the current Reference Dietary Intake (RDIs) and DRVs. However, the recent IOM/NAS

report on DRIs for macronutrients (Ref. 140) did not make quantitative recommendations for *trans* fat for establishing a DRV. Accordingly, in the absence of a scientific basis or recommendation by an authoritative body, FDA is not establishing a DRV for *trans* fat. FDA intends to revisit this issue when there is more scientific information that the agency can use to establish an appropriate reference level for *trans* fat intake.

The agency recognizes that the absence of a DRV, and thus, the absence of a % DV for *trans* fat on food labels, nutrition educators will need to direct efforts at educating consumers further about the effects of *trans* fat on LDL–C levels and CHD risk. However, because of the public health impact of CHD in the United States, the agency believes it is necessary to proceed at this time with this final rule to list *trans* fat in nutrition labeling so that consumers will have quantitative information to use in implementing dietary guidelines to cut back on *trans* fat. By adding quantitative information on *trans* fat content, consumers will have information to use in comparing products and making diet selections that will reduce their intake of *trans* fat in the context of their daily diet by substituting lower *trans* fat products for those previously consumed that were higher in *trans* fat.

The agency does not believe it would be any more difficult for consumers to look at a separate line for information on *trans* fats than it has been for any other separate fat listing. Listing them separately will allow consumers to readily see levels of each in food products and make decisions accordingly. In addition, the agency stated earlier that it believes public awareness about *trans* fat has increased since publication of the November 1999 proposal as a result of media attention, press releases, label statements, and industry announcements. FDA concludes that this increased awareness, in conjunction with an education program about the change, will allow consumers to use this new information to help maintain healthy dietary practices and will minimize any confusion caused by the change. To maximize the impact of declaring *trans* fat in the Nutrition Facts panel, a coordinated educational effort among public health professionals and organizations focusing on all three cholesterol-raising dietary components, i.e., saturated fat, *trans* fat, and cholesterol, will be required. Such a program is discussed in Comment 28 below.

The comment that was concerned that use of a separate line for *trans* fat would not encourage industry to reduce ''heart-unhealthy'' fats did not present any data to show the effectiveness of the various options in achieving this goal. Following implementation of mandatory nutrition labeling rules in 1993, the industry reformulated many foods products to reduce levels of nutrients about which consumers were concerned (Ref. 96). Accordingly, FDA believes that the required addition of information on *trans* fat content to nutrition labels, coupled with a consumer education program on the health effects of dietary *trans* fat, will provide incentive to the food industry to minimize the level of *trans* fat present in individual food products. Some parts of the food industry have responded to consumer concerns, e.g., levels of *trans* fat in margarine products have been lowered (Ref. 104), and companies have announced plans to use reformulated fats that are lower in *trans* fat (Refs. 149 and 150). The agency believes that requiring *trans* fat labeling will prompt others in the food industry to reformulate some of their products to offer lower *trans* fat alternatives.

Accordingly, FDA is revising § 101.9(c) by adding paragraph § 101.9(c)(2)(ii) to require the quantitative declaration of *trans* fat in the Nutrition Facts panel. This new paragraph requires the listing of *trans* fat on a separate line under the statement for saturated fat. As is the case for all subcomponents of total fat, it is to be indented and separated by a hairline, with the amount expressed as grams per serving to the nearest 0.5 g increment below 5 g and to the nearest gram increment above 5 g. If the serving contains less than 0.5 g, the content must be expressed as 0, except when the statement ''Not a significant source of *trans* fat'' is used. In addition, the agency is clarifying that the word ''*trans*'' may be italicized to indicate its Latin origin. This provision to allow for italics provides an exception to § 101.9(d)(1)(ii)(A) that requires that a single easy-to-read type style be used throughout the nutrition label. Therefore, paragraph (d)(1)(ii)(A) is being revised to state that ''except as provided for in paragraph (c)(2)(ii) of this section,'' a single easy-to-read type style is to be used throughout the nutrition label.

As a result of adding paragraph (c)(2)(ii) for *trans* fat, the agency is redesignating current paragraph (c)(2)(ii) (polyunsaturated fat) as paragraph (c)(2)(iii) and current paragraph (c)(2)(iii) (monounsaturated fat) as (c)(2)(iv).

(Comment 17) In response to the November 2002 reopening of the comment period on the November 1999 proposal to require a footnote stating ''Intake of *trans* fat should be as low as possible'' when *trans* fat is listed, FDA received some comments that supported the proposed footnote statement. A few comments noted that the proposed footnote was needed to raise consumer awareness and understanding about the relevance of *trans* fat in the diet and to assist them in making healthy food choices. Another comment stated that the footnote is consistent with the IOM/NAS report on macronutrients. Two of the comments strongly recommended that the footnote be modified to state that ''Combined total intake of saturated and *trans* fats should be as low as possible.'' The comments argued that the footnote proposed by FDA gives undue emphasis to *trans* fat and will cause some consumers to evaluate products based on the content of *trans* fat instead of on the content of both *trans* and saturated fats, as is recommended in dietary guidance. One of the comments included the results of a national online survey that tested the communication effectiveness of the proposed footnote relative to no footnote and to the alternative footnote ''Combined total intake of saturated and *trans* fats should be as low as possible.'' Respondents were faced with a food comparison that required them to take both saturated fat and *trans* fat into account to correctly identify the ''more healthful'' of two food products, described by the comment as the product with the lowest total amount of saturated and *trans* fats combined. The two foods being compared were both high in saturated fat (70% DV (14 g) and 35% DV (7 g) saturated fat) but the food highest in saturated fat (14 g) had no *trans* fat (food 1) while the one with half as much saturated fat (7 g) had 2g of *trans* fat (food 2). With no footnote, over half of the respondents who identified a product as more healthful (57 percent) correctly identified the more healthful food (food 2) and 12 percent chose food 1. In the presence of the FDA proposed footnote, 39 percent of the respondents who identified a product as more healthful incorrectly chose food 1 as more healthful, presumably focusing on the zero *trans* fat content in the higher fat food, with only 45 percent choosing the food with the lowest total amount of saturated and *trans* fats combined. In the presence of the alternative footnote, which mentioned the need to keep the intake of both saturated and *trans* fats low a majority of respondents again correctly chose food 2 (69 percent) as

more healthful, with 17 percent choosing food 1.

The majority of the comments strongly opposed the proposed footnote statement and recommended that FDA drop the footnote and finalize the quantitative (grams per serving) label declaration of *trans* fat on a separate line below saturated fat with no % DV. Several comments stated that the proposed footnote statement is inconsistent with the IOM/NAS macronutrient report and incorrectly establishes a de facto DV or UL of zero for *trans* fat intake that the IOM/NAS never intended to establish. Some of these comments explained that the proposed footnote statement takes into consideration part of the recommendation from the IOM/NAS report that recommends the intake of *trans* fat be as low as possible, while ignoring the part that states ''* * * while consuming a nutritionally adequate diet.'' The comments claimed that the omission of the latter part of the recommendation significantly changes the meaning of the statement and the recommendation of the IOM/NAS, namely that the IOM did not intend to recommend that *trans* fat be totally eliminated from the daily diet. These comments noted that the IOM/NAS report did not establish an UL for *trans* fat despite the relationship between intake of *trans* fat and CHD stating that *trans* fatty acids are unavoidable in ordinary, nonvegan diets, and to attempt to eliminate them would require significant changes in dietary intake patterns which may result in unknown and unquantifiable health risks. The comments went on to say that the IOM committee indicated that ''[I]t is possible to consume a diet low in *trans* fatty acids by following the dietary guidance provided in Chapter 11'' of their report. The comments concluded that the proposed footnote statement is inconsistent with the IOM/NAS report and could mislead consumers into substituting more foods with saturated fat in an effort to avoid foods containing *trans* fat.

Similarly, several comments described the proposed footnote statement as an unjustified warning statement on the label of foods that contain *trans* fat. Some of these comments stated that consumers will perceive the footnote as a de facto % DV of zero and will not understand the meaning of the portion of the proposed footnote statement ''as low as possible;'' consumers will perceive it as a warning to avoid *trans* fat-containing foods at all costs. Several comments stated that the footnote would be misleading because consumers would be confused about the relative impact of saturated fat (by thinking up to 20 g, i.e., the DV for saturated fat, is heart healthy) compared to *trans* fat (thinking *trans* fat intake must be kept to zero to be heart healthy). Some of these comments mentioned that the dietary recommendation to reduce saturated fat is a well established goal of federal agencies and other health organizations and that Americans consume much more saturated fat than *trans* fat. The comments stressed, therefore, that any footnote statement on the nutrition label about *trans* fat should not undermine the important health message consumers have learned over the years about limiting saturated fat intake.

Comments also criticized the proposed footnote for being more prescriptive than, and inconsistent with, other Federal Government dietary recommendations, such as the Dietary Guidelines for Americans 2000 and the NCEP Adult Treatment Panel III Report, 2001. According to the comments, the recommendations of these reports support the need for Americans to choose diets that are low in saturated fat and cholesterol and moderate in fat while reducing, not eliminating, dietary consumption of *trans* fat.

Comments also pointed out that the IOM/NAS report gives essentially identical advice for saturated fat and cholesterol as it gives for *trans* fat, yet FDA's proposed footnote singled out only their recommendation for *trans* fat. The comments argued that this placed undue emphasis on the role of *trans* fat in heart health.

Many of the comments expressed concern that the proposed footnote statement is potentially misleading to consumers and will undermine the key goals of this rulemaking. To that end, the comments strongly recommended that FDA drop the proposed footnote statement from the final rule and take time to conduct consumer research to determine the impact of the proposed footnote statement on consumers' understanding and comprehension. A few comments cited FDA's obligation under the 1990 amendments (paragraph 2(b)(1)(A)) to ensure that nutrition labeling is ''conveyed to the public in a manner which enables the public to readily observe and comprehend such information and to understand its relative significance in the context of a total daily diet.'' The comments argued that the proposed footnote statement should be consumer tested to ensure that the nutrition information provides meaningful guidance to consumers and drives the market in a nutritionally beneficial direction. The majority of comments that opposed the proposed footnote statement commented that even in the absence of a DV, consumers can still find quantitative information useful (similar to the listing of monounsaturated and polyunsaturated fats on the nutrition label).

Many of the comments recommended that FDA not move forward with the proposed footnote until the IOM/NAS completes a study, which is underway, of the uses of DRIs in nutrition labeling. The comments noted that the IOM is under contract with FDA, USDA and Health Canada to assess the objectives, rationale, and recommendations for the methodology for selecting reference values for nutrition labeling of foods based on DRIs and will identify guiding principles for use in setting reference values for nutrients on the food label. The comments also noted that the IOM committee is expected to complete its work on this project in mid–2003 and to issue a report in September 2003.

One comment stated that the prescriptive nature of the proposed footnote may also violate international obligations of the United States under the World Trade Organization (WTO). The comment stated that WTO's Agreement on the Sanitary and Phytosanitary (SPS) Measures requires that SPS measures intended to protect human health be based upon sound science. The comment questions this regarding the proposed footnote statement because it implies a benefit to consumers who avoid consuming *trans* fat foods when the IOM/NAS suggests that eliminating *trans* fats entirely in the diet would lead to greater harm by impeding dietary intake of essential nutrients. The comment also stated that if the proposed footnote statement was not a SPS measure, it would violate WTO's Agreement on Technical Barriers to Trade, which requires that ''technical'' regulations fulfill a legitimate purpose and be no more trade restrictive than necessary. The comment expressed the opinion that the proposed footnote statement oversimplifies and misrepresents the IOM/NAS report on which it is based and that the statement is more trade restrictive than necessary because alternatives to such a footnote statement, such as a consumer education program, are available to assist consumers in understanding the quantitative *trans* fat labeling in the absence of a DV.

Some comments expressed concern that the proposed footnote statement would provide a disincentive to the industry such that many foods would be reformulated to reduce or remove *trans* fat but, as a result, saturated fat content would be increased. Other comments expressed concern about the lack of

label space for the proposed footnote statement. One comment stated that the Nutrition Facts panel would no longer be simple and uncluttered and, as a result, consumers would be discouraged from reading the label. Other comments complained that the 30-day comment period for the November 2002 proposal was inadequate to address footnote issues and to conduct needed consumer research.

Many of the comments stated that FDA did not carry its burden under the first amendment. The comments argued that the proposed footnote statement fails to serve a substantial government interest in alleviating a genuine public harm, does not directly advance that interest and is not narrowly tailored. Several comments stated that the footnote statement is tantamount to a warning statement and is misleading.

Some comments stated that the use of the footnote statement would be establishing a new precedent by providing guidance, not just quantitative information on the Nutrition Facts panel. They argued that there were no consumer data to show that the footnote will help consumers understand the information. Comments stated that the agency had such data when it decided on the Nutrition Facts panel labeling format that only included quantitative information and should have consumer data here, where a new precedent is being considered.

Lastly, a few comments opposed FDA's offer to consider exercising our enforcement discretion to allow products to begin declaring *trans* fat and include the proposed footnote statement prior to publication of the final rule. One comment stated that the agency should publish a ''clarification notice'' to stop companies that are changing their labels now.

The agency is persuaded by comments that the statement it proposed may have unintended consequences. It was not FDA's intent to distract consumers from dietary guidance to minimize intake of saturated fat, but rather, in the absence of a DV for *trans* fat, to inform consumers of recommendations concerning its consumption.

While the online survey was small, its results support concerns expressed by the food industry that some consumers would interpret the footnote as a de facto DV of zero or as a warning statement that they should avoid all *trans* fat. The agency agrees with comments that this interpretation is inconsistent with dietary guidance given in the IOM/NAS report to keep intake of *trans* fat ''as low as possible while consuming a nutritionally adequate diet'' (Ref. 140), as well as guidance in the Dietary Guidelines 2000 to cut back on saturated and *trans* fats when reducing total fat intake (Ref. 87) or in the 2001 NCEP report to keep the intake of *trans* fatty acids low (Ref. 89). FDA also agrees that these scientific reviews have similar dietary recommendations for the intake of saturated fat and cholesterol that are important for consumers to take into consideration when making decisions about heart-healthy dietary choices. The agency addressed only *trans* fat in the footnote statement, not because saturated fat or cholesterol had different recommendations or were less important, but because they have established DVs from which to determine the % DV for nutrition labeling purposes.

The agency agrees with comments that support consumer testing to ensure that information on the food label provides meaningful guidance to consumers and drives the market in a nutritionally beneficial direction. FDA concludes, therefore, that based on arguments presented in the comments, that while the footnote would provide guidance on dietary recommendations for *trans* fat, it is premature to require the use of the proposed footnote statement in the nutrition label without further research. Consumer research would likely need to provide information on the impact of the statement in a footnote on consumers' food selections.

Accordingly, as a result of concerns expressed in the comments, asserting that consumers may place undue emphasis on *trans* fat information relative to other heart-unhealthy fats from the presence of the *trans* fat proposed footnote, the agency is not proceeding at this time to incorporate a requirement for a footnote statement in this final rule. Instead, FDA is issuing an ANPRM elsewhere in this issue of the **Federal Register** that will solicit comment and additional consumer research on the use of a footnote and the language that may be used in a footnote to better reflect the dietary recommendations given in the previously-mentioned scientific reviews. The ANPRM will also solicit information and data that potentially could be used to establish new nutrient content claims about *trans* fat, to establish qualifying criteria for *trans* fat in current nutrient content claims for saturated fat and cholesterol, lean and extra lean claims, and health claims that contain a message about cholesterol raising fats, and to establish disclosure and disqualifying criteria for *trans* fat.

The agency is also requesting comments on whether it should consider statements about *trans* fat, either alone or in combination with saturated fat and cholesterol, as a footnote in the Nutrition Facts panel or as a disclosure statement in conjunction with claims to enhance consumer's understanding about cholesterol-raising lipids. In light of the need for consumer research to evaluate consumers' understanding of the totality of dietary recommendations that address the selection of foods for a heart-healthy diet, the agency notes in the ANPRM that it intends to conduct such research and looks forward to receiving additional research from other interested parties.

In the meantime, as noted in the preceding comment, FDA is issuing this final rule to require the quantitative declaration of *trans* fat in the Nutrition Facts panel. To help consumers understand more about this heart-unhealthy fat, the agency plans to initiate consumer education programs about this final rule following publication (see Comment 28). As noted earlier, most comments that opposed the proposed footnote stated a belief that even in the absence of a DV, consumers can still find quantitative information useful, and pointed to current labeling of mono- and polyunsaturated fats. In light of previous research that shows that consumers often use information on the Nutrition Facts panel to compare levels of nutrients in two or more foods, FDA concludes that it is important to proceed to list the quantitative information on *trans* fat at this time so that consumers will have information to use in comparing products and making dietary selections to reduce their intake of *trans* fat. The agency believes a footnote or other labeling approach about saturated fat, cholesterol, and *trans* fat may provide additional assistance to convey the relative importance of each of these fats to consumers in a manner which enables them to understand their relative significance, to each other and in the context of a total daily diet. However, because of the public health impact of CHD in the United States and the additional time it will take to conduct the necessary consumer research, the agency concludes that it is essential to proceed at this time to mandate the listing of the quantitative information on *trans* fat so that consumers will be able to use that information to help maintain healthy dietary practices and to address an added footnote statement at a later time.

FDA acknowledges concerns, expressed in response to the November

2002 notice (67 FR 69171) to reopen the comment period, about the shortness of the comment period and requests to extend the comment period. However due to the high level of interest in the public health and economic aspects of this rule, the agency did not believe it was in the public interest to provide for additional time for comment. A longer comment period, however, will be provided for the ANPRM being published elsewhere in this issue of the **Federal Register**.

(Comment 18) A few comments requested that the term ''*trans* fatty acids'' not be used interchangeably with ''*trans* fat'' as proposed in § 101.9(c)(2)(i)(B) in the November 1999 proposal. These comments stated that the term ''fatty acid'' would be confusing to consumers and is inconsistent with the terminology used in nutrition labeling and claims for other fatty acids, i.e., ''saturated fat,'' ''polyunsaturated fat,'' and ''monounsaturated fat.'' The comments stated that while ''fatty acid'' is technically correct, labels should use the easier term to understand, i.e., ''*trans* fat.''

The agency agrees that there should be consistent terminology used on the food label and notes that proposed § 101.9(c)(2)(i)(B), which dealt primarily with the proposed footnote about *trans* fat content, is deleted from this final rule. The agency did not move the sentence providing for the use of the term ''*trans* fatty acids'' to new § 101.9(c)(2)(ii). Therefore, the term ''fatty acids'' is not to be used on the Nutrition Facts panel.

Conforming Amendments

Because this final rule is making *trans* fat a mandatory nutrient to be placed on a separate line in nutrition labeling, there are a number of conforming amendments throughout § 101.9 that must be made. Section 101.9(c) requires that information on mandatory nutrients, such as saturated fat and *trans* fat, be included in all nutrition labeling unless otherwise excepted from such labeling as provided for in specified paragraphs.

Special provisions within § 101.9(c) allow for shortened formats that provide manufacturers flexibility to omit noncore nutrients (i.e., mandatory nutrients other than calories, total fat, sodium, total carbohydrate, and protein) that are present in insignificant amounts from the list of nutrients and group them in a summary statement at the bottom of the label that states ''Not a significant source of _____'' (see 58 FR 2079 at 2083, Comment 8, January 6, 1993). These special provisions are found in § 101.9(c)(1)(ii) for calories from fat, § 101.9(c)(2)(i) for saturated fat, § 101.9(c)(3) for cholesterol, § 101.9(c)(6)(i) for dietary fiber, § 101.9(c)(6)(ii) for sugars, and § 101.9(c)(8)(iii) for vitamin A, vitamin C, calcium, or iron. For consistency with the labeling scheme for these other noncore mandatory nutrients, new § 101.9(c)(2)(ii) provides that if the *trans* fat content is not required and, as a result, not declared, the statement ''Not a significant source of *trans* fat'' must be placed at the bottom of the table of nutrient values. Also, for added consistency, new § 101.9(c)(2)(ii) will point to an exception to this requirement under § 101.9(f). Section 101.9(f) provides for a simplified format to be used on labels of products containing insignificant amounts of more than half the nutrients required to be in the Nutrition Facts label. Except as specified in § 101.9(f)(4), products that qualify for the simplified format do not have to use the statement ''Not a significant source of _____'' for noncore nutrients that are omitted from the label under § 101.9(c). An example of such an exception would include when nutrition claims are made for the product.

Current § 101.9(c)(2)(i) requires label declaration of saturated fat content information on a separate line (the ''Not a significant source of ____'' statement would not be an option), if claims are made about fat or cholesterol and if ''calories from saturated fat'' is declared. In the November 1999 proposal, § 101.9(c)(2)(i) was amended to also require label declaration of saturated fat content information when claims are made about fatty acids. Current § 101.9(c)(2)(i) did not include claims about fatty acids because at the time that regulation was proposed (56 FR 60478, November 27, 1991), it was thought unnecessary since no claims were proposed for fatty acids that were present at less than 0.5 g per reference amount. However, when the ''saturated fat free'' claim was established in the final rules (58 FR 2302 at 2331), FDA inadvertently did not amend § 101.9(c)(2)(i) to require the declaration of saturated fat content on a separate line when fatty acid claims were made. As a result, the declaration of saturated fat content was not required when ''saturated fat free'' claims were made. This is inconsistent with regulations governing claims for all other nutrients that require the listing of the nutrient that is the subject of the claim within the Nutrition Facts panel so that consumers can easily find quantitative information supporting claims made for a product. Because no comments objected to the proposed requirement in the November 1999 proposal for a label declaration of saturated fat content when fatty acid claims are made, which would require that saturated fat content be listed when a ''saturated fat free'' claim is used, FDA is finalizing this part of the regulation as proposed. Similarly, new § 101.9(c)(2)(ii) also requires label declaration of *trans* fat content information if claims are made about fat, fatty acids, or cholesterol.

In reference to the statement ''Not a significant source of _____'' that is to be placed at the bottom of the list of nutrient values, the agency proposed in the November 1999 proposal (64 FR 62746 at 62757) to remove the phrase ''in the same type size'' in § 101.9(c)(2)(i) where it refers to the size of the statement. This action was intended to correct a technical error in the regulations caused by the fact that current § 101.9(d)(1)(iii) allows the statement, along with all footnotes, to be in type size no smaller than 6 point type while it requires the listing of nutrient values to be in type size no smaller than 8 point type. Accordingly, the phrase ''in the same type size'' in § 101.9(c)(2)(i) would require the ''Not a significant source of ____'' statement to be in 8 point type, conflicting with § 101.9(d)(1)(iii). This technical error was addressed in amendments published on August 18, 1993 (58 FR 44063 at 44065–66). To correct the problem, FDA stated at that time (58 FR 44063 at 44065–66) that it was removing the sentence from § 101.9(c)(8)(iii) that required the ''Not a significant source of ___'' statement to be in the same type size as nutrients listed in the Nutrition Facts panel. However, the agency failed to notice the same error in § 101.9(c)(2)(i), (c)(3), (c)(6)(i), and (c)(6)(ii). Inadvertently, the conflicting sentence was never removed from § 101.9(c)(8)(iii), nor were the statements requiring ''in the same type size'' removed from any of the other paragraphs. In this final rule, FDA is making the correction in § 101.9(c)(2)(i) and in new § 101.9(c)(2)(ii). The agency intends to remove the phrase ''in the same type size'' from the remaining sections of § 101.9(c) in the future.

In addition, current nutrition labeling rules provide exemptions for select nutrients when food products qualify for simplified formats (see § 101.9(f)).

FDA is revising § 101.9(f) that pertains to the use of a simplified format when a food product contains insignificant amounts of seven or more of the mandatory nutrients. This section implements section 403(q)(5)(C) of the act, which states that ''If a food contains

insignificant amounts ... of more than one-half the nutrients required * * * to be in the label or labeling of the food, the Secretary shall require the amounts of such nutrients to be stated in a simplified form prescribed by the Secretary.'' Current regulations considered 13 required nutrients (calories, total fat, saturated fat, cholesterol, sodium, total carbohydrate, dietary fiber, sugars, protein, vitamin A, vitamin C, calcium, and iron) and calculated ''more than one-half'' to mean that seven or more nutrients must be at insignificant levels for a product to use the simplified format (58 FR 2709 at 2140, comment 173). Accordingly, in conformance with the statutory requirements, the inclusion of *trans* fat as a mandatory nutrient results in a total of 14 required nutrients. This new total necessitates changing the number of nutrients that must be present in insignificant amounts in § 101.9(f) from seven to eight to qualify a food for the simplified format. Therefore, FDA is revising § 101.9(f) to state ''The declaration of nutrition information may be presented in the simplified format set forth herein when a food product contains insignificant amounts of eight or more of the following: Calories, total fat, saturated fat, *trans* fat, cholesterol, sodium, total carbohydrate, dietary fiber, sugars, protein, vitamin A, vitamin C, calcium, and iron * * *''

FDA is modifying sample labels throughout § 101.9 to be consistent with the revisions described previously. The citations for the sample labels that have been modified are as follows: § 101.9(d)(11)(iii) (the tabular display of the nutrition label), paragraph (d)(12) (the full nutrition label), paragraph (d)(13)(ii) (an example of an aggregate nutrition label), and paragraph (e)(5) (nutrition information presented for a food ''as purchased'' and ''as prepared''). Likewise, the sample labels in § 101.9(j)(13)(ii)(A)(*1*) and (j)(13)(ii)(A)(*2*) (tabular display and linear displays, respectively, of nutrition labels for foods in packages with a total surface area available to bear labeling of 40 or less square inches) are also being revised to include *trans* fat.

Other conforming amendments to § 101.9 that are required as a result of this rulemaking include revisions to paragraphs (g)(5) and (g)(6) that inform the industry of how FDA will determine compliance with this section. Paragraph (g)(5) addresses those nutrients for which dietary guidance generally recommends limitations on intake. Accordingly, FDA will include *trans* fat as one of the nutrients that are deemed to be misbranded under section 403(a) of the act if the nutrient content of the composite sample is greater than 20 percent in excess of the value for that nutrient declared on the label. Likewise, § 101.9(g)(6) is being revised to state that reasonable deficiencies in a food of calories and specified nutrients, including *trans* fat, under labeled amounts are acceptable within current good manufacturing practice.

Section 403(q)(5)(F) of the act specifies that dietary supplement products shall bear nutrition labeling ''in a manner which is appropriate for the product and which is specified in regulations... .'' Accordingly, FDA issued regulations in § 101.36 that specify the nutrition information that must be on the label or labeling of dietary supplements (62 FR 49826, September 23, 1997). In the November 1999 proposal, FDA proposed to amend § 101.36 to maintain consistency in the nutrition labeling of conventional foods and of dietary supplements. Comments unanimously supported revising § 101.36 to be consistent with § 101.9 as it pertains to the provisions for *trans* fat. Accordingly, FDA is revising paragraph § 101.36(b)(2)(i) to provide for *trans* fats in the nutrition labeling of dietary supplements.

This final rule also impacts on the voluntary nutrition labeling program of raw fruits, vegetables, and fish in that § 101.45(a)(2) requires that nutrients be declared in accordance with § 101.9. However, because section 403(q)(4)(A) of the act requires the Secretary, and by delegation FDA, to furnish nutrition information for that program and the agency has proposed to update those values (67 FR 12918, March 20, 2002), the agency is deferring action on § 101.45 until a final rule is published on that rulemaking.

C. Definition of Trans Fatty Acids

In the November 1999 proposal, FDA defined *trans* fatty acids as ''unsaturated fatty acids that contain one or more isolated (i.e., nonconjugated) double bonds in a *trans* configuration (64 FR 62746 at 62757).

(Comment 19) Most of the comments on the definition of *trans* fat supported the proposed definition that excludes fatty acids with conjugated bonds, stating that *trans* fatty acids with conjugated bonds are metabolized differently than those with nonconjugated bonds and that this definition adequately identifies the fatty acids intended to be covered by the rule. A few comments recommended that *trans* fatty acid precursors of conjugated linoleic acid (CLA) should also be excluded from the definition. These comments noted that *trans*-vaccenic acid (*trans*–11 18:1), which is the dominant *trans* fatty acid in products of ruminant origin (e.g., cows' milk), can be desaturated in the body and converted to CLA. For this reason, the comments recommended that *trans* fatty acids of ruminant origin not be included in the definition of *trans* fatty acids.

Other comments stated that *trans* fatty acids with conjugated bonds should be included in the definition of ''*trans* fatty acids.''

Another comment requested that FDA explicitly state that the rules on the labeling and claims for *trans* fatty acids apply equally to naturally occurring *trans* fats.

FDA notes that the comments requesting that *trans* vaccenic acid and other *trans* fatty acids of ruminant origin be excluded from the definition of *trans* fatty acids and that fatty acids with conjugated bonds be included focused on functional or metabolic aspects of these compounds (e.g., their metabolic *trans*formations to other types of fatty acids) rather than on their actual chemical structures. Since most of the comments agreed with the proposed definition, which identifies *trans* fatty acids by their chemical structures, the agency is taking no action in response to suggestions to define *trans* fatty acids by their functional attributes. Thus for the purposes of this rule, the origin of the *trans* fatty acid does not matter. *Trans* vaccenic acid, a *trans* fatty acid with a single double bond, and other *trans* fatty acids of ruminant origin with either a single double bond or nonconjugated double bonds are included in this chemical definition of *trans* fatty acids. *Trans* fatty acids with conjugated bonds will not be included because they do not meet the Agency's regulatory chemical definition of *trans* fatty acids which is ''all unsaturated fatty acids that contain one or more isolated double bonds in a *trans* configuration.'' FDA notes also that while the proposal combined saturated fat and *trans* fatty acids on a single line, this final rule provides for a separate line for *trans* fat. The declarations of saturated fat and *trans* fat will now be separate and both declarations will be based on chemical definitions of these components. Again, *trans* fatty acids, regardless of origin, that meet the above definition are to be included in the label declaration of *trans* fat.

FDA notes that, in classifying fatty acids, the IOM report on macronutrients uses a chemical definition of *trans* fatty acids that differs from FDA's regulatory chemical definition. The IOM report includes all fatty acids with a double bond in the *trans* configuration in the broad category of *trans* fatty acids (Ref.

140). Thus, the IOM definition includes both conjugated and non-conjugated double bonds in the *trans* configuration, whereas FDA's definition only includes *trans* fatty acids with nonconjugated double bonds. In addition, the IOM report considers conjugated linoleic acid as a collective term for geometric and positional fatty acids in which the double bonds (*trans* and/or *cis*) are conjugated. In the IOM report, the categories, *trans* fatty acids and conjugated linoleic acid, overlap. Under FDA's definition, conjugated linoleic acid would be excluded from the definition of *trans* fat. Thus, using FDA's regulatory chemical definition, the categories ''*trans* fatty acids'' and ''conjugated fatty acids'' are mutually exclusive. The definition of *trans* fatty acids, excluding fatty acids with conjugated double bonds, is consistent with the way that *cis* isomers of polyunsaturated fatty acids are defined in redesignated § 101.9(c)(2)(iii).

D. Methodology

(Comment 20) One comment asked whether the Association of Official Analytical Chemists (AOAC) Official Method 996.01 can be used for measuring *trans* fat in foods. The comment noted that, at present, AOAC Official Method 996.01 is the ideal method for the measurement of total fat, saturated fat, and mono- and polyunsaturated fat in foods. The comment noted further that AOAC Official Method 996.01 was originally intended for cereal products containing 0.5–13 percent total fat and that recently, a study by Ali et al. (Ref. 30) demonstrated its applicability to all types of food matrices with fat contents ranging from 0.7 to 97.5 g/100 g food. The comment noted that the method of Ali et al. (Ref. 30) used an SP–2560 fused silica capillary column (100 meters (m) x 0.25 millimeter (mm)) and can be used for the accurate determination of *trans* fatty acids. The comment noted that if appropriate gas chromatography (GC) operating conditions are selected, the SP–2560 column as well as columns of similar polarity give a very good separation of *cis* and *trans* isomers.

FDA notes that, as currently written, AOAC Official Method 996.01 is not suitable for quantifying *trans* fatty acids for food labeling purposes because the capillary column specified (i.e., 30 m x 0.25 mm id., 0.2 μm film, non-bonded 90 percent cyanopropyl, 10 percent phenyl siloxane) is not sufficiently long to obtain adequate separation of the *cis* and *trans* fatty acids. Ali et al., (Ref. 30) modified the method and used a 100 m flexible fused silica column (SP–2560, 100 m x 0.25 mm id., 0.20 μm film thickness) to obtain better separation of isomers in food samples. Specifically, better resolution in the complex 18:1 and 18:2 regions was obtained with the longer column. FDA has found that when appropriate operating conditions are selected, the SP–2560 column and other columns of similar polarity give a very good separation of *cis* and *trans* isomers. We point out, however, that the modification described by Ali et al., (Ref. 30) has not been subjected to a collaborative study and is not an official method.

It is important to note that FDA regulations do not specify the methodology that firms are to use in obtaining values for nutrition labeling purposes. Rather, under § 101.9(g)(2), FDA determines compliance with nutrition labeling rules by using appropriate analytical methods ''as given in the 'Official Methods of Analysis of the AOAC International' 15th Ed. (1990) or, if no AOAC method is available or appropriate, by other reliable and appropriate analytical procedures.'' Firms may choose to use a method other than that which the agency uses to determine compliance, but the firm would be subject to, for compliance purposes, a method the agency considers appropriate under § 101.9(g). With respect to analysis of fats (including *trans* fat), FDA laboratories utilize the most recent editions (including revisions of methods from the Association of Official Analytical Chemists International (AOACI; *Official Methods of Analysis of AOAC International*, 17th edition, Revision 1, 2002; AOAC International, Gaithersburg, MD) (Ref. 143) and the American Oil Chemists Society (AOCS; *Official Methods and Recommended Practices of the AOCS*, 2002–2003 Methods-Additions and Revisions, AOCS Press, Champaign, IL) (Ref. 144)).

(Comment 21) Several comments asked that FDA recognize AOAC Method 996.06 as modified in the *Journal of the Association of Official Analytical Chemists* in January 2000, as a suitable method for the analysis of *trans* fatty acids for food labeling purposes.

FDA points out that recommendations for the modification of AOAC Official Method 996.06 (Ref. 105) were published in the *Journal of the Association of Official Analytical Chemists* (Ref. 106). The recommendations are based on the work of DeVries et al. 1999 (Ref. 107). DeVries and coworkers report that while quantitation of fat in foods has been performed successfully with AOAC Official Method 996.06, a number of situations have been encountered that render the following method note inaccurate: ''For any unknown or uncalibrated peaks, use the nearest calibrated fatty acid response factors and conversion factors'' (Ref. 107). Specifically, the identification of extraneous compounds and availability of additional standard fatty acid methyl esters combined with mass spectral data led to the recommendation of modifications in AOAC Official Method 996.06.

Specific recommendations for modifications include recommendations that the column requirements for the method be changed to a performance-based specification such that a capillary column capable of separating adjacent peaks of C18:3 and 20:1 and the fatty acid methyl ester trio of adjacent peaks of C22:1, C20:3 and C20:4 with a resolution of 1 or greater be used. Column SP–2560, 100 m x 0.25 mm with a 0.20 μm film was identified as a suitable column.

The recommendations referenced in the paragraph above have now been incorporated into AOAC Method 996.06 (*Official Methods of Analysis of AOAC International*, 17th edition, Revision 1, 2002; chapter 41.1.28A) (Ref. 105). This method is suitable for use in a wide range of food matrices for measuring *trans* fat for labeling purposes.

AOAC Method 996.06 cited above for *trans* fat analysis is the most current AOAC gas chromatography method available and FDA will consider it an appropriate method under § 101.9(g)(2) for determining compliance with nutrition labeling provisions for *trans* fat. AOAC Method 996.06 is not included in the 15th edition (1990) of *Official Methods of Analysis of AOAC International* (which is incorporated by reference in § 101.9(g)(2)) because the process of development and validation of this method was not completed until 1996. Therefore, AOAC Method 996.06 as it is reported in Revision 1, 2002 of the 17th edition of *Official Methods of Analysis of AOAC International* (Ref. 105) may be used as an ''other reliable and appropriate analytical procedure'' as provided for in § 101.9(g)(2). FDA intends to propose amendments in the future on the edition of the AOAC method listed in § 101.9(g)(2) and other needed revisions of § 101.9.

(Comment 22) One comment noted that detection methodology is not sophisticated enough to accurately measure *trans* fat in all food products. The comment stated that significant work is needed to validate the AOCS methods for food matrices other than fat and oils.

FDA disagrees with this statement. While the agency recognizes that AOCS methods have not been extended to cover matrices other than fats and oils, the AOAC method 996.06 (*Official Methods of Analysis of AOAC International*, 17th edition, Revision 1, 2002) (Ref. 105) is suitable for the analysis of *trans* fat in a wide range of foods of varying fat content. As noted in comment 19, above, AOAC Method 996.01 is not suitable for quantifying *trans* fatty acids for food labeling purposes because the capillary column specified is not sufficiently long to obtain adequate separation of the *cis* and *trans* fatty acids.

(Comment 23) A few comments recommended that FDA consider listing amounts of *trans* fat to the nearest tenth or hundredth of a gram, rather than to the nearest 0.5 g. One of these comments stated that Canada has established a rounding limit of 0.1 g for food labeling indicating that analytical methods are capable of detecting that amount.

FDA disagrees with these recommendations. FDA notes that while these recommended levels might be quantifiable by laboratories using GC methodology such as that described in AOAC method 996.06 (*Official Methods of Analysis of AOAC International*, 17th edition, Revision 1, 2002) (Ref. 105), they will pose a problem for laboratories that are set up to quantify *trans* fatty acids by infrared spectroscopy (IR) methodology because the detection limits of the currently available IR methods are higher than those of the GC methods. More importantly, however, there are no unambiguous methods for confirming the very low levels suggested by the comment.

Moreover, FDA notes that the increment for listing *trans* fat is consistent with increments used for listing total fat and saturated fat. Therefore, the agency is finalizing § 101.9(c)(2)(ii) to state that *trans* fat shall be expressed, as proposed, to the nearest 0.5 g increment below 5 g and to the nearest gram increment above 5 g.

(Comment 24) One comment noted that the IR method of choice in the November 1999 proposal, AOCS Recommended Practice Cd 14d–96 (Ref. 45), generally overestimates *trans* fat at low levels because of interferences and issues with both accuracy and detection limits. The comment noted further that the AOCS GC method Ce 1f–96 (Ref. 46) has better sensitivity, but has not been validated for many types of food products and that significant work is needed to validate this method for other food matrices.

FDA agrees that the detection limits of the AOCS GC method (Ce 1f-96) (Revised 2002, Ref. 146) are lower than those of the AOCS IR recommended practice (Cd 14d-96) (Revised 1999, Ref. 145). FDA notes that AOCS Recommended Practice Cd-14d-96 is applicable to the determination of isolated *trans* double bonds in natural or processed oils and fats with *trans* levels equal or greater than about 0.8 percent. The lower limit of quantitation for this IR recommended practice may be higher (i.e., the method may be less accurate for determination of low levels of *trans* fat) for complex systems such as commercial food products (Ref. 145).

The AOCS Official Method Ce 1f–96 (Ref. 146) is designed to evaluate the level of *trans* isomers formed during refining or during hydrogenation of vegetable oils or fats and the scope of the method does not extend beyond these matrices. FDA notes that the recent improvements in AOAC Official Method 996.06 as referenced in Revision 1, 2002 (Ref. 105), have resulted in the applicability of this GC method to a wide range of food products.

(Comment 25) One comment asked if *trans* fat values below 0.5 g are to be declared as ''0,'' how FDA will address the labeling of foods like butter, where *trans* fat content fluctuates seasonally above and below 0.5 g per serving. The comment stated that FDA should err on the side of conservatism and require that labeling be based on the highest levels found in such products over the entire year.

FDA has long recognized that variations occur naturally in the nutrient content of foods. The compliance procedures that FDA follows, which are found in § 101.9(g)(2), provide that a sample for nutrient analysis must consist of a composite of 12 subsamples, taken one from each of 12 randomly chosen shipping cases. FDA will then analyze the nutrient content of this composite test sample. Upon determination of the laboratory analyses, FDA uses the compliance procedures set forth in § 101.9(g)(5) and (g)(6) to determine if the values declared for those nutrients that have recommended dietary limits, such as saturated fat and cholesterol, misbrand the label. The content of a sample composite of these nutrients is in compliance if the analyzed value is no more than 20 percent greater than the value declared on the label. Stated another way, for nutrients listed in § 101.9(g)(5), the ratio between the nutrient level obtained by laboratory analysis and the product's label value, multiplied by 100, cannot be greater than 120 percent for the product to be in compliance. For example, if the laboratory value is 4 grams, and a product's label value is 2 gram, the ratio (4/2) x 100 = 200 percent. This value is greater than 120 percent, hence, the product is out of compliance.

FDA did not address this issue in the proposal because the declaration of ''saturated fat'' included *trans* fats, and saturated fats are addressed in § 101.9(g)(5) and (g)(6). Now that FDA is requiring that *trans* fat be declared in the main body of the nutrition label (i.e., the amount of *trans* fat is not in a footnote), FDA is making a conforming amendment to § 101.9(g)(5) and (g)(6) to include *trans* fatty acids.

FDA's policy since the 1970s assigns the manufacturer the responsibility for assuring the validity of a product label's stated nutrient values (Ref. 108). Accordingly, the source of the data used to calculate nutrition labeling values is the manufacturer's prerogative, but FDA's policy recommends that the nutrient values for labeling be based on product composition, as determined by laboratory analysis of each nutrient. If a manufacturer knows that a nutrient is likely to vary over seasons or due to other factors (e.g., location, growing conditions, product *trans*port, or processing practices), in order to assure compliance, the manufacturer should analyze samples of the product over the various seasons or relative to other factors to account for variability of nutrient content.

To ensure that label values will accurately represent the nutrient content of food products to consumers and also have a high probability of being in compliance with nutrition labeling regulations, FDA recommends the calculation of a one-sided 95 percent prediction interval as the most appropriate and the preferred method to use in computing label values (Ref. 108).

Prediction intervals take into account the variability of a nutrient. Mean values do not. A manufacturer of a product, like butter, whose *trans* fat content fluctuates seasonally, would want to analyze samples of *trans* fat during each season and statistically consider using 95 percent prediction intervals to calculate the nutrition label value for *trans* fat. A predicted value on a nutrition label may sometimes indicate a level of a nutrient such as saturated fat at a higher level than is actually in the product, but it will never show a lower level than the product contains. While sometimes predicted values and mean values round to the same nutrient level, products bearing mean values on their nutrition labels

have a lower probability of meeting FDA compliance requirements.

VI. Nutrient Content Claims, Health Claims, Disclosure and Disqualifying Levels

In its November 1999 proposal, FDA proposed a definition for the nutrient content claim ''*trans* fat free'' and proposed limits on the amounts of *trans* fat wherever saturated fat limits are placed on nutrient content claims, health claims, or disclosure and disqualifying levels. Several comments to that proposal requested that the final rule define the claim ''reduced *trans* fat'' or amend the claim ''reduced saturated fat'' to require a reduction of saturated and *trans* fats combined. To address this issue, the agency reopened the comment period (65 FR 75887) to consider ''reduced *trans* fat'' and ''reduced saturated and *trans* fat'' claims.

With regard to the specific definitions, FDA proposed that ''*trans* fat free'' and ''saturated fat free'' should be defined as less than 0.5 g *trans* fat and less than 0.5 g saturated fat per reference amount and per labeled serving; ''low saturated fat'' as 1 g or less of saturated fat and less than 0.5 g of *trans* fat per reference amount and not more than 15 percent of calories from saturated fat and *trans* fat combined; ''reduced saturated fat'' as at least 25 percent less saturated fat and at least 25 percent less saturated fat and *trans* fat combined; ''lean'' as 4.5 g or less of saturated fat and *trans* fat combined; and ''extra lean'' as less than 2 g of saturated fat and *trans* fat combined. In addition, cholesterol claims were allowed only on foods containing 2 g or less of saturated fat and *trans* fat combined, and disqualifying and disclosure levels were set at 4 g or less of saturated fat and *trans* fat combined. FDA did not propose to define ''low *trans* fat.''

The comments relating to claims were very diverse and indicated strongly opposing views. With regard to the ''*trans* fat free'' claim, some comments favored the proposed definition, while other comments suggested increasing the saturated fat limit, eliminating the saturated fat limit , or not defining this claim. Similarly, some comments supported the ''saturated fat free'' claim, while other comments recommended that the *trans* limit be increased to 2 g. For ''low saturated fat'' some comments favored the proposed definition, while others suggested increasing the *trans* fat limit as high as 2 g. One comment recommended that this claim be less than or equal to 1.5 g of saturated and *trans* fats combined.

A number of comments supported having a ''reduced *trans* fat'' claim and others were against it. The vast majority of the comments in favor of this claim suggested that *trans* fat be reduced by at least 25 percent, but there was little agreement on the secondary saturated fat criterion. The comments ranged from no limit on saturated fat, to no increase in the level of saturated fat, a limit of less than or equal to 2 g, or at least a 25 percent reduction. The comments on ''reduced saturated'' fat were similar to the comments on ''reduced *trans* fat'' in that there was no agreement on the level of the secondary criterion, i.e., *trans* fat for this claim. In addition, some comments recommended having the claim ''reduced saturated and *trans* fats'' for greater flexibility, while others opposed such a claim. Of those in favor, some comments recommended a reduction of at least 25 percent in saturated and *trans* fats combined, one comment favored a 33 to 50 percent in saturated and *trans* fats combined, and one comment wanted a 25 percent reduction in saturated fat and a 25 percent reduction in *trans* fat.

Finally, the comments on disclosure and disqualifying levels were equally divergent. Some comments favored the proposed criterion of 4 g or less of saturated and *trans* fats combined, while others recommended a limit of 4 g of saturated fat and 4 g of *trans* fat, or believed that there should be no limit on *trans* fat. One comment stated that *trans* fat thresholds should be incorporated into the criteria defining nutrient content claims and health claims only to the extent that such criteria are necessary to prevent the claim from misleading consumers. The comment stated that this is the approach FDA applied in establishing the saturated fat thresholds for cholesterol content claims in § 101.62(d) and is an appropriate construct for nutrient content claims about *trans* fat.

The objections in the comments against the proposed definitions were generally based on scientific, legal, or economic arguments. Some of the comments believed that the agency is acting in advance of sufficient scientific justification, while others stated that the agency should have acted sooner. There was disagreement as to whether the adverse effects of *trans* fat are comparable to that of saturated fat. Some of the comments stated that the proposed definitions assume that *trans* fat and saturated fat are ''bioequivalent.'' These comments particularly objected to changing the disclosure and disqualifying level of 4 g of saturated fat to 4 g of saturated and *trans* fat combined (i.e, holding the current level constant and including *trans* fat). These comments argued that the effects of saturated fat and *trans* fat have not been proven to be the same on a gram-for-gram basis and, therefore, should not be treated interchangeably. Other comments stated that there is no scientific evidence showing any adverse effects on serum cholesterol levels or cardiovascular health from *trans* fat in a mixed diet to support FDA's proposed definitions for nutrient content claims.

Other comments argued that the proposed claims should be included in the final rule for public health reasons, while others argued that less restrictive claims would benefit the public health to a greater extent because they would encourage more reformulation. Some of these comments pointed out that the ''*trans* fat free'' claim, in particular, is not meaningful because very few foods could meet the proposed criteria and therefore would not be used enough to be helpful.

Several comments asserted that FDA did not meet its burden under the first amendment because the threshold levels proposed by FDA for *trans* fat for certain nutrient content and health claims, which, if exceeded, would prohibit the use of the claims on food and have the effect of restricting the use of specific claims that would be truthful and not misleading. The comments reasoned that FDA could only limit claims where the level of *trans* fat in a food product would make the claim misleading. Further, the comments reasoned that, before FDA could prohibit a claim, FDA would need to establish that the use of a disclaimer on the label or the disclosure of *trans* fat on the label could not prevent the claim from being potentially misleading.

Economic concerns regarding the proposed nutrient content claims are discussed in section IX of this document.

FDA has carefully reviewed the comments and finds that it has insufficient scientific information at this point in time to support a decision on the appropriate definition for the nutrient content claims discussed in the November 1999 proposal and the December 5, 2000, notice to reopen the comment period. The comments that expressed a preference for a specific threshold level of *trans* fat for various claims did not provide a scientific rationale to support the level. In the past, the development of definitions for nutrient content claims and the establishment of disclosure and disqualifying levels generally have been dependent upon scientific agreement of appropriate quantitative reference values for daily consumption of the

nutrient that is the subject of the claim. In proposing nutrient content claims, the agency stated that ''With the exception of the term ''sugar free'' and terms related to caloric levels in foods, the agency has limited the proposed definitions to nutrients for which there are proposed DRVs or RDIs'' (56 FR 60421 at 60429, November 27, 1991). The approach of having an appropriate reference value for daily consumption provides a consistent and quantitative basis for defining claims. As stated in section V of this document, in the absence of the type of quantitative information from authoritative scientific groups on which the agency could support the establishment of a DRV for *trans* fat, the agency is providing for mandatory *trans* fat labeling, without a %DV. The agency does not believe that the current level of scientific evidence supports the establishment of such a value for *trans* fat at this time. Many comments supported this position. As a result of the absence of an appropriate reference value for *trans* fat, the agency has been hampered in developing an integrated approach that responds to the issues raised in the comments. Accordingly, the agency is withdrawing those sections of the November 1999 proposal pertaining to the establishment of a definition for ''*trans* fat free,'' consideration of ''reduced *trans* fat'' and ''reduced saturated and *trans* fat'' claims and limits on the amounts of *trans* fatty acids wherever saturated fatty acid limits are placed on nutrient content claims, health claims, or disclosure and disqualifying levels. FDA plans to continue to evaluate the evolving science and, when the science has evolved to a point where the agency believes it can proceed with scientifically-based definitions and levels for these claims, it will proceed to do so through a new rulemaking. FDA will seek to ensure that it acts consistent with its obligations under the first amendment to allow truthful and nonmisleading speech.

As discussed under comment 17, FDA is issuing an ANPRM elsewhere in this issue of the **Federal Register** that will solicit comment and data that potentially could be used to establish new nutrient content claims about *trans* fat, to establish qualifying criteria for *trans* fat in current nutrient content claims for saturated fat and cholesterol, lean and extra lean claims, and health claims that contain a message about cholesterol raising fats, and to establish disclosure and disqualifying criteria for *trans* fat.

VII. Other Issues

(Comment 26) Several comments requested that FDA defer rulemaking on *trans* fat labeling until both FDA and USDA are able to concurrently take this action.

FDA consulted with USDA and both agencies agree that it is important that nutrition labeling rules for both agencies be consistent and that labeling of *trans* fat is necessary to assist consumers in maintaining healthy dietary practices. USDA is considering a similar policy for *trans* fat labeling based on the view that the approach to nutrition labeling should be consistent, but currently does not have a rulemaking on *trans* fat labeling on its regulatory agenda. Because *trans* fat levels are expected to be higher in foods regulated by FDA, as compared to foods under USDA jurisdiction, and because FDA has a citizen petition on the labeling of *trans* fat, FDA has determined that it is necessary to proceed with this final rule based on the public health interest. FDA notes that it is committed to cooperating with USDA, as needed, on *trans* fat labeling in any future action that USDA may consider.

(Comment 27) Some comments requested that *trans* fat not be used in restaurant food or its use be reduced.

These comments are outside the scope of this rule on the nutritional labeling of *trans* fat. This rulemaking is about *trans* fat labeling and not about whether or not *trans* fat is used in food generally or in particular food products. Although restaurant foods are not required to provide full nutrition labeling, they are required under § 101.10 (21 CFR 101.10), ''Nutrition Labeling of Restaurant Foods,'' to provide information on nutrients that are relevant to any nutrient content claims made. Further guidance on labeling of restaurant foods may be found in ''Questions and Answers Volume II, A Guide for Restaurants and Other Retail Establishments'' (Ref. 111).

(Comment 28) A number of comments to the November 1999 proposal and the November 2002 notice reopening the comment period of the November 1999 proposal stated that there is a great need for consumer education about *trans* fatty acids and the nutrition label.

FDA agrees that consumer education will be needed as a result of this final rule so that consumers are better able to utilize the new *trans* fat labeling information to assist them in maintaining healthy dietary practices. Since the first edition of ''Dietary Guidelines for Americans'' in 1980 (Ref. 112), Americans have been advised to avoid too much saturated fat to reduce the risk of heart disease. This message has also been a major factor in the National Cholesterol Education Program, which has been in existence since 1985 (http://www.nhlbi.nih.gov/about/ncep/index.htm) that focuses on individuals at higher risk for CHD. Some success of these educational programs was demonstrated by the third National Health and Nutrition Examination Survey (Ref. 89) conducted during 1988–94, that showed that the public's intake of saturated fat has declined since the previous survey conducted from 1976–80 (Ref. 113). Also, the 1994–96 CSFII showed a decline in the public's intake of saturated fat since a previous survey conducted in 1989–91 (Ref. 142). Therefore, in introducing new messages about *trans* fatty acids, FDA intends to work with existing public health programs to build upon the extensive work done by them to educate consumers about saturated fatty acids and cholesterol and their relationship to heart health.

The agency also plans to initiate a variety of outreach and consumer education programs about this final rule following publication. Electronic dissemination of this information will be provided at FDA's Web site and briefings will be provided to representatives of a variety of health professionals, government agencies, industry representatives, trade associations, and press and consumer groups so that they can communicate *trans* fat information to their constituencies. To assist in this effort, education and press materials will be developed to facilitate communication to consumers about changes they will see as *trans* fat is added to the nutrition label and how they can use that information in their efforts to maintain a healthy diet.

(Comment 29) A few comments suggested using color coding to help consumers quickly recognize unhealthy products, including those containing *trans* fat. One of the comments mentioned applying this technique to ingredient listing and another comment said that a graphic could show the proportion of saturated, *trans*, polyunsaturated, and monounsaturated fats. The latter comment noted that horizontal color bars were used quite successfully in the introduction of canola oil in the United States.

These comments are outside the scope of this final rule on the nutrition labeling of *trans* fatty acids. The agency notes that manufacturers are free to use color bars on the product label outside of the Nutrition Facts panel (i.e., the box), to illustrate the kinds of fatty acids

in their products, provided it is done in a manner that is not misleading, but the panel itself is to be in compliance with this final rule.

(Comment 30) FDA received only one comment in response to the November 1999 proposal to deny the petitioner's request to require that ''partially hydrogenated'' fat be listed on food labels as ''partially saturated'' fat (64 FR 62746 at 62762). The comment concurred with the agency's tentative conclusion to deny the request stating that ''partially hydrogenated'' fat is the most appropriate terminology for use on food label ingredient statements.

The agency concurs with the comment and, accordingly, is denying this request.

(Comment 31) Although a great many comments supported CSPI's petition in general, these comments did not specifically address the petitioner's request to limit ''vegetable oil'' claims to foods that are low in saturated and *trans* fats combined.

In the November 1999 proposal, the agency referred to § 101.65(c)(3), which states, in part, that a claim ''that a food is made only with vegetable oil is a claim that the food is low in saturated fat,'' and tentatively concluded that the petitioner's request was being addressed by the action taken in the proposed rule to limit the amount of *trans* fat in foods bearing ''low in saturated fat'' claims (64 FR 62746 at 62762). However, in this final regulation those sections of the proposed rule pertaining to limiting the amount of *trans* fat in foods making a ''low in saturated fat'' claim are being withdrawn. Therefore, the agency is not restricting ''vegetable oil'' claims as proposed or as petitioned at this time.

As discussed in section VI of this document, FDA plans to proceed with a new rulemaking pertaining to limits on the amount of *trans* fat in claims relating to saturated fat when the science on *trans* fat has evolved to a point where the agency believes it can proceed with scientifically-based definitions and levels for these claims.

VIII. Effective Date

In the November 1999 proposal, the agency proposed that any final rule that may issue based upon the proposal become effective in accordance with the uniform effective date for compliance with food labeling requirements that is announced by notice in the **Federal Register** and that it not be sooner than 1 year following publication of any final rule based on the proposal. Also, the agency said it will not object to voluntary compliance immediately upon publication of the final rule.

(Comment 32) FDA received several comments about the effective date for a final rule. One comment stated that the proposed effective date was appropriate while a few other comments recommended that it be sooner than proposed. Several comments suggested that the effective date be 24 months after publication of the final rule or January 1, 2004, whichever comes later. Some comments, however, requested that the effective date be extended several years (e.g., 4 to 7 years) for small businesses. These comments stated that it was important for small businesses to be able to phase in the cost associated with the new label requirements so that they have extra time to absorb the costs of these changes. Many small manufacturers reported that they have significant inventories of labels. Also, smaller manufacturers indicated that they would incur costs including loss and disposal of obsolete packaging inventories, product in obsolete packages, and new printing plates. These small businesses believe that a longer compliance period would allow these companies to more easily manage their inventories and phase in the *trans* fat labeling requirements along with other scheduled labeling revisions. This will help minimize unnecessary labeling costs and costs passed on to consumers. At least one comment requested that the effective date be one year after establishment of an official AOAC method for measuring *trans* fatty acids in complex food matrices.

To minimize the need for multiple labeling changes and to provide additional time for compliance by small businesses to allow them to use current label inventories and phase in label changes, the agency is setting the effective date at January 1, 2006, the next uniform effective date following publication of this rule. This allows firms more than 2 years to implement this final rule providing some regulatory relief and economic savings for small businesses. Extending the effective date for products containing *trans* fat would delay the benefits of this rule to the public health.

The agency notes that there are several methods for measuring the amounts of *trans* fat in food products including but not limited to AOAC Method 996.06, as modified (17th edition of the ''Official Methods of Analysis of the AOAC International'') (Refs. 105 and 106). Consequently, the agency does not believe that there is any need to extend the effective date because of the lack of appropriate methodology.

Although the effective date of the final rule is some time away, FDA encourages manufacturers to have new labels printed that are in compliance with these final rules so they may be used as soon as current inventories are exhausted to ensure a smooth and timely changeover. The agency will not object to voluntary compliance immediately upon publication of the final rule.

IX. Final Regulatory Impact Analysis

FDA has examined the economic implications of this final rule as required by Executive Order 12866. Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). Executive Order 12866 classifies a rule as significant if it meets any one of a number of specified conditions, including: Having an annual effect on the economy of $100 million, adversely affecting a sector of the economy in a material way, adversely affecting competition, or adversely affecting jobs. A regulation is also considered a significant regulatory action if it raises novel legal or policy issues. FDA has determined that this final rule is a significant regulatory action as defined by Executive Order 12866.

The Small Business Regulatory Enforcement Fairness Act of 1996 (Public Law 104–121) defines a major rule for the purpose of congressional review as having caused or being likely to cause one or more of the following: An annual effect on the economy of $100 million; a major increase in costs or prices; significant adverse effects on competition, employment, productivity, or innovation; or significant adverse effects on the ability of U.S.-based enterprises to compete with foreign-based enterprises in domestic or export markets. In accordance with the Small Business Regulatory Enforcement Fairness Act, Office of Management and Budget (OMB) has determined that this final rule is a major rule for the purpose of congressional review.

A. The Current Situation and the Need for This Regulation

Current nutrition labeling regulations do not allow manufacturers to disclose information about *trans* fat content of their products in the Nutrition Facts panel of product labels. The regulation, in § 101.9(c) reads, in part, ''No nutrients or food components other than those listed in this paragraph as either mandatory or voluntary may be

included within the nutrition label.'' Some of the nutrients listed are total fat, saturated fat, polyunsaturated fat (voluntary), and monounsaturated fat (voluntary). Prior to publication of this final rule *trans* fat was not included as either mandatory or voluntary, and therefore, no information about *trans* fat could have been included in the Nutrition Facts panel.

As explained in the November 1999 proposal and in section IV of this document, there is a scientifically established link between the consumption of *trans* fat and CHD. As described in table 1 of this document, for purposes of economic analysis, FDA estimated *trans* fat intake based on dietary intakes reported in a national food consumption survey. FDA estimates that average *trans* fat intake from partially hydrogenated fat is about 2.03 percent of energy, and average total *trans* fat intake, including *trans* fat of ruminant origin, is about 2.55 percent of energy. Because *trans* fat increases serum LDL–C (''bad'' cholesterol), reducing *trans* fat intake reduces CHD risk. The amount of risk reduction depends on what replaces *trans* fat in the diet (64 FR 62746 at 62768 to 62770). For example, as shown later in this section, reducing *trans* fat intake by 0.1 percent reduces CHD risk by 0.072 to 0.163 percent.[1] CHD is a common disease in the general U.S. population, with about 1.1 million heart attacks annually, 40 percent of them fatal (Ref. 134). Therefore, a small decrease in risk corresponds to a large number of heart attacks and deaths prevented. Thus, as shown later in this section, reducing *trans* fat intake by about 0.04 percent of energy (projected to decrease CHD risk by about 0.05 percent), prevents approximately 600 heart attacks per year, including 200 fatal heart attacks. Preventing these heart attacks is valued at $4.1 billion per year (present value discounted at 7 percent).

Although the effect of *trans* fat on LDL–C and CHD risk is the primary basis for *trans* fat labeling, *trans* fat may also increase CHD risk by lowering high-density lipoprotein cholesterol (HDL–C) (''good'' cholesterol). In a second method for estimating the health benefits of *trans* fat labeling, the expected changes in LDL–C and HDL–C can be considered together (64 FR 62746 at 62768 to 62770). For example, as shown later in this section, each 0.1 percent of energy decrease in *trans* fat intake reduces CHD risk by 0.237 to 0.293 percent.[2] Thus, as shown later in this section, reducing *trans* fat intake by about 0.04 percent of energy (projected to decrease CHD risk by about 0.1 percent), prevents approximately 1,200 heart attacks, including 480 fatal heart attacks, annually, valued at $8.3 billion per year (present value discounted at 7 percent).

This final regulation is needed to amend existing regulations so that manufacturers will be able to provide important health-related information to consumers regarding the amount of *trans* fat in food products.

FDA believes that the requirements of this final rule will provide consumers with information they need so that they may consider the amount of *trans* fat in products in their food purchasing decisions. Increased consumer attention to *trans* fat content because of nutrition labeling may also provide an incentive to food manufacturers to reduce the amount of *trans* fat in their products.

B. Regulatory Alternatives

In the analysis of the proposed rule, FDA listed a number of regulatory alternatives regarding *trans* fat, including: (1) Take no new regulatory action; (2) take the proposed regulatory action; (3) propose to permit the voluntary labeling of *trans* fat and to permit *trans* fat nutrient content claims; (4) alter the proposed regulatory action—propose reporting of *trans* fat on a separate line below saturated fat; (5) alter the proposed regulatory action—propose to report *trans* fat differently than in the proposal; (6) expand the proposed regulatory action—propose ''low *trans* fat'' and ''reduced *trans* fat'' claims; (7) expand the proposed regulatory action—propose labeling at food service establishments. We evaluated these regulatory alternatives in the economic discussion of the proposed rule, although we lacked sufficient data to evaluate all of the options quantitatively. FDA received no comments on the economic discussion of these alternatives, so we do not include them in this document. In addition to the alternatives described in the proposed rule, FDA considered and asked for comments on a proposed required footnote. Because the agency is withdrawing the proposed requirement for a footnote and intends to ask for comments in an ANPRM published elsewhere in this issue of the **Federal Register**, we will not estimate the costs and benefits of that option in this document.

C. Changes Resulting From This Rule

As stated in the analysis to the proposed rule (64 FR 62746 at 62764), to estimate the impacts of this rule, FDA is following the general approach used to estimate the health benefits for the implementation of the 1990 amendments (56 FR 60856 at 60869, November 27, 1991). Accordingly, FDA is estimating: (1) The changes in *trans* fat intakes that would result from labeling changes; (2) the changes in health states that would result from changes in *trans* fat intakes; and (3) the value of changes in health states in terms of life-years gained, number of cases or deaths avoided, and dollar value of such benefits.

1. Changes in Existing Labeling Regulations

This final rule requires the mandatory declaration in the nutrition label of the amount of *trans* fat present in foods. According to this final rule, the amount of *trans* fat must be on a separate line immediately under the amount of saturated fat, but it will not include a % DV that is required for some of the other mandatory nutrients, such as saturated fat. These changes must be made within a period of 30 months. This change to the existing regulations will increase the information available to consumers that they can use to maintain a healthy diet. It will also change the constraints and incentives faced by producers of food.

The final rule will increase the information provided to consumers on food packages. This change in the nutrition label will reduce the cost to consumers of obtaining information on the *trans* fat content of food. FDA anticipates that, once the rule takes effect, consumers will use information on the Nutrition Facts panel to adjust their purchasing practices among foods, consistent with their consumption preferences.

The final rule will also change the incentives and constraints that food producers face in manufacturing and marketing their products. Because these provisions will not be effective until months after publication of the final rule, food manufacturers can use the time between publication of the final rule and its effective date to study the requirements of the rule and the

[1] Using Method 1 (LDL–C), described later in section IX.E, and the factors shown in tables 8 and 9 below, replacement of 0.1 percent of energy from *trans* fat would decrease CHD risk by 0.072 percent when replaced with the same percent of energy from half *cis*-monounsaturated fat and half saturated fat (-0.1 x 0.74 x 0.7 x 1.4 = -0.072) and by 0.163 when replaced with half *cis*-monounsaturated fat and half *cis*-polyunsaturated fat (-0.1 x 1.66 x 0.7 x 1.4 = -0.163).

[2] Using Method 2 (LDL–C and HDL–C), replacement of 0.1 percent of energy from *trans* fat would decrease CHD risk by 0.237 percent when replaced with the same percent of energy from half *cis*-monounsaturated fat and half saturated fat (-0.1 x -0.47 x -2.5 x 1.4 = -0.165 and -0.072 plus -0.165 = 0.237) and by 0.293 when replaced with half *cis*-monounsaturated fat and half *cis*-polyunsaturated fat (-0.1 x -0.37 x -2.5 x 1.4 = -0.130 and -0.163 plus -0.130 = -0.293).

composition of their products, to anticipate the response of consumers and competitors to the new information, to change the labeling, and possibly to change the composition of their existing food products. Even after the effective date of the rule, food manufacturers will observe the response of consumers to the information on *trans* fat, and some may develop and market new products with less *trans* fat than similar existing products.

FDA assumes that producers will decide whether or not to change the composition of existing products on a product-by-product basis, depending on expected private returns. They will choose to reformulate the existing products when the expected private benefits exceed the expected private costs of reformulating the products. In other words, if a product is expected to lose market share without reformulation because of the new disclosure, then manufacturers will compare the private costs from decreased sales to the cost of reformulation.

2. Anticipated Changes in *Trans* Fat Intake

FDA anticipates that, taken together, changes in food purchases by consumers and reformulation by producers in response to this rule will result in an overall decrease in *trans* fat intake in the U.S. population. In the November 1999 proposal, FDA developed four scenarios to demonstrate potential quantitative changes in *trans* fat intake (64 FR 62746 at 62767). FDA also estimated the current *trans* fat intake of the population as a starting point for its scenarios for projected intake changes.

a. *Revised estimate of current trans* fat intake. In section IV of this document, FDA discussed the uncertainties associated with estimates of *trans* fat intake from: (1) National food consumption survey, (2) national disappearance data, and (3) food frequency questionnaires done in observational studies of U.S. population groups. Although there are uncertainties associated with each type of estimate, FDA chose estimation of *trans* fat intake based on a national food consumption survey as most suitable for use in this economic analysis. Estimates of intake based on national disappearance data generally overestimate intake dues to losses in processing and use, and food groups derived from disappearance data correspond to commodities rather than to foods as consumed. Therefore, an estimate based on a national food consumption survey was better suited to the present analysis than was an estimate based on national disappearance data. Estimates of *trans* fat intake based on food frequency questionnaires may have the advantage of having been validated versus biomarkers such as *trans* fat content of adipose tissue. Such estimates are suitable for their intended use in ranking and classifying *trans* fat intake of subjects in observation studies. However, food frequency questionnaires are not necessarily designed to provide accurate absolute (numerical) intake estimates. As described in the November 1999 proposal (64 FR 62746 at 62753), estimates of nutrient intakes based on food frequency data may be subject to systematic bias toward either over- or underestimation of intake, depending on the design of the food frequency questionnaire (Ref. 27). Available estimates of *trans* fat intake from food frequency questionnaires in observational studies are lower than estimates of *trans* fat intake from a national food consumption survey (Ref. 26), as summarized in the November 1999 proposal (64 FR 62746 at 62752 to 62753) and in section IV of this document. Additionally, the available food frequency results pertain to the intake of specific U.S. population groups in the observation studies, not to the overall U.S. population. Therefore, an estimate based on a national food consumption survey was better suited to the present analysis than was an estimate based on food frequency questionnaires done in observational studies. One disadvantage of an estimate based on a national food consumption survey is that, as described in section IV, food intake is generally under-reported in consumption surveys (Ref. 26). Therefore, intake of *trans* fat, in grams, estimated from a national consumption survey is likely to underestimate actual intake. However, intake of *trans* fat from national consumption survey data is likely to underestimate actual intake to a lesser extent than does the lower reported intake of *trans* fat from food frequencies done in observation studies. Additionally, intake of *trans* fat, as a percent of total energy, from a national consumption survey is more likely to be an unbiased estimate (Ref. 26).

As described in the November 1999 proposal (64 FR 62746 at 62765), information on *trans* fat content of foods is limited, and there have been few estimates of *trans* fat intake based on national dietary surveys using food records or recalls. As described in section IV of this document and in the November 1999 proposal (64 FR 62746 at 62752 and 62765), an available estimate by Allison et al. (Ref. 26), based on CSFII 1989–91, reported mean *trans* fat intake of 5.3 g/day (d) (2.6 percent of energy). However, for the purposes of economic analysis, FDA needed to estimate the mean intake of *trans* fat from specific food groups. Therefore, in the November 1999 proposal, FDA indirectly estimated *trans* fat intake based on a report from the Research Triangle Institute (RTI) (Ref. 73). The RTI report used a special 1995 USDA database of *trans* fat content of foods (Ref. 40), together with the mean intake of food groups from USDA's CSFII 1994–96, and matched the CSFII 1994–96 food groups with Standard Industrial Classification (SIC) Codes for food product categories. FDA limited its estimate to foods with *trans* fat from partially hydrogenated fats and oils (64 FR 62746 at 62765). (Although *trans* fat does occur naturally in dairy foods, it is generally present in dairy products at less than 0.5 g *trans* fat per serving, and therefore most dairy products would not have been affected by the November 1999 proposal (64 FR 62746 at 62775)).

In the November 1999 proposal, FDA estimated that current average *trans* fat intake from hydrogenated fat was 2.91 percent of energy (calories) for adults, which is about 7.62 g/d for men and 5.54 g/d for women (Ref. 73 and 64 FR 62746 at 62765). Among food product categories, average *trans* fat intake of adults, as a percent of energy, was: margarine, 0.39 percent; bread/cake, 0.67 percent; cookies/crackers, 0.98 percent; other food groups, 0.87 percent. The estimated intake of *trans* fat from margarine included FDA's adjustment based on the assumption that approximately 30 percent of margarines currently on the market had already been reformulated to remove *trans* fat.

(Comment 33) Comments generally agreed that FDA's estimate of current *trans* fat intake was reasonable and in the range of other estimates of *trans* fat intake. Comments from the margarine industry agreed with FDA's overall estimate of *trans* fat intake from margarine but stated that FDA had overestimated the percent of margarines (30 percent) that had already been reformulated to remove *trans* fat. One comment indicated that the proportion of margarines with less than 0.5 g *trans* fat per serving is about half of FDA's estimate, or 15 percent of margarines. Some comments pointed out the importance of *trans* fat intake from food groups that were not itemized separately in FDA's summary table, including chips and snacks and French fried potatoes. Because FDA had restricted its estimate to *trans* fat intake from partially hydrogenated fats and oils, some comments requested clarification

regarding whether naturally-occurring *trans* fat of ruminant origin would be regulated by the provisions of the proposed rule. One comment from a manufacturer agreed with FDA that the USDA *trans* fatty acid database contains relatively few foods. This comment recommended that a large database be developed of *trans* fat food values that have been analyzed using standardized methods, and that the database be used to establish reference or ''normative'' intake data on *trans* fat in the U.S. population. The comment stated that this information would be helpful in developing a Daily Value for *trans* fat intake. A comment from the dressings and sauces industry disagreed with FDA's statement that ''some salad dressings contain substantial amounts of *trans* fatty acids'' (64 FR 62746 at 62752). The comment stated that the oils used in dressing and sauce products contain less than one percent *trans* fatty acids. Additionally, according to the comment, the contribution of *trans* fat of ruminant origin is negligible in dressings and sauces that contain dairy products, as demonstrated in the reference cited by FDA regarding *trans* fat in salad dressings (Refs. 29 and 30).

FDA's original estimate that about 30 percent of margarine had been reformulated to remove *trans* fat was based on an informal market survey in the Washington, DC area (Ref. 80 and 64 FR 62746 at 62781). FDA accepts the comment's estimate that 15 percent of margarines currently on the market contain less than 0.5 g per serving. In its own estimate of total intake, FDA did include the contribution to average *trans* fat intake of other food groups containing partially hydrogenated fat, such as chips and French fried potatoes. These food groups were itemized in the RTI report (Ref. 73) but FDA summarized them under ''All other'' in the November 1999 proposal.

In response to the comments requesting clarification about whether naturally-ocurring *trans* fat of ruminant origin would be regulated by this rule, FDA reiterates that this final rule applies to all FDA-regulated foods and covers all fatty acids that meet the regulatory definition of ''*trans* fatty acids,'' regardless of origin. Naturally occurring *trans* fat in dairy products and in ruminant meat (e.g., meat from cows and sheep) present in FDA-regulated food products will be subject to this rule. FDA did not include *trans* fat of ruminant origin in its original intake estimate in the November 1999 proposal because, in these products, *trans* fat is generally present at less than 0.5 g per serving and declaration of the amount of *trans* fat in these products would not have been required by the November 1999 proposal. As noted later in this section, we have revised our estimate of *trans* fat intake and extended our revised estimate to include *trans* fat of ruminant origin. Although FDA agrees with the comment stating that development of a large database of *trans* fat food values would be beneficial, database development is beyond the scope of the present rulemaking. FDA agrees with the comment regarding the *trans* fat content of dressing and sauces and acknowledges that FDA's earlier statement about *trans* fat in salad dressings (64 FR 62746 at 62752) was inaccurate. However FDA's earlier statement was part of a general summary of possible limitations of data regarding *trans* fat intake of the population, and was not incorporated into FDA's estimates of *trans* fat intake in the November 1999 proposal. As noted previously, FDA based its estimates of *trans* fat intake on the special 1995 USDA database of *trans* fat content of selected foods.

As described previously in this section, although there are uncertainties associated with each type of estimate, FDA chose estimation of *trans* fat intake based on a national food consumption survey as most suitable for use in this economic analysis. In reevaluating its November 1999 *trans* fat intake estimate based on a national survey, CSFII 1994–96, FDA notes that the CSFII 1994–96 food group categories used to generate the estimate were very broad (Refs. 73 and 114) and the match between the broad CSFII food group categories and the SIC Codes was not always exact. Recently, USDA has published more detailed tables of food group intake for CSFII 1994–96 (Ref. 115). FDA has used the new tables to recalculate its estimate of average *trans* fat intake in the United States. For clarity, FDA now includes the itemized *trans* fat intake for the various food groups rather than creating a summary category for ''All other.'' FDA has also extended its estimate to incorporate *trans* fat of ruminant origin. FDA has estimated the intake of *trans* fat from margarine from the USDA intake data, without assumptions regarding the percent of margarine that may have been reformulated to remove *trans* fat. We will describe our assumptions about current margarine reformulation in later sections of this document.

The revised estimate of average *trans* fat intake of adults in the United States for this economic analysis is shown in table 1 of this document. The revised estimate is slightly lower than that in the November 1999 proposal. Table 1 shows that average *trans* fat intake from partially hydrogenated vegetable oils is about 5.36 g/d for men and 3.89 g/d for women, or about 2.03 percent of energy. Adding the *trans* fat of ruminant origin gives an overall total *trans* fat intake of 6.86 g/d for men and 4.78 g/d for women, about 2.55 percent of energy. Major sources of *trans* fat intake as a percent of energy include margarine, 0.42 percent; cake and related products, 0.61 percent; cookies and crackers, 0.25 percent; fried potatoes, 0.21 percent; chips and snacks, 0.12 percent; and household shortening, 0.11 percent.

TABLE 1.—AVERAGE *Trans* FAT INTAKE OF U.S. ADULTS FROM FOOD GROUPS

CSFII 94–96[1]	Men	Women	All	All
Mean daily energy intake, kcal[2]	2455	1646	2058	
Mean daily *trans* fat intake[3 4]				
Food group	Grams	Grams	Grams	% of energy
Hydrogenated products				
Total yeast bread	0.475	0.330	0.404	0.177%
Cakes, pies, doughnuts, sweet rolls, biscuits, muffins, quick breads, pancakes, waffles, tortillas	1.607	1.163	1.391	0.607%
Cookies, crackers	0.624	0.515	0.571	0.249%
Ready to eat breakfast cereal	0.093	0.074	0.084	0.037%
French-fried, home-fried potatoes	0.635	0.332	0.486	0.213%
Potato chips, corn chips, popcorn	0.345	0.215	0.281	0.123%

TABLE 1.—AVERAGE *Trans* FAT INTAKE OF U.S. ADULTS FROM FOOD GROUPS—Continued

CSFII 94–96[1]	Men	Women	All	All
Pourable and mayo type salad dressing	0.181	0.136	0.159	0.069%
Total candy containing chocolate	0.048	0.040	0.044	0.019%
Total margarine	1.072	0.859	0.967	0.423%
Household shortening	0.277	0.222	0.250	0.109%
Total hydrogenated products	5.357	3.886	4.637	2.026%
Animal products				
Total milk, including on cereal	0.125	0.085	0.105	0.046%
Ice cream and ice milk	0.092	0.057	0.075	0.033%
Total cheese and cottage cheese	0.227	0.148	0.188	0.083%
Total beef, ground and not ground	0.569	0.319	0.447	0.195%
Total frankfurter and lunch meat	0.360	0.188	0.276	0.121%
Total fluid and sour cream	0.061	0.044	0.052	0.023%
Total butter	0.071	0.049	0.060	0.026%
Total animal products	1.505	0.890	1.203	0.527%
Total all products	6.862	4.776	5.840	2.553%

[1] Continuing Survey of Food Intakes of Individuals, 1994–1996
[2] kcal: kilocalories
[3] Source of *trans* fat content of foods: Ref. 40.
[4] Source of food intake data: Smiciklas-Wright H., D.C. Mitchell, S.J. Mickle, A.J. Cook and J.D. Goldman. Foods Commonly Eaten in the United States. Quantities per Eating Occasion and in a Day, 1994–1996. U.S. Department of Agriculture NFS Report No 96–5, pre-publication version, 2002. www.barc.usda.gov/bhnrc/foodsurvey/Products9496.html.

The revised estimate of *trans* fat intake based on CSFII 1994–96 and shown in table 1 is slightly lower than the estimate in the November 1999 proposal (64 FR 62746 at 62765). Table 1 shows that average *trans* fat intake from partially hydrogenated vegetable oils is about 5.36 g/d for men and 3.89 g/d for women, or about 2.03 percent of energy. Adding the *trans* fat of ruminant origin gives an overall total *trans* fat intake of 6.86 g/d for men and 4.78 g/d for women, about 2.55 percent of energy. For comparison, FDA also calculated the *trans* fat intake based on CSFII 1989–91, using the same method as for the estimate based on CSFII 1994–96 (Ref. 116 and 117). The overall total *trans* fat intake from CSFII 1989–91 is 6.47 g/d for men, 4.51 g/d for women and 5.32 g/d for all adults, or 2.71 percent of energy (not shown in table 1), very similar to the 6.86 g/d for men and 4.78 g/d for women and 5.84 g/d for all adults, or 2.55 percent of energy intake based on CSFII 1994–96 (table 1 of this document) (Ref. 116). FDA's estimates of 2.55 percent of energy from *trans* fat based on CSFII 1994–96 and 2.71 percent of energy based on CSFII 1989–91 can be compared with other available estimates from national food consumption surveys. FDA's estimates are very similar to the intake estimated by Allison et al. based on CSFII 1989–91 (Ref. 26), using a different method. As described in the November 1999 proposal, Allison et al. reported that average *trans* fat intake for persons age 3 and older was 2.6 percent of energy, or 5.3 g/d (64 FR 62746 at 62752 and 62765).

Allison et al. linked the special 1995 USDA database of *trans* fat content of foods to the food intake reported by each individual in CSFII 1989–91 (Ref. 26). They also separated the ingredients in food mixtures, so that the *trans* fat content of the ingredients could be included in the total intake. These researchers reported the *trans* fat intake for various age and gender groups in the United States, but did not report the amount of *trans* fat contributed by various foods and food groups. To make its estimate, FDA began with USDA reports of average intake of food groups in CSFII 1989–91 and 1994–96 (Refs. 115 and 117). In its reports, USDA also separated the ingredients in food mixtures. For example, in CSFII 1994–96, USDA found that the average intake of margarine reported separately by survey participants was 2.8 g/d. However, when margarine, used as an ingredient in other foods, was added to the total, the average margarine intake rose to 7.0 g/d. FDA then linked the average intake of the food groups with the *trans* fat content of foods from the special 1995 USDA database (Ref. 40) to give the *trans* fat intake estimate in table 1 of this document. The similarity of the estimates of FDA and of Allison et al. can be explained by use of common data—the CSFII intake report and the 1995 USDA *trans* fat database. Linking the two data sets resulted in comparable overall *trans* intake, whether linked at the level of each individual's intake by Allison et al., or linked at the level of average intake of food groups by FDA.

FDA's estimates are also similar to a recently-published estimate from another national food consumption survey, the National Health and Nutrition Examination Survey III (NHANES III), 1988–94 (Refs. 152 and 153). The estimate from NHANES III for mean *trans* fat intake for age 20 to 59 was 5.6 g/d or 2.2 percent of energy (mean energy intake was 2,325 kcal/d, and (5.6 g/d x 9 kcal/g x 100)/2,325 kcal = 2.2 percent of energy).

b. *Projected change in trans fat intake.* In the November 1999 proposal, we developed four scenarios of projected changes in *trans* fat intake due to labeling. Scenario 1 demonstrated the effect of the hypothetical removal of all of the *trans* fat originating from partially hydrogenated fats and oils, corresponding to a decrease of 2.91 percent of energy from *trans* fat. Scenarios 2 through 4 predicted three possible levels of product reformulation, together with an estimate of consumer behavior. We estimated that *trans* fat intake would have decreased by 0.58 percent of energy, 0.50 percent of energy and 0.42 percent of energy in Scenarios 2, 3 and 4, respectively (64 FR 62746 at 62767). For each scenario, the full health benefits would have been realized years after the rule took effect: 10, 8, and 3 years after the effective date for Scenarios 2, 3, and 4. These time periods included the time for reformulation and the 3 years that would have passed before changes in diet would have begun to reduce the risk of CHD.

Consumer awareness

(Comment 34) Several comments suggested that FDA overstated consumer response to the proposed change to food labeling. Some comments said that a

footnote might be ignored. Some comments said that consumers rarely look at any nutrition information beyond calories and total fat and that consumer concerns about fat have dwindled. One comment argued that consumers have not significantly altered their dietary habits because of the implementation of the 1990 amendments. One comment stated that educated consumers probably already know enough to look for and avoid *trans* fat. There was also one comment arguing that shelf labeling is more likely to attract consumer attention than are product labels, and the use of shelf labeling is probably more prevalent than that of product labels. One comment stated that FDA has underestimated consumer awareness of *trans* fatty acids. Another comment stated that consumer awareness is likely to increase as *trans* fat dietary recommendations accumulate and consumer education devotes more attention to *trans* fat.

FDA is not going forward with the proposed asterisk for saturated fat and footnote listing the amount of *trans* fat. Instead, this final rule requires *trans* fat to be listed on a separate line immediately below saturated fat. Consumers who look at the Nutrition Facts panel for information on total fat and its fatty acid subcomponents are likely to notice the information on *trans* fat.

In the November 1999 proposal, FDA used results of earlier research and estimated that direct consumer choice in response to *trans* fat labeling would result in a 1 percent decrease in *trans* fat intake (64 FR 62746 at 62766). This final rule requires that the amount of *trans* fat be declared in nutrition labels on a separate line immediately under the line for saturated fat. This placement of *trans* fat is more prominent than the footnote specified in the November 1999 proposal and may be more readily noticed by consumers. In the November 1999 proposal, the amount of *trans* fat was to be included in the amount and % DV declared for saturated fat. This association of *trans* fat with saturated fat, which also may have assisted consumers in using the information on *trans* fat, is absent in this final rule. Also, as a result of this final rule, consumer response to *trans* fat information will be based solely on the declaration of the amount of *trans* fat in grams. As discussed in section V of this document, there will not be information on a % DV for *trans* fat. In the November 1999 proposal, the agency proposed to define the nutrient content claim for ''*trans* fat free'' and also proposed that the amount of *trans* fat be limited wherever saturated fat limits are placed on nutrient content claims, health claims, or disclosure and disqualifying levels. As explained in sections V and VI of this document, this final rule does not establish definitions for nutrient content claims about *trans* fat and does not place *trans* fat limits on claims regarding saturated fat, cholesterol or other nutrients. In summary, the declaration of *trans* fat in this final rule is prominent and straightforward. This feature of the final rule may tend to increase the magnitude of consumer response to the *trans* fat information. However, the provisions of this final rule also do not link *trans* fat with saturated fat or with a % DV for *trans* fat and do not change existing regulations regarding claims. The absence of these features in the final rule may tend to decrease the magnitude of consumer response to the *trans* fat information.

Based on previous research, the November 1999 proposal projected a 1 percent decrease in *trans* fat intake from direct consumer choice in response to *trans* fat labeling (64 FR 62746 at 62766). This overall 1 percent decrease in *trans* fat intake could be thought of as a 2.2 percent decrease in *trans* fat intake by the 45 percent of consumers shown in previous research to use food labels to make purchase decisions (Refs. 68 and 74) (64 FR 62746 at 62766).

In the process of evaluating these comments about consumer awareness, FDA has identified additional data relevant to these issues. In the 1999 Discovery Health survey, 66 percent of those responding to the survey knew that saturated fat was related to disease and 31 percent knew that partially hydrogenated fat was related to disease (Ref. 118). In the 2001–2002 Consumer Attitudes About Nutrition survey, 83 percent of respondents reported that saturated fat is unhealthy, 46 percent reported that *trans* fat is unhealthy and 44 percent reported that hydrogenated fat is unhealthy (Ref. 135). These results indicate that survey respondents were about half as likely to know that partially hydrogenated fat was ''unhealthy'' or related to disease as to know that saturated fat was related to disease. If these surveys are representative of the population, this indicates a significant level of awareness of the health effect of partially hydrogenated fat, and its component, *trans* fat, even though consumers have very little easily obtainable information on *trans* fat and even though nutrition education efforts, until very recently, have focused on saturated fat to the exclusion of *trans* fat. Once nutrition education efforts include *trans* fat in their messages and once consumers have information on nutrition labels about *trans* fat content, consumer awareness of the relationship between saturated fat, *trans* fat, and cholesterol and heart disease will increase. Another recent study, by Kim et al., estimated that food label use has a large effect on nutrient intake. (Ref. 119) This study reported that 73 percent of individuals surveyed use nutrition labels and look for information on saturated fat.

In the study by Kim et al., 73 percent of individuals surveyed who use nutrition labels and look for information on saturated fat had 15 percent lower saturated fat intake than those who did not use nutrition labels. This corresponds with an overall 11 percent decrease (0.15 x 73 percent = 11 percent) in saturated fat intake because of nutrition labeling. Thus, the study by Kim et al. gave a high estimate of an 11 percent decrease in saturated fat intake because of nutrition labeling and FDA's earlier research gave a low estimate of a 1 percent decrease in saturated fat intake.

The Discovery Health study and the Consumer Attitudes About Nutrition survey indicated that consumer awareness of a nutrient-disease relationship involving *trans* fat was about half as prevalent as consumer awareness of a nutrient-disease relationship involving saturated fat. Accounting for the lower prevalence of awareness of the nutrient-disease relationship for *trans* fat, would reduce, by about one-half, the estimates for decreases in saturated fat intake. This would give a high estimate of a 5.5 percent decrease and a low estimate of a 0.5 percent decrease in *trans* fat intake because of labeling.

The estimates for decreases in *trans* fat intake due to nutrition labeling may also be affected by the features of this final rule. As noted previously, the prominence of the declaration of *trans* fat in this final rule may tend to increase the magnitude of consumer response to the *trans* fat information. However, the magnitude of consumer response to the *trans* fat information may decrease because there is no link with saturated fat or with a % DV and there are no changes in existing regulations regarding claims. Recognizing that different features of this final rule may tend to either increase or decrease consumer response to the *trans* fat information, FDA acknowledges considerable uncertainty in incorporating the features of this final rule into its estimate of the consumer response to *trans* fat labeling. One possibility is that the increased and decreased responses related to features

of the rule will be about equal and will cancel each other out. This would leave a high estimate of 5.5 percent decrease and a low estimate of a 0.5 percent decrease in *trans* fat intake as discussed above. However, for the purpose of this final analysis, FDA has chosen a very low estimate of consumer response to the new label. FDA is using an estimate even lower than the low estimate above: a decrease of 0.1 percent of *trans* fat intake. The actual change that occurs may be larger. However, FDA chose this amount so as not to overestimate benefits of this rule. To the extent that actual consumer response is higher than FDA's estimate, this analysis will underestimate the benefits of *trans* fat labeling.

i. *Margarine reformulation*. In the November 1999 proposal, in scenarios 2 through 4, FDA estimated that 30 percent of margarine products had already been reformulated to eliminate *trans* fat, and that all of the remaining margarine products would be reformulated to remove *trans* fat by the effective date for *trans* fat labeling.

(Comment 35) A comment stated that FDA had overestimated the proportion of margarine that had already been reformulated and said that the actual amount was about 15 percent of margarine products. Several comments disagreed with FDA's estimate that all margarine would reformulate by the effective date for *trans* fat labeling. These comments noted that reformulation is very expensive, requires a long time to accomplish, and would, under certain circumstances, require the use of more expensive inputs. Other comments stated that private benefits of reformulating margarine products would not exceed the private costs for manufacturers unless the margarine products could make nutrient content claims. These comments gave a number of examples to demonstrate that even reformulated margarines were not likely to be able to comply with the proposed definitions for nutrient content claims.

FDA accepts the comment about current margarine products. For this analysis, FDA estimates that about 15 percent of margarine has already been reformulated to remove *trans* fat. In response to the comments about projected margarine reformulation, FDA notes that the analysis for the November 1999 proposal did include the cost of reformulation and the time needed for reformulation. In that analysis, FDA did not include higher ingredient costs for margarine reformulation, because the price of reformulated margarine products that are already on the market is no higher than the price of margarine products containing 0.5 g or more per serving of *trans* fat. The different ingredients used in the products appear to have had no impact on the cost of production. However, in response to the comments, FDA acknowledges that, as greater numbers of products are reformulated, the increased demand for the substitute ingredients may increase costs.

As noted earlier regarding consumer response to *trans* fat labeling, the declaration of *trans* fat in this final rule is prominent and straightforward. This feature may tend to increase the incentives for manufacturers to reformulate their products to be lower in *trans* fat. However, the provisions of this final rule also do not link *trans* fat with saturated fat or with a % DV for *trans* fat and do not change existing regulations regarding claims. The absence of these features may tend to decrease the incentives for manufacturers to reformulate their products to be lower in *trans* fat in comparison to the incentive that would have been introduced by the proposed rule. Therefore, in response to the comments regarding projected margarine reformulation, FDA recognizes that different features of this final rule may tend to either increase or decrease the incentive for reformulation in comparison to the incentive that would have been introduced by the proposed rule.

Although FDA acknowledges considerable uncertainty in the likelihood of additional margarine reformulation, FDA is aware of evidence suggesting that at least some margarine products are likely to reformulate in response to *trans* fat labeling. As stated in the analysis for the proposed rule, in several European countries, the actual, demonstrated market response to consumer concern about *trans* fat is that margarine products have been reformulated to reduce or eliminate *trans* fat (64 FR 62746 at 62781) (Refs. 102, 124, 125, and 127). Also, many people who now consume margarine products do so in order to consume a more heart-healthy product than butter. Because the rule would require the prominent declaration of the amount of *trans* fat on a separate line below saturated fat, these margarine consumers are likely to search for margarine products with lower levels of both saturated fat and *trans* fat. Additionally, publicity generated about the issue by consumer groups and the media has highlighted margarine as a source of *trans* fat and has given prominent attention to reformulated margarine products. As more margarine products are reformulated, consumer groups may shift their focus to those remaining margarine products that have not reformulated. This suggests that with sufficient information on *trans* fat content consumers are likely to pressure margarine producers to reduce *trans* fat. This consumer pressure will generate some competitive pressures among margarine producers to reduce *trans* fat content even in the absence of nutrient content claims.

In response to comments received, because of the absence of *trans* fat claims in this rule, and recognizing the uncertainty, FDA is using a low estimate of margarine reformulation in this final rule. FDA estimates that reformulation will reduce the *trans* fat content of margarines as a whole by 10 percent due to *trans* fat labeling. Because the *trans* fat in margarine accounts for about 0.36 percent of energy intake, this reduction corresponds to a decrease in *trans* fat intake of 0.036 percent of energy. The actual decrease may be larger, but FDA chose this lower amount so as not to overestimate benefits of this rule. The additional 10 percent margarine reformulation will mean that, including previous reformulations, about 23 percent of *trans* fat will have been removed from margarine. This estimated reduction is far lower than the 100 percent reduction seen in several European countries. The estimated 10 percent reformulation has the advantage of being an underestimate. To the extent that more *trans* fat is removed from margarine than FDA's estimate, this analysis will underestimate the benefits of *trans* fat labeling.

ii. *Reformulation of other products*. In two scenarios in the November 1999 proposal, FDA projected that some baked products would be reformulated to remove *trans* fat (64 FR 62746 at 62767). In that analysis, the baked products were separated into two categories corresponding to SIC codes: breads, cakes and similar products (SIC code 2051) and cookies and crackers (SIC code 2052). Considering the *trans* fat contributions of the two categories of baked goods (64 FR 62746 at 62765), the overall projected reformulation of baked goods corresponded to a 5 percent reduction in *trans* fat intake in scenario 3 and a 10 percent reduction in scenario 2.

(Comment 36) A number of comments stated that FDA had overestimated the proportion of baked goods products that would reformulate or the proportion of *trans* fat that could realistically be removed from baked goods by reformulation. Some comments noted that reformulation was very expensive, required a long time to accomplish, and would under certain circumstances

require the use of more expensive inputs. Some of these comments, from the shortening or baked products industries, gave examples of recently developed commercial shortenings that were lower in *trans* fat than currently used shortenings. Several comments stated that, although alternative shortenings exist, they may not be a practical solution for reformulation because of expense or limited supply of the alternative shortenings and because time and expense for product development for reformulation would still be needed. Other comments stated that the private benefits of reformulation would not exceed private costs unless the declaration of *trans* fat on the food label was on a separate line on the Nutrition Facts panel or was in some way more prominent than in the November 1999 proposal. Some comments emphasized the disadvantages of reformulation for the cookies and crackers category, stating that FDA's estimate of 15 percent reduction in *trans* fat from those products was an overestimate.

In response to the comments about difficulties of reformulation, FDA notes that the analysis for the November 1999 proposal did include the cost of reformulation and the time needed for reformulation, but did not include higher ingredient costs for reformulation. In the long run, ingredient costs may not actually increase, because of increased industrial capacity to produce ingredients made with new technologies. In response to the comments about the cookies and crackers category, FDA acknowledges that its own projection of much higher reformulation for this category than for other baked products may have been unrealistic. Also in response to the comments, FDA notes that the emergence of commercial shortenings with lower *trans* fat content indicates that the reformulation of some baked products is feasible. Moreover, within these baked product categories there is a significant variation in *trans* fat content. Therefore, products with significantly higher than average amounts of *trans* fat compared with competing products will face competitive pressures to reduce the amount of *trans* fat in their products. In response to the comment about prominence of *trans* fat on the nutrition label, FDA notes that, in this final rule, the declaration of *trans* fat is prominent and straightforward, on a separate line below *trans* fat.

After consideration of the comments and our own re-evaluation, we continue to believe that, ultimately, some proportion of baked products will be reformulated in most subcategories: Crackers, cookies, biscuits, tortillas, quick breads and muffins, doughnuts and sweet rolls, cakes, pies, pancakes and waffles. (In the categories of yeast breads and rolls, it is unlikely that reformulation will occur because yeast breads are relatively low in fat and typically contain less than 0.5 g *trans* fat per labeled serving.) However, there were disparate views among the comments regarding the availability of reformulated shortenings and the technical difficulty of baked product reformulation. Therefore, because of this uncertainty, we have opted for a more conservative approach and are not including a quantitative estimate of reformulation of baked goods in the analysis of the benefits and cost of *trans* fat labeling. We chose not to include a quantitative estimate of reformulation of baked goods so as not to overestimate the benefits of this rule. To the extent that reformulation of baked goods does occur, this analysis will underestimate the benefits of *trans* fat labeling.

Because of the existence of commercial shortenings with lower *trans* fat content, as pointed out in comments, FDA evaluated whether *trans* fat labeling might also result in reformulation of household shortenings to be lower in *trans* fat. Current household shortenings are lower in *trans* fat than current commercial shortenings, with some household products having only about half as much *trans* fat as some commercial products. This fact suggests that the potential for lowering the *trans* fat content of household shortening is not as great as the potential for lowering the *trans* fat in current commercial shortenings. However, some household shortenings are currently making comparative saturated fat claims related to butter, and household shortenings may experience competitive pressure from some reformulated stick margarines due to *trans* fat labeling. Because of the uncertainty, FDA chose not to include a quantitative estimate of reformulation of household shortening so as not to overestimate benefits of this rule. To the extent that reformulation of household shortening does occur, this analysis will underestimate the benefits of *trans* fat labeling.

(Comment 37) Some comments discussed reformulation of other products, including potato chips, corn chips and similar snacks, microwave popcorn, and candy. Several of these comments emphasized the difficulty of reformulating products in these categories because of the expense, the time required, and the need for costly ingredients. Some of the comments suggested that, because of the difficulties of reformulation, *trans* fat labeling would put these categories of products at a competitive disadvantage. Other comments suggested that FDA's projected decrease in *trans* fat intake was an overestimate because *trans* fat labeling would not apply to a major source of *trans* fat: foods eaten at restaurants, especially French fried potatoes.

FDA did not project quantitative decreases in *trans* fat intake due to reformulation of other products, such as chips, microwave popcorn and candy, because these products contribute a smaller proportion of *trans* fat intake and because FDA did not have enough information to make quantitative reformulation estimates for these product categories. FDA is aware of the development of stable frying oils low in *trans* fat and suitable for chips, and notes that there is interest in development of fats and oils lower in *trans* fat for many product categories (Refs. 120 to 122 and 151). At least one manufacturer has announced the reformulation of its snacks and chips to decrease *trans* fat (Ref. 150). To the extent that these product categories reformulate to decrease *trans* fat, the decrease in *trans* fat intake projected in this analysis will be an underestimate.

FDA acknowledges that a large proportion of the U.S. French fried potato intake is consumed in restaurants. Foods typically consumed in restaurants also include other food sources of *trans* fat. Restaurant food is not subject to mandatory nutrition labeling requirements, unless a nutrition-related claim is made. In its estimate of reformulation, FDA did not project reformulation of French fries or of baked goods. Therefore, FDA's estimate did not assume reformulation of restaurant foods. However, FDA is aware of some interest by restaurants in using the absence of *trans* fat as a marketing device to gain competitive advantage (Ref. 123). If, as seems possible, frying oils and shortenings are developed for reformulation of packaged foods and become available in the market, they may become competitive choices with traditional fats and oils, even for restaurants that do not wish to use absence of *trans* fat for competitive advantage. To the extent that restaurants adopt reformulated baking and frying oils and purchase other products reformulated to be lower in *trans* fat, the decrease in *trans* fat intake projected in this analysis will be an underestimate.

iii. *Quantitative decrease in intake.* Table 2 of this document summarizes FDA's revised estimate of projected decreases in *trans* fat intake due to

labeling. In table 2, current *trans* fat intake from margarine is 0.359 percent of energy, reduced 15 percent from the 0.423 percent of energy intake in table 1 of this document to adjust for the estimated 15 percent of margarine that has already been reformulated to remove *trans* fat. This adjustment reduces the total *trans* fat intake from hydrogenated products to 1.96 percent of energy in table 2, compared with 2.03 percent of energy in table 1. Table 2 shows that, by the effective date of the rule, FDA projects that *trans* fat intake will decrease by 0.0378 percent of energy. This decrease will be composed of 0.0359 percent of energy due to removal of 10 percent of *trans* fat from margarine by reformulation, and an additional 0.0019 percent of energy due to direct consumer choice. The additional 0.0019 percent of energy represents 0.1 percent of all remaining *trans* fat from hydrogenated fat after margarine reformulation (1.964 percent - 0.0359 percent = 1.928 percent; 0.1 percent x 1.928 percent = 0.0019 percent).

TABLE 2.—ESTIMATED DECREASES IN *Trans* FAT INTAKE AND CONTRIBUTION FROM FOOD GROUPS DUE TO LABELING, AT EFFECTIVE DATE OF RULE

	Before Effective Date of Rule	Change at Effective Date of Rule	
	Mean daily *trans* intake[1]	Decrease in *trans* fat contribution from food group	Decrease in *trans* fat intake
Food group	Percent of energy from *trans* fat	Percent decrease in *trans* fat	Decrease in percent of energy from *trans* fat
Total Margarine	0.359%[2]	10%	0.0359%
Other food groups with partially hydrogenated fats and oils	1.605%	none	
Total from hydrogenated products	1.964%		
Total decrease due to reformulation			0.0359%
Additional decrease due to consumer choice			0.0019%[3]
Total decrease			0.0378%

[1] *Trans* fat intake for men and women age 20 and over from CSFII 1994–96, see table 1 of this document.
[2] *Trans* fat intake from margarine, 0.359 percent of energy, already decreased by 15 percent from intake in table 1, to account for margarine that has already been reformulated to decrease *trans* fat.
[3] Estimated decrease due to consumer choice at effective date is 0.1 percent of all remaining *trans* fat from hydrogenated fat after margarine reformulation.

iv. *Substitutions for trans fat.* In the November 1999 proposal, FDA assumed that manufacturers would most likely replace *trans* fat in margarine with: (1) *Cis*-monounsaturated fat, (2) 50 percent *cis*-monounsaturated fat and 50 percent *cis*-polyunsaturated fat, or (3) 50 percent *cis*-monounsaturated fat and 50 percent saturated fat, and that they would most likely replace *trans* fat in baked products with 50 percent *cis*-monounsaturated fat and 50 percent saturated fat (64 FR 62746 at 62771). In making these assumptions, FDA relied, in part, on a report from RTI estimating that current food technology would require the incorporation of about 0.5 g saturated fat for every 1 g *trans* fat removed by reformulation (64 FR 62746 at 62767).

(Comment 38) Some comments stated that FDA had ignored the question of macronutrient substitutions, or had assumed that reformulation would replace *trans* fat with 100 percent *cis*-monounsaturated fat. According to the comments, functional requirements for margarines, shortenings and baked products would require that some *trans* fat be replaced by saturated fat, and this requirement was not accounted for in FDA's projections for reformulation. Other comments noted FDA's assumptions regarding macronutrient substitutions, but stated that FDA had overestimated the extent to which *trans* fat could be replaced by *cis*-unsaturated fat, because of functional and cost requirements of various products. These comments generally implied that FDA had overestimated the expected amount of reformulation because saturated fat would need to replace *trans* fat in any reformulation. Comments pointed out that the amount of saturated fat, a cholesterol-raising fat, is already declared on the nutrition label. Therefore, according to the comments, replacement of *trans* fat with saturated fat would not provide a competitive advantage or an incentive to reformulate and, with higher total saturated fat, the reformulated product might not meet the criteria for proposed defined nutrient content claims.

In response to the comments, FDA notes that it did consider the type of macronutrients substituted for *trans* fat, and these were accounted for in the mathematical model used to calculate the health benefits (64 FR 62746 at 62771). FDA is aware that there is a range of functional requirements for margarines and spreads, including tub and stick forms and regular and lower fat varieties. Therefore, FDA assumed a range of ingredient substitutions for margarines and spreads, including both saturated and *cis*-unsaturated fat. Replacement of *trans* fat with a range of combinations of saturated and *cis*-unsaturated fat in margarines and spreads is consistent with reports from North America and Europe (Refs. 104, 124, 125, 126, 127, and 128). In a survey of U.S. margarines, tub margarines with *trans* fat less than 0.5 g per serving did not have increased saturated fat compared with other tub margarines (Ref. 104). In the U.S. study, a stick margarine with less than 0.5 g *trans* fat per serving had higher saturated fat than other stick margarines with comparable fat content, but had lower saturated fat plus *trans* fat than the other stick margarines (Ref. 104). FDA is aware that the functional requirements for baked

products and shortenings may not allow the wide range of substitutions possible in margarines and spreads. Rather, the functional requirements for baked products will likely require replacement of at least some of the *trans* fat with saturated fat. This partial replacement of *trans* with saturated fat is consistent with reports by industry observers (Refs. 121 and 122) and with the examples of the alternative commercial shortenings described in several of the comments. In these examples, the shortenings reformulated to be lower in *trans* fat were higher in saturated fat but were lower in total saturated fat plus *trans* fat than were the traditional, nonreformulated shortenings. Under this final rule, products lower in both saturated fat and *trans* fat will have a competitive advantage because the rule requires prominent declaration of both types of fat on the label.

Based on its consideration of the comments and its own evaluation, FDA continues to believe that the likely substitutions for *trans* fat for margarines will be as described in the November 1999 proposal (64 FR 62746 at 62771). FDA does not have enough information to project the substitutions for *trans* fat due to direct consumer choice, and therefore assumes (for simplicity) that direct consumer choice will show the same range of substitutions as does margarine reformulation. We will describe the effects of these substitutions for *trans* fat on the health benefits of *trans* fat labeling in section VI.E of this document.

Because of the functional requirements for baked products, FDA continues to believe that the most plausible replacement for *trans* fat in baked products is 50 percent *cis*-monounsaturated fat and 50 percent saturated fat. However, because of the uncertainty in quantitative estimation of baked product reformulation, FDA is not including baked product reformulation in its quantitative estimate of benefits and costs of *trans* fat labeling. As note earlier, to the extent that baked products are reformulated, this analysis will be an underestimate of the actual benefits of this rule.

D. Costs

The costs of this rule are the activities that change as a result of this rule. The total cost of these regulations is the sum of the total testing costs, total relabeling costs, and total reformulation costs. All labels must be in compliance with this final rule by a single effective date. All costs are estimated at the effective date, taken to be 30 months from the publication date of this final rule. If the effective date is more than 30 months from the date of publication, then the actual costs of this rule will be lower than estimated here.

1. Products Affected

This final rule covers all food and dietary supplement labeling within FDA's jurisdiction. With a few exceptions, labeling for all FDA regulated foods and dietary supplements will have to be changed by the next uniform effective date following publication of this rule, or about 2 to 3 years after the date of publication. One exception is for products with less than 0.5 g *trans* fat per serving that also use the ''simplified format'' for labeling and that do not make nutrition claims or declare vitamins or minerals. The labeling for these products will not have to be changed. FDA does not have data to estimate how many products fall into this category, so the cost estimate does not reflect this exception and is therefore an overestimate of the actual cost of the rule. The other exception is for products that sell less than 100,000 units per year in the United States, that are made by firms that have fewer than 100 employees, that do not make nutrition or health claims, and that have filed a notification with FDA in accordance with § 101.9(j)(18). These products are not required to display the Nutrition Facts panel that is being amended by this rule. Again, FDA does not have data to estimate how many products fall into this category, so the cost estimate does not reflect this exception and is therefore an overestimate of the actual cost of the rule.

To estimate the costs of this rule, FDA has used the FDA Labeling Cost Model developed for FDA under contract by RTI International in April 2002 (Ref. 129). This labeling model has more current data than the previous labeling cost model developed for the implementing rules of the 1990 amendments (Ref. 74). The model indicates that there are approximately 308,000 food and dietary supplement stock keeping units (SKUs) sold in the United States in categories for which some products will need to be relabeled. A SKU is a specific product sold in a specific size. For example, there is one SKU for 16 ounce (oz) containers of Brand X Diet Peach Tea. The same brand and flavor of tea (a product) in a 12 oz container would be another SKU, and a 12 oz container of the same brand but different flavor of tea would be still another SKU. The model also indicates that there are about 154,000 products potentially affected by this rule. Table 3 of this document shows the data on the number of SKUs and products affected. From the categories listed in table 3 as ''Selected Baking Ingredients,'' ''Selected Candy,'' ''Selected Condiments, Dips and Spreads,'' and ''Selected Dressings and Sauces,'' FDA excluded products, such as baking powder, bottled water, gum, jam, and vinegar, that qualify for the ''simplified'' format and are certain not to be affected by this rule. Even with these products removed, this estimate is still certain to be an overestimate of the actual SKUs and products affected by this rule because FDA has imputed costs to all products and SKUs within these broad product categories. Labels on many products categories such as ''Selected Beverages'' and ''Dietary Supplements'' are not likely to need to be changed. However, FDA has no basis to make better estimates of the actual number of products and SKUs affected by this rule.

TABLE 3.—NUMBER OF SKUS AND PRODUCTS AFFECTED BY PRODUCT CATEGORY

Product Categories	Number of SKUs	Number of Products
Baked Goods	47,200	29,600
Selected Baking Ingredients	7,700	3,300
Baby Foods	1,100	800
Selected Beverages	32,100	8,400
Breakfast Foods	3,600	2,400

TABLE 3.—NUMBER OF SKUS AND PRODUCTS AFFECTED BY PRODUCT CATEGORY—Continued

Product Categories	Number of SKUs	Number of Products
Selected Candy	20,600	12,200
Selected Condiments, Dips and Spreads	15,200	2,300
Dairy Foods	33,800	22,100
Desserts	10,700	7,200
Dietary Supplements	29,500	9,800
Selected Dressings and Sauces	14,200	11,300
Eggs	5,800	1,800
Entrees	10,300	7,900
Fats and Oils	3,100	1,900
Fruits and Vegetables	25,100	2,500
Seafood	6,800	4,200
Side Dishes and Starches	18,000	13,200
Snack Foods	17,800	10,000
Soups	3,700	2,800
Weight Control Foods	1,300	700
Total	307,600	154,400

2. Testing Costs

In the proposed analysis, FDA assumed that all product formulations that include partially hydrogenated oil as an ingredient would be tested to determine the quantity of *trans* fat (except for margarine products, which were all expected to reformulate). Some comments stated that FDA's estimate of the number of products that would need to be tested was too low because products in other categories than those acknowledged by FDA could potentially contain a reportable amount of *trans* fat. Indeed, other comments stated that all products would have to be tested for *trans* content. FDA disagrees with the comment that all products need to be tested because manufacturers will know that some products do not contain *trans* fat, but does agree that more products need to be tested than previously estimated. In the proposed analysis, FDA estimated costs for testing only for the estimated portion of products containing partially hydrogenated oil in several categories of foods anticipated to be most affected by the rule (an estimated 42,000 products). In this final analysis, based on information in the FDA Labeling Cost Model (Ref. 129), FDA estimates that about 154,000 food products in categories that could possibly include *trans* fat will be tested for *trans* fat content as a result of this rulemaking.

In the proposed rule, FDA used a per product cost of testing for *trans* fat of $200. Some comments stated that this estimate is too low. They stated that tests had to be calibrated for each type of food to demonstrate accuracy of the test in the food matrix. FDA notes that manufacturers of many different types of foods have already had their products tested, so that much of the calibration has already been done. The new Labeling Cost Model includes data on the cost of testing for *trans* fat. Included in the analytical testing estimate is the cost of testing two samples of the product, one hour of labor to prepare and package the product (at $14.73 per hour) and delivery charges for one two-pound package delivered overnight (at $26.30). The labor cost estimate was based on the average total compensation (wages and benefits) for handlers, equipment cleaners, helpers, and laborers in manufacturing industries. Overhead beyond benefits on the time to prepare a sample for testing is negligible. The model reports a range of testing costs for *trans* fat given in table 4.

TABLE 4.—RANGE OF PER PRODUCT AND TOTAL TESTING COSTS

	Low	Medium	High
Cost per Product	$261	$291	$371
Total Testing Cost	$40,298,000	$44,930,000	$57,282,000

One comment suggested that butter and other products with high butter fat contents, such as some ice cream, would contain a reportable amount of naturally occurring *trans* fat, and that therefore, FDA had underestimated the costs of testing these products. In this final analysis, FDA has included testing and relabeling costs for all dairy products

including butter and other products that are high in butter fat.

3. Relabeling Costs

In the analysis of the proposed rule, FDA estimated that 39,000 SKUs were associated with the 32,000 products that would change their information panels at a cost of $30 million. During the comment period reopened November 2002, FDA received comments that we would have to reestimate the relabeling costs for the final rule. Under this final rule many more labels will have to be changed than under the proposed rule. FDA has used the new Labeling Cost Model to reestimate the relabeling costs of this final rule. Based on information in the model, three-quarters of the labels normally will be scheduled to be changed during the 30 month compliance period. FDA estimates that about 78,000 (25 percent) of the almost 308,000 SKUs will have to be changed earlier than would have been planned without this rule. Included in the cost of relabeling are administrative, graphic design, pre-press preparation, printing and engraving, and the lost value of discarded labels. Across product categories, the average low relabeling cost per SKU is about $1,100 and the average high relabeling cost per SKU is $2,600. The reported estimated costs of changing labels varies within a product category because different packaging converters and food manufacturers reported different costs to RTI International. Table 5 shows the total SKUs changed earlier than planned and the total estimated costs of relabeling per product category and for the entire industry.

TABLE 5.—RANGE OF RELABELING COSTS BY PRODUCT CATEGORY

Product Categories	SKUs Changed	Low	Medium	High
Baked Goods	12,500	$10,941,000	$16,137,000	$27,231,000
Baking Ingredients	1,700	$1,615,000	$2,380,000	$3,899,000
Baby Foods	200	$164,000	$249,000	$404,000
Selected Beverages	9,000	$11,871,000	$16,659,000	$25,437,000
Breakfast Foods	1,000	$801,000	$1,237,000	$2,044,000
Selected Candy	4,100	$4,801,000	$6,974,000	$10,846,000
Selected Condiments, Dips and Spreads	3,700	$4,026,000	$5,970,000	$9,283,000
Dairy Foods	8,700	$10,744,000	$16,025,000	$25,032,000
Desserts	3,500	$2,762,000	$4,263,000	$7,042,000
Dietary Supplements	8,100	$13,449,000	$20,110,000	$34,041,000
Selected Dressings and Sauces	2,800	$2,908,000	$4,352,000	$6,757,000
Eggs	2,400	$1,983,000	$2,896,000	$5,086,000
Entrees	2,400	$2,012,000	$3,078,000	$5,032,000
Fats and Oils	800	$759,000	$1,160,000	$1,848,000
Fruits and Vegetables	7,500	$7,426,000	$10,915,000	$17,882,000
Seafood	1,400	$1,732,000	$2,541,000	$3,786,000
Side Dishes and Starches	4,100	$3,361,000	$5,124,000	$8,494,000
Snack Foods	3,600	$3,604,000	$5,288,000	$8,499,000
Soups	700	$809,000	$1,194,000	$1,854,000
Weight Control Foods	200	$196,000	$283,000	$489,000
Total	78,400	$85,964,000	$126,835,000	$204,986,000

4. Margarine Reformulation Costs

One consequence of this regulation will be the reformulation of some foods to reduce levels of *trans* fat. Because those changes in food composition are attributable to this rule, the costs of reformulation are counted here. The benefits to consumers of being able to choose reformulated foods containing less *trans* fat will be counted in section VI.E of this document. In the analysis of the proposed rule, FDA estimated the average reformulation would cost $440,000 per product and would take a full year. Some comments stated that reformulation was very expensive, required a long time to accomplish and would, under certain circumstances, require the use of more expensive inputs. No comments contradicted FDA's estimate of the per product cost of reformulation or provided information to change that estimate, so FDA will continue to use a per product reformulation cost of $440,000. In the proposed analysis FDA assumed that only large firms would reformulate. There was no controversy over this assumption.

As mentioned previously, based on comments, FDA estimates that 15 percent of margarine products have

already been reformulated to eliminate *trans* fat. For margarine reformulation, FDA has estimated no increase in ingredient costs, because the price of reformulated margarine products that are already on the market is no higher than the price of margarine products containing 0.5 g or more per serving of *trans* fat. The different ingredients used in the products appear to have had no impact on the cost of production. However, as greater numbers of products are reformulated, the increased demand for the substitute ingredients may increase costs. However, given that increases in costs of inputs, if any, have not been passed on with a change in 15 percent of margarine products, it seems quite reasonable that an additional smaller change (10 percent) will not result in significant increases in ingredient costs.

Therefore, FDA estimates that 10 percent of the margarine products that have not yet been reformulated will be reformulated to reduce *trans* fat content to less than 0.5 g per serving. We assume that reformulating 10 percent of margarine products will result in a 10 percent reduction in the average *trans* fat content of margarine as a product category. The reformulation will therefore reduce the *trans* fat content of margarines as a whole by 10 percent. In the analysis for the proposed rule, FDA estimated that there were 820 margarine products. Data in the new Labeling Cost Model indicate only 300 margarine products. The new data was used to estimate that 30 margarine products will reformulate as the result of this rule from 8 (10 percent of 84) to 82 (10 percent of 820), if 10 percent of the total number of margarine products are reformulated. Table 6 shows the cost of margarine reformulation.

TABLE 6.—COST OF MARGARINE REFORMULATION

Cost of Reformulating per Product	$440,000
Products Reformulating	30
Total Cost	$13,200,000

FDA has not attempted to estimate the ongoing increased cost of substitutes for partially hydrogenated oil. Competition provides producers with incentives to use the least expensive ingredients that are acceptable for the quality of product they are making. Therefore, in general, any change in existing formulations (such as is expected to occur as a result of this rule) can increase the cost of ingredients. Even a very small increase in the price of a minor ingredient can amount to an increase in production costs of millions of dollars when multiplied by millions of units. However, there is good reason to believe that, in the long run, ingredient costs may not increase. To the extent that producers rely on newly formulated ingredients made with new technologies, the price of these ingredients largely depends on the industrial capacity to produce them. As the demand for such ingredients increases, producers will have more incentive to increase capacity and the prices of these ingredients will fall. In the case where producers make use of different mixes of oils, agricultural inputs are well known for being able to be supplied in greater and greater quantities without an increase in price. FDA does not have sufficient information on the types of substitutes that will be used, on the volume of substitutes that will be needed, or on the future price of the substitutes at the time that reformulation is completed.

5. Cost Summary

Costs for testing, relabeling, and reformulation are all expected to occur by the first effective date of the final rule, or about 2 to 3 years after publication. Table 7 shows the estimates of total cost.

TABLE 7.—RANGE OF COSTS BY CATEGORY AND TOTAL COST

Cost Category	Low	Medium	High
Testing	$40,298,000	$44,930,000	$59,282,000
Relabeling	$85,964,000	$126,835,000	$204,986,000
Reformulation	$13,200,000	$13,200,000	$13,200,000
Total	$139,000,000	$185,000,000	$275,000,000

FDA acknowledges that there is a significant degree of uncertainty in the cost estimates provided here. The most significant source of potential divergence from the reported estimates would be an ongoing increased cost of substitutes for partially hydrogenated oil for producers of reformulated products. FDA has not included any costs for this item in this analysis, so that, if substitute oils do cost more, the costs here are underestimates.

Reformulation is a second significant area of uncertainty. The unknowns include the number of products that will be reformulated, the cost of reformulation, the number of abandoned attempts at reformulation, the length of time actually needed to reformulate products, and the degree to which the reformulation of some products reduces the cost of reformulating other products of the same or different type. The estimates that are provided in this analysis might be either over- or underestimates of the actual costs of reformulation.

A third major area of uncertainty includes the number of labels that will be changed. Actual costs are likely to be lower than those estimated here because this analysis estimated costs based on broad categories of products some of which will not have to change their labels.

E. Benefits

To estimate the health benefits of *trans* fat labeling in the November 1999 proposal, FDA followed the general approach used to estimate the health

benefits for the implementation of the 1990 amendments (56 FR 60856 at 60869, November 27, 1991). Accordingly, FDA estimated: (1) The changes in *trans* fat intake that would result from labeling changes; (2) the changes in health states that would result from changes in *trans* fat intakes; and (3) the value of changes in health states in terms of life-years gained, number of cases or deaths avoided and dollar value of such benefits. The rule may generate other benefits, but we do not quantify them. For example, consumers who are aware of the risks associated with *trans* fat will more readily find information on the *trans* fat content of various foods. The value of the reduction in search time for those consumers is an additional benefit of this final rule.

1. Changes in *Trans* Fat Intake

FDA has estimated the current *trans* fat intake of the population and the estimated changes in *trans* fat intake. Based on comments received and on its own reevaluation, FDA revised its estimate of current *trans* fat intake, shown in table 1 (section IX.C) and its projected estimate for changes in *trans* fat intake due to labeling (table 2, section IX.C). The estimate projects quantitative decreases in *trans* fat intake with implementation of the final rule, and discusses the qualitative replacement of *trans* fat by other types of fat.

2. Changes in Health States

In the November 1999 proposal, FDA used two methods to estimate the potential decrease in CHD likely to result from decreased intake of *trans* fat in response to the labeling change.

a. *Method 1*. Decrease in CHD risk due to decreased serum concentrations of LDL–C.

b. *Method 2*. Decrease in CHD risk due to decreased serum concentrations of LDL–C and increased serum concentrations of HDL–C. FDA also reviewed the association of CHD risk with *trans* fat intake found in large prospective observational cohort studies.

As described in section IV of this document, in the November 1999 proposal FDA concluded that the effects of *trans* fatty acids on serum LDL–C should be the primary criterion for whether *trans* fatty acids influence CHD risk. In Method 1, FDA used changes in the primary criterion, serum LDL–C, to evaluate the effects of *trans* fat intake on CHD risk (64 FR 62746 at 62768). Additionally, as described in section IV of this document, although FDA did not place primary reliance upon the relationships among *trans* fat intakes and adverse effects on HDL–C and CHD risk in deciding that nutrition labeling was warranted, FDA also recognizes this possible relationship, so concerns about possible adverse effects cannot be ignored. Therefore, the economic analysis used changes in both HDL–C and LDL–C as a second method to quantify the effects of *trans* fat intake on CHD risk, with the noted qualification that the primary basis for the rule was the effect of *trans* fat on LDL–C (64 FR 62746 at 62769).

Section IV of this document notes that observational epidemiological studies can provide evidence of an association between a risk factor and a disease, but cannot establish direct cause and effect. Therefore, FDA considered the evidence from observational epidemiological studies, including large prospective (cohort) studies, as indirect evidence for a relationship between *trans* fat intake and CHD risk. In the November 1999 proposal, FDA found that the prospective studies of *trans* fat intake and CHD risk consistently reported a greater risk of CHD attributable to *trans* fat intake than would be accounted for by either Method 1 (changes in LDL–C) or by Method 2 (changes in both LDL–C and HDL–C) (64 FR 62746 at 62770 to 62771). The estimates in Method 1 and Method 2 are calculated using factors from regression equations summarizing the results of short-term feeding trials (intervention studies). In the intervention studies, *trans* fat is fed to people for a few weeks, changes in serum lipids are measured, and it is assumed that the CHD risk associated with *trans* fat intake occurs through the mechanism of changes in LDL–C and possibly HDL–C. In contrast, the prospective studies measure actual CHD occurrence in a large group of people over a period of years, and describe all CHD risk associated with *trans* fat intake, regardless of the mechanism of action by which *trans* fat intake may be associated with CHD. Thus, the results of the prospective studies suggest that there may be additional mechanisms by which *trans* fat contributes to CHD risk. Because prospective studies do not show direct cause and effect, and because the relative risks determined in observational studies are imprecise, FDA did not use the results of the prospective studies in quantitative estimates of changes in *trans* fat intake and CHD risk. However, FDA noted that, if there are additional mechanisms by which *trans* fat contributes to CHD risk, as suggested by the prospective studies, then the actual benefits may be greater than estimated using either Method 1 (changes in LDL–C) or Method 2 (changes in LDL–C and HDL–C) (64 FR 62746 at 62771).

As described in the November 1999 proposal (64 FR 62746 at 62768 and 62769), the regression equations of Katan et al. (Ref. 62) and Zock et al. (Ref. 69) were based on five intervention studies that made, in total, six dietary comparisons between consumption of *trans* fat and cis-unsaturated fat (Refs. 7, 8, and 11 through 13). The regression equation for LDL-C showed that each additional percent of energy from *trans* fat was predicted to increase LDL-C by 1.5 mg/deciliter (dL) (0.040 millimol/liter) ($R^2 = 0.86$, $p = 0.0028$) when substituted for the same percent of energy from cis-monounsaturated fat, holding total energy intake constant. The regression equation for HDL-C showed that each additional percent of energy from *trans* fat was predicted to decrease HDL-C by 0.4 mg/dL (0.013 millimol/liter) ($R^2 = 0.88$, $p = 0.0019$), when substituted for the same percent of energy from cis-monounsaturated fat. The regression lines were forced through the origin because a zero change in intake will produce a zero change in lipoprotein concentrations (Refs. 62, 69, and 154). In carrying out the regression, differences between diets in fatty acids other than *trans* fat and cis-monounsaturated fat were adjusted for by using regression coefficients from a previous meta-analysis of 27 intervention studies (Ref. 65).

Sample calculations using Method 1 and Method 2 are summarized in table 8 in this document. The table illustrates a decrease in *trans* fat intake of 0.1 percent of energy (calories) and shows the factors FDA used to relate a given decrease in *trans* fat intake to a corresponding change in CHD risk. To estimate the change in CHD risk with change in *trans* fat intake, for each type of serum lipid, LDL-C and HDL-C, we multiplied the change in *trans* fat intake by three factors, representing: (1) the change in serum lipid with change in *trans* fat intake, (2) the change in CHD risk with change in serum lipid, and (3) an adjustment for regression dilution. Table 8 shows that, for Method 1, based on changes in LDL-C, replacement of 0.1 percent of energy from *trans* fat with the same percent of energy from cis-monounsaturated fat would decrease CHD risk by 0.147 percent (-0.1 percent of energy from *trans* fat x 1.5 mg LDL-C/dL per percent of energy from *trans* fat x 0.7 percent change in CHD risk per mg LDL-C/dL x 1.4 adjustment factor for regression dilution = -0.147 percent change in CHD risk). Based on changes in HDL-C, replacement of 0.1 percent of energy from *trans* fat would decrease

CHD risk by 0.140 percent (-0.1 percent of energy from *trans* fat x -0.4 mg HDL-C/dL per percent of energy from *trans* fat x -2.5 percent change in CHD risk per mg HDL-C/dL x 1.4 adjustment factor for regression dilution = -0.140 change in CHD risk based on changes in HDL-C). For Method 2, based on changes in both LDL-C and HDL-C, the decrease in CHD risk would be 0.287 percent (-0.147 percent based on LDL-C plus -0.140 percent based on HDL-C = -0.287 percent based on LDL-C + HDL-C). FDA used these estimation methods to project the decrease in CHD risk in the November 1999 proposal (64 FR 62746 at 62767).

TABLE 8.—SAMPLE CALCULATION FOR CHANGE IN CHD RISK WITH SUBSTITUTION OF *CIS*-MONOUNSATURATED FAT FOR *TRANS* FAT

Estimation Method	Change in *Trans* Intake (% of Energy)	Type of Serum Lipid	Factor for Change in Serum Lipids (mg/dL per 1% of Energy)	Factor for Change in CHD Risk (% per mg/dL)	Factor for Adjustment of Regression Dilution	Change in CHD Risk (%)
Method 1 LDL	-0.1	LDL	1.5	0.7	1.4	-0.147
Method 2 LDL + HDL	-0.1	LDL	1.5	0.7	1.4	-0.147
		HDL	-0.4	-2.5	1.4	-0.14
		LDL+HDL				-0.287

In the scientific literature, *cis*-monounsaturated fat is commonly used as a reference point in describing effects of *trans* fat intake. Therefore, FDA first estimated the effect on CHD risk by assuming that a given amount of *trans* fat would be replaced by the same amount of *cis*-monounsaturated fat in the diet (table 8 in this document and 64 FR 62746 at 62767). However, it is likely that *trans* fat in the diet would actually be replaced by a combination of *cis*-monounsaturated fat, *cis*-polyunsaturated fat, and saturated fat. Therefore, FDA also considered the changes in LDL–C and HDL–C associated with replacement of *trans* fat by different types of fatty acids or carbohydrate (64 FR 62746 at 62767 to 62770). Table 9 in this document summarizes the factors for changes in LDL–C and HDL–C with different macronutrients and combinations of macronutrients replaced by *trans* fat. The first four columns of data show the factors for substitution of *trans* fat for 100 percent of individual types of fatty acids or carbohydrate. We project that, due to *trans* fat labeling, *trans* fat will be replaced by combinations of different types of fatty acids or carbohydrate. By combining the factors in the first four data columns, we obtained the factors for substitution of *trans* fat for combinations of different fatty acids and carbohydrate, shown in the last three data columns.

We generated the factors in table 9 by combining the results of two sets of metaanalyses. Table 9 shows the result of linking: (1) The regression equation coefficients of Katan et al. (Ref. 62) and Zock et al. (Ref. 69), for substitution of *trans* fat for cis-monounsaturated fat and (2) the regression equation coefficients of Mensink and Katan (Ref. 65), for substitution of saturated and cis-unsaturated fat for carbohydrate. The regression equations of Mensink and Katan (Ref. 65) were based on 27 intervention studies that made dietary comparisons for consumption of carbohydrate, saturated fat, cis-polyunsaturated fat and cis-monounsaturated fat. The regression equation for LDL-C included 57 dietary comparison data points from 24 studies, and showed that, holding total energy intake constant, when substituted for one percent of energy from carbohydrate, each additional percent of energy from saturated fat was predicted to increase LDL-C by 1.28 mg/dL (0.033 millimol/liter) ($p < 0.001$), each additional percent of energy from cis-monounsaturated fat was predicted to lower LDL-C by 0.24 mg/dL (0.006 millimol/liter) ($p = 0.114$) and each additional percent of energy from cis-polyunsaturated fat was predicted to lower LDL-C by 0.55 mg/dL (0.014 millimol/liter) ($p = 0.002$). The regression equation for HDL-C included 59 dietary comparison data points from 25 studies, and showed that holding total energy intake constant, when substituted for one percent of energy from carbohydrate, each additional percent of energy from saturated fat was predicted to increase HDL-C by 0.47 mg/dL (0.012 millimol/liter) ($p < 0.001$), each additional percent of energy from cis-monounsaturated fat was predicted to increase HDL-C by 0.34 mg/dL (0.009 millimol/liter) ($p < 0.001$) and each additional percent of energy from cis-polyunsaturated fat was predicted to increase HDL-C by 0.28 mg/dL (0.007 millimol/liter) ($p = 0.002$).

Comparison with the observed data showed that the predicted regression lines explained 64 percent of the variation in changes in LDL-C and 88 percent of the variation in changes in HDL-C. The coefficients of Mensink and Katan (Ref. 65) are expressed as substitution of each type of macronutrient for carbohydrate, but the coefficients of Katan et al. (Ref. 62) and Zock et al. (Ref. 69) are expressed as substitution of *trans* fat for cis-monounsaturated fat. For comparability with the coefficients for *trans* fat, we expressed the coefficients of Mensink and Katan in terms of substitution of each type of macronutrient for cis-monounsaturated fat. As stated in the November 1999 proposal (64 FR 62746 at 62769), when substituted for one percent of energy from cis-monounsaturated fat, saturated fat raised LDL-C by 1.52 mg/dL, cis-polyunsaturated fat lowered LDL-C by 0.31 mg/dL, and carbohydrate raised LDL-C by 0.24 mg/dL. When substituted for one percent of energy from cis-monounsaturated fat, saturated fat raised HDL-C by 0.13 mg/dL, cis-polyunsaturated fat lowered HDL-C by 0.06 mg/dL, and carbohydrate lowered HDL-C by 0.34 mg/dL. We then combined these coefficients with the coefficients for *trans* fat, to obtain the changes in lipoprotein levels with *trans* fat substituted for different macronutrients, as shown in table 9.

Table 9 also gives examples of changes in CHD risk with replacement of 0.1 percent of energy from *trans* fat by different macronutrients and combinations of macronutrients. Table 8 shows the general method and illustrates the calculation of estimated changes in CHD risk with replacement

of *trans* fat by cis-monounsaturated fat. To account for each type of macronutrient substitution, we used the corresponding factors from table 9 for changes in serum lipids. For example, for cis-polyunsaturated fat, table 9 gives the factor, 1.81 mg LDL-C/dL, for replacement of 1 percent of energy from cis-polyunsaturated fat by *trans* fat. For Method 1, based on changes in LDL-C, the replacement of 0.1 percent of energy from *trans* fat with the same percent of energy from cis-polyunsaturated fat would decrease CHD risk by 0.177 percent (-0.1 percent of energy from *trans* fat x 1.81 mg LDL-C/dL per percent of energy from *trans* fat x 0.7 percent change in CHD risk per mg LDL-C/dL x 1.4 adjustment factor for regression dilution = -0.177 percent change in CHD risk). As noted previously, we project that, due to *trans* fat labeling, *trans* fat will be replaced by combinations of different types of fatty acids or carbohydrate. The changes in CHD risk associated with specific combinations of fatty acids or carbohydrate are shown in the last three data columns. The first four data columns show the change in CHD risk associated with each individual type of fatty acid and carbohydrate. The column showing *trans* fat replaced by 100 percent saturated fat is included in table 9 for completeness in illustrating the data and methods we used to estimate changes in CHD risk with different macronutrient substitutions. The inclusion of this column does not indicate that FDA projects that *trans* fat will be replaced by 100 percent saturated fat, or that FDA would encourage such an inappropriate substitution. Rather, the substitutions for *trans* fat that FDA considers most likely are shown later, in table 10.

As mentioned earlier, and in the November 1999 proposal (64 FR 62746 at 62769), the economic analysis used changes in both LDL-C and HDL-C as a second method to quantify the effects of *trans* fat intake on CHD risk, with the noted qualification that the primary basis for the rule was the effect of *trans* fat on LDL-C. To allow readers to reproduce all of our estimated changes in CHD risk, table 9 shows changes in CHD risk based on Method 2, LDL-C and HDL-C, as well as Method 1, LDL-C. In addition, the cells that show a decrease in CHD due to a 100 percent replacement of *trans* fat for saturated fat represent the relationship between HDL-C and CHD, a relationship that is more uncertain than the causal relationship between LDL-C and CHD. FDA accounted for the replacement of *trans* fat with different combinations of macronutrients by projecting a range of changes in health states in terms of life-years gained, number of cases or deaths avoided, and dollar value of such benefits (64 FR 62746 at 62771–62773).

TABLE 9.—SUMMARY OF CHANGES IN SERUM LIPIDS AND CHD RISK WITH DIFFERENT MACRONUTRIENT SUBSTITUTIONS

A. CHANGE IN SERUM LIPIDS WITH SUBSTITUTION OF *Trans* FATTY ACIDS FOR DIFFERENT TYPES OF FATTY ACIDS OR CARBOHYDRATE

Macronutrient	*Cis*-monounsaturated Fatty Acid	*Cis*-polyunsaturated Fatty Acid	Saturated Fatty Acid	Carbohydrate	Half *cis*-monounsaturated and half *cis*-polyunsaturated	Half *cis*-monounsaturated and half saturated	Half *cis*-monounsaturated and half carbohydrate
Change in Serum Lipid When Replaced by *Trans* Fat	mg/dL per 1% of energy	mg/dL per 1% of energy	mg/dL per 1% of energy	mg/dL per 1% of energy	mg/dL per 1% of energy	mg/dL per 1% of energy	mg/dL per 1% of energy
LDL	1.5	1.81	-0.02	1.26	1.66	0.74	1.38
HDL	-0.4	-0.34	-0.53	-0.06	-0.37	-0.47	-0.23

B. CHANGE IN CHD RISK WITH REPLACEMENT OF *Trans* FATTY ACIDS BY DIFFERENT TYPES OF FATTY ACIDS OR CARBOHYDRATE

Macronutrient	*Cis*-monounsaturated Fatty Acid	*Cis*-polyunsaturated Fatty Acid	Saturated Fatty Acid	Carbohydrate	Half *cis*-monounsaturated and half *cis*-polyunsaturated	Half *cis*-monounsaturated and half saturated	Half *cis*-monounsaturated and half carbohydrate
Change in CDH Risk With Replacment of *Trans* Fat	Percent per 0.1% of energy	Percent per 0.1% of energy	Percent per 0.1% of energy	Percent per 0.1% of energy	Percent per 0.1% of energy	Percent per 0.1% of energy	Percent per 0.1% of energy
Method 1, LDL	-0.147	-0.177	0.002	-0.123	-0.162	-0.073	-0.135
HDL	-0.140	-0.119	-0.186	-0.021	-0.130	-0.163	-0.081
Method 2, LDL + HDL	-0.287	-0.296	-0.184	-0.144	-0.292	-0.235	-0.216

(Comment 39) As described previously in this document, FDA received numerous comments in support of the November 1999 proposal. Several of these comments noted specifically that labeling of *trans* fat has the potential for substantial public health benefits. A number of comments noted that consumption of *trans* fat increases the risk of CHD by increasing total blood cholesterol and LDL–C, and that *trans* fat labeling would enable consumers to decrease their *trans* fat intake and therefore decrease their risk of CHD. Some comments added that, because *trans* fat also increases the risk of CHD by decreasing HDL–C, therefore the health benefits of *trans* fat labeling would be greater than the benefits associated with the effect of *trans* fat on LDL–C alone. A few comments

specifically stated that the prospective studies suggest that there may be other biological mechanisms by which *trans* fat contributes to CHD, in addition to the effects of *trans* fat on LDL–C and HDL–C. These comments therefore supported the possibility that the actual benefits of *trans* fat labeling may be greater than FDA's estimate using either Method 1 (LDL–C) or Method 2 (LDL–C and HDL–C).

Other comments, which were opposed to the November 1999 proposal or some of its provisions, questioned FDA's conclusions regarding the net health benefits of *trans* fat labeling. Some comments stated that the potential harm to the public remedied by *trans* fat labeling was not sufficient to outweigh the cost burden to specific industries. These comments suggested that, although *trans* fat was shown to increase LDL–C in some studies, the evidence was inconclusive on how to quantify the increase in LDL–C and CHD risk due to *trans* fat intake and on whether the increase in LDL–C and CHD risk due to *trans* fat intake were as large as those due to saturated fat. These comments suggested that FDA's estimate of health benefits of *trans* fat labeling was too high. One comment stated that it is premature to conclude that *trans* fat intake lowers HDL–C because many intervention studies showed that *trans* fat intake causes only a small decrease or has no effect on HDL–C. The comment implied that consumption of *trans* fat may not increase CHD risk by decreasing HDL–C. A few comments cited an FDA statement from the November 1999 proposal that no dose-response relationship had been demonstrated between *trans* fat intake and CHD (64 FR 62746 at 62752). The comments argued that, therefore, it is not possible to project quantitative health benefits due to *trans* fat labeling. One comment also stated that the health benefits estimate was inaccurate because it did not account for either other CHD risk factors, such as obesity, or other CHD prevention efforts.

A few comments questioned whether health benefits could result from *trans* fat labeling because the in the intervention studies the intakes of *trans* fat were very high and not representative of U.S. intakes of about 5.3 g/d (3 percent of calories). Some comments stated that, even if *trans* fat has adverse health effects at higher levels of intake, there is no clinical evidence that lower levels of intake, such as 0.5 g *trans* fat in a serving of a food product, has any adverse effect. These comments therefore questioned whether health benefits could result from labeling of *trans* fat present in relatively small amounts in individual foods. Other comments suggested that the emphasis on *trans* fat in the proposed labeling regulations was out of proportion to the emphasis on saturated fat, because the overall amount of saturated fat in the diet is approximately five times that of *trans* fat. The comments stated that, therefore, decreased *trans* fat intake has much less potential for lowering CHD risk than does decreased saturated fat intake, and this should be considered when estimating the health benefits of *trans* fat labeling.

Regarding the comments that questioned whether the increase in LDL–C and CHD risk due to *trans* fat intake could be quantified and whether the increase in LDL–C and CHD risk due to *trans* fat intake were as large as those due to saturated fat, FDA stated in the review of the science in the 1999 proposal (64 FR 62746 at 62753) that the available studies did not provide a definitive answer about whether *trans* fat has an effect on LDL–C and CHD risk equivalent to saturated fat on a gram-for-gram basis. FDA noted that interpretation of the intervention studies is complicated because, in the individual studies, *trans* fatty acids replace other dietary fatty acids that also affect serum cholesterol levels (64 FR 62746 at 62751). This evaluation was based on a review and analysis of the individual studies, it was not done for purposes of an economic analysis. To overcome the difficulties in interpreting individual intervention studies, in the November 1999 proposal FDA used regression equations based on a meta-analysis of intervention trials to quantitatively estimate the relationship between *trans* fat and LDL (Refs. 62, 65, and 69) in its calculation of the health benefits of *trans* fat labeling (64 FR 62746 at 62768–62770). As noted in section IV of this document, and in the November 1999 proposal, the regression equations do predict a very similar increase in LDL–C with each one percent of energy increase in either saturated fat or *trans* fat. Thus, table 9 in this document shows that the change in LDL–C is negligible when one percent of energy from *trans* fat is substituted for saturated fat. Therefore, FDA disagrees with the comments that stated that the increases in LDL–C and CHD risk due to *trans* fat intake could not be quantified and were not as large as those due to saturated fat and that FDA's estimate of these health benefits of *trans* fat labeling was too high.

Regarding the comment suggesting that it is premature to conclude that *trans* fat intake lowers HDL–C, section IV of this document states that Federal Government advisory groups (Refs. 88 to 90, 140) and an advisory group of health professionals (Ref. 91) have stated that substitution of *trans* fat for saturated fat lowers HDL–C. Specifically, the Dietary Guidelines 2000 Advisory Report states that *trans* fatty acids tend to lower a protective form of serum cholesterol (HDL cholesterol) (Ref. 88). NCEP 2001 states that randomized clinical trials show that when *trans* fatty acids are substituted for saturated fatty acids, HDL cholesterol levels are lower, with a dose response effect observed (Ref. 89). The IOM/NAS states that the preponderance of the data suggest that hydrogenated fat/*trans* fatty acids, relative to saturated fatty acids, result in lower HDL cholesterol concentrations (Ref. 90). AHA 2000 states that it has been established that dietary *trans*-unsaturated fatty acids can increase LDL cholesterol and reduce HDL cholesterol (AHA 2000, p. 2300) (Ref. 91). Therefore, FDA disagrees with the comment that it is premature to conclude that *trans* fat intake may lower HDL–C. As described in Section IV of this document, although FDA did not place primary reliance upon the relationships among *trans* fat intakes and adverse effects on HDL–C and CHD risk in deciding that nutrition labeling was warranted, FDA also recognizes this possible relationship, so concerns about possible adverse effects cannot be ignored. Therefore, we used changes in both HDL–C and LDL–C as a second method to quantify the effects of *trans* fat intake on CHD risk, with the noted qualification that the primary basis for the rule was the effect of *trans* fat on LDL–C (64 FR 62746 at 62769).

Regarding the comments discussing FDA's statement in the November 1999 proposal (64 FR 62746 at 62752) that no dose response relationship had been demonstrated between *trans* fat intake and CHD, this statement referred to the effect of *trans* fat on CHD risk in the observational studies, not to the effect of *trans* fat on LDL–C which was used to estimate the health benefits in Method 1 (LDL–C) and Method 2 (LDL–C and HDL–C). FDA's statement was a generalization regarding the observational studies overall, including both case control studies and prospective observational studies. However, the four large prospective studies did all show dose-response relationships between *trans* fat intake and CHD risk, but in two of the studies the dose-response relationship was not statistically significant in all analyses. In the Nurses Health Study, the dose response relationship at both 8 years

and 14 years of followup was highly statistically significant (Refs. 21 and 38). In a Finnish study, the dose response relationship of *trans* fat with risk of CHD death was significant (p = 0.004), but was not significant for risk of major coronary event (p = 0.158) (Ref. 20). In a study of U.S. men, the dose response relationship was significant after statistical adjustment for major CHD risk factors (p = 0.01) but was not significant after additional adjustment for dietary fiber (p = 0.2) (Ref. 19). Therefore, the prospective studies were consistent with a dose-response relationship, although the relationship was not statistically significant in all analyses. Moreover, as discussed previously in this section, FDA's quantitative estimate of health benefits was not based on the prospective studies, but was based on the regression equations summarizing the results of the intervention feeding studies (tables 8 and 9 in this document and 64 FR 62746 at 62757–62770). The regression equations summarizing the effect of *trans* fat on LDL–C and HDL–C in the intervention studies did show a dose response relationship, as discussed in the November 1999 proposal and noted in section IV of this document. Additionally, the regression equations used by FDA in this document and in the November 1999 proposal were for purposes of making a quantitative estimate of the health benefits as part of an economic analysis and are consistent with newer regression equations in a study published in 2001 (Ref. 130). Therefore, FDA does not agree with the comment that it is not possible to calculate health benefits because there is no dose-response relationship for the adverse effects of *trans* fat.

FDA disagrees with the comment that the health benefits estimate did not account for other CHD risk factors. In the health benefits estimate, FDA used the factors shown in table 8 to calculate the amount of CHD risk associated with the expected amount of change in LDL–C and HDL–C. These factors were derived from large population studies of serum lipids and CHD risk, in which statistical methods accounted for other positive and negative risk factors for CHD.

Regarding the comment about the level of *trans* fat intake in the intervention studies, Section IV of this document explains that, because of uncertainty in intake estimates, caution must be exercised to avoid over-interpretation of the available dietary intake estimates and their relationship to the *trans* fat levels used in the intervention trials. However, in response to the comment, FDA notes some specific examples of intervention studies with lower *trans* fat intake. One example is the study of Judd et al., 1998 (Ref. 34), which found a significant increase in LDL–C with a difference in *trans* fat intake of 1.5 percent of calories between the *trans* fat test diet (3.9 percent of calories from *trans* fat) and the comparison diet (2.4 percent of calories from *trans* fat). Another example is the study of Lichtenstein and coworkers (Ref. 82) which studied six test diets and reported a positive coefficient, i.e., a linear trend, for the association of the change in LDL–C levels among diets with the change in *trans* fat intake (including *trans* fat changes of 0.4 percent and 2.8 percent of calories). Such a linear trend does suggest that *trans* fat intakes below 3 percent of calories may influence LDL–C levels, and thus, CHD risk. Therefore, significant increases in LDL were found in specific intervention studies with *trans* fat intake at or below the reported average intake for the U.S. population.

FDA disagrees with the comment that disclosure of 0.5 g *trans* fat or greater in a food product has no public health importance and that health benefits may not result from labeling of *trans* fat present in relatively small amount in individual foods. As described earlier in sections III and V of this document, FDA does not need to demonstrate adverse health effects of 0.5 g *trans* fat in a food product in order to justify requiring disclosure of 0.5 g *trans* fat on food labels. Rather, FDA determined that the consistent provision of *trans* fat information on foods consumed throughout the day is of public health importance and can assist consumers in maintaining healthy dietary practices. Further, FDA has determined that the absence of *trans* fat information on foods requiring mandatory labeling would be misleading. However, for the purposes of economic analysis, the health benefits of decreasing *trans* fat intake by 0.5 g can be estimated quantitatively. In a 2,000 calorie diet, 0.5 g *trans* fat corresponds to approximately 0.2 percent of energy. (This correspondence holds because 1 g of fat = 9 kcal, so (0.5 x 9 x 100)/2000 = 0.2 percent of energy). Using the factors in table 8, replacement of 0.2 percent of energy from *trans* fat with *cis*-monounsaturated fat would decrease CHD risk by 0.29 percent based on LDL–C and 0.57 percent based on LDL–C and HDL–C. Because CHD is so common in the U.S. population, a relatively small decrease in risk corresponds to a large number of cases and deaths avoided and large dollar value of such benefits, as shown in the example in section IX.A of this document. Awareness of *trans* fat contributions from food products containing 0.5 g and above will assist individual consumers in maintaining healthy dietary practices, reducing the average 2.6 percent of energy from *trans* fat consumed throughout the day.

FDA agrees with the comments that average saturated fat intake in the United States is about 5 times greater than average *trans* fat intake. FDA stated in the November 1999 proposal that it did not want to distract consumers from years of dietary guidance messages about saturated fat (64 FR 62746 at 62755). But the potential health benefits from decreasing *trans* fat intake compared with decreasing saturated fat intake do not depend solely upon the average total amount of each in the diet. The potential health benefits also depend upon the feasibility of decreasing intake of saturated fat compared with *trans* fat. Average U.S. saturated fat intake in 1980 was about 13 percent of energy and decreased to 11 or 12 percent of energy by the mid-1990s (Ref. 113). Many additional heart attacks and deaths might be prevented if saturated fat intake could be decreased to the recommended less than 10 percent of energy. The targeted decrease in saturated fat intake of one or two percent of energy can be compared with the average *trans* fat intake of 2 percent of energy from partially hydrogenated fats and oils. Labeling of *trans* fat will create new potential for decreased *trans* fat intake by providing an incentive to food manufacturers to reduce the amount of *trans* fat in their products and by providing consumers with information they need to include *trans* fat content in their food purchasing decisions.

(Comment 40) Among the comments that supported the potential public health benefits of *trans* fat labeling, many noted that benefits would result from provision of *trans* fat information on product labels so that consumers could incorporate this information into their purchasing decisions. Several comments also specifically noted the likelihood that *trans* fat labeling would result in reformulation of products to be lower in *trans* fat, and suggested that the public health benefits would be large because reducing *trans* fat intake as a result of reformulation requires little effort by consumers. However, some comments did not agree that *trans* fat labeling would be read or understood by consumers, or that the labeling would affect purchasing decisions. These comments suggested that the net health benefits of *trans* fat labeling would be much smaller than FDA's estimate. Other comments did not agree that

products could be reformulated in a manner that would result in net health benefits. Some of these comments stated that *trans* fat is beneficial because foods with *trans* fat replace foods with higher amounts of saturated fat. Some comments stated that feasible reformulations that would lower *trans* fat would also increase saturated fat, thereby reducing or eliminating health benefits. Other comments emphasized that manufacturers need competitive incentives in order to incur the costs of reformulation, and did not agree that the Nutrition Facts panel and label claims in the November 1999 proposal provided sufficient incentives for reformulation.

In the November 1999 proposal, FDA based its estimate of health benefits on scenarios of projected decreases in *trans* fat intake due to labeling and reformulation. As summarized in section VI.C of this document, FDA received specific comments regarding the likely decrease in *trans* fat intake due to expected consumer responses to *trans* fat labeling and due to the projected amount of product reformulation. Based on the comments received, on the provisions of this final rule and on its own reevaluation, FDA has revised its estimate of the expected decrease in *trans* fat intake due to labeling (table 2, section VI.C). Because of uncertainties regarding the magnitude of consumer response to *trans* fat labeling we have chosen a very low estimate of consumer response to the new label, a decrease of 0.1 percent of *trans* fat intake (section VI.C.). As described in section IV of this document, current dietary guidance does not consider *trans* fat to be beneficial, but recommends that intake of both *trans* fat and saturated fat should be limited. When products containing partially hydrogenated fats or oils are reformulated to lower the *trans* fat content, functionality may require the reformulated products to have more saturated fat than the original product. However, as shown in a number of examples included with comments, the total amount of saturated fat plus *trans* fat in the reformulated product is commonly lower than in the original product. Substitution of the reformulated product for the original product in the diet would have net health benefits using Method 1, LDL–C, and even higher health benefits using Method 2, LDL–C and HDL–C. FDA acknowledges that different products have different functionality requirements for fats and oils, and the constraints on reformulation alternatives are different for tub and stick margarines and spreads, household shortenings, frying fats for snacks and chips, and baking fats for cookies, crackers, cakes and other baked goods. FDA has summarized specific comments regarding reformulation alternatives in section IX.C of this document, has taken these into account in projecting the expected amount of margarine reformulation (table 2), and is accounting for the replacement of *trans* fat with different combinations of macronutrients in its models for calculating changes in valuation of health states in section IX.E.3 of this document. Therefore, FDA does not agree with the comments that feasible reformulations would eliminate health benefits by increasing saturated fat. In section V of this document, FDA stressed the importance of providing information on *trans* fat on the nutrition label to assist consumers in choosing healthier diets. As described in section IX.E.3 of this document, in response to comments regarding reformulation, FDA recognizes that different features of this final rule may tend to either increase or decrease the incentives for reformulation. Therefore, because of this uncertainty, in this analysis FDA is using a deliberately low estimate, 10 percent, for the decrease in *trans* fat intake due to margarine reformulation. Also, FDA is not using a quantitative estimate for any decrease in *trans* fat intake due to reformulation of baked products or of other products containing hydrogenated fats and oils. To the extent that the decrease in *trans* fat intake due to reformulation is greater than FDA's estimate, this analysis will underestimate the benefits of *trans* fat labeling.

(Comment 41) As summarized in section IV.9 of this document, one comment recommended that comparisons of the health effects of saturated fat and *trans* fat should be explicit and consistent throughout the final rule. The comment noted that in FDA's November 1999 proposal, the preliminary regulatory impact analysis estimated that the effects of *trans* fat and saturated fat on LDL–C were similar for a given percent of energy, but the review of the science did not make a gram-for-gram comparison of the effects of saturated and *trans* fat. The comment stated that if there is uncertainty about the comparative effects of saturated fat and *trans* fat on LDL–C, then this should be reflected in FDA's estimate of health benefits. The comment also noted that, in the preliminary regulatory impact analysis, use of Method 2, LDL–C and HDL–C, would approximately double the expected health benefits of *trans* fat labeling, compared with Method 1, LDL–C. The comment suggested that if the adverse health effects of *trans* fat are approximately double those of saturated fat, this should be taken into account in the provisions for labeling and claims. This comment also suggested that FDA had misinterpreted the relative risk results of the prospective observational studies and questioned whether these studies actually indicated that the risk of CHD due to *trans* fat intake was much greater than would be expected due to LDL–C and HDL–C. According to the comment, relative risk estimates in prospective studies depend on the base risk used for comparisons. Individuals in some study groups, such as the Nurses Health Study, may have lower overall CHD risk than individuals in the general population because the participants are volunteers whose lifestyles may be healthier than average. A systematic difference between the study and general populations may result in inaccuracies when the relative risk from the study population is related to the absolute risk in the general population.

A few comments to the November 15, 2002, notice to reopen the *trans* fat comment period questioned the scientific validity of certain of the observations and conclusions in the IOM/NAS report. The comments stated that the IOM/NAS report relied upon a regression equation in an article by Ascherio et al. (Ref. 83), published in the NEJM, for its observation that *trans* fatty acids may have a more adverse effect on CHD risk than saturated fatty acids and for its conclusion that, similar to saturated fatty acids, there is a positive linear trend between *trans* fatty acid intake and LDL–C and risk of CHD. The comments stated that the Ascherio et al. article was a commentary that was not peer-reviewed and should not be accorded the weight given by the IOM report. Additionally, comments suggested that additional research is needed to establish whether there is a positive linear trend between *trans* fat intake and LDL–C. The comments asserted that there may be an alternate explanation for the results described by Ascherio et al., and mentioned unpublished work done at the University of Cincinnati. The comments did not mention the existence of any other evidence for a linear trend between *trans* fat intake and LDL–C, and implied that, in the absence of the Ascherio article (Ref. 83), there would be no basis for the existence of such a linear trend.

As stated in section IV.9 of this document, regardless of whether FDA reviewed the effects of saturated fat and

trans fat on LDL–C and CHD risk for the science section or the regulatory impact section, the basic conclusion about those effects is the same. That is, both *trans* fatty acids and saturated fatty acids raise LDL–C levels, a major risk factor for CHD risk. FDA did state in the review of the science in the 1999 proposal (64 FR 62746 at 62753) that the available studies did not provide a definitive answer about whether *trans* fat has an effect on LDL–C and CHD risk equivalent to saturated fat on a gram-for-gram basis. However, as stated previously in both this section and section IV of this document, to overcome the difficulties in interpreting individual intervention studies, in the November 1999 proposal FDA used regression equations based on a meta-analysis of intervention trials to quantitatively estimate the relationship between *trans* fat and LDL (Refs. 62, 65, and 69) in its calculation of the health benefits of *trans* fat labeling (64 FR 62746 at 62768–62770). The regression equations do predict a very similar increase in LDL–C with each one percent of energy increase in either saturated fat or *trans* fat. The regression equations used by FDA in this document and in the November 1999 proposal are appropriate for purposes of making a quantitative estimate of the health benefits as part of an economic analysis and are consistent with newer regression equations in a study published in 2001 (Ref. 130).

As previously described in this section and in section IV of this document, although FDA did not place primary reliance upon the relationships among *trans* fat intakes and adverse effects on HDL–C and CHD risk in deciding that nutrition labeling was warranted, FDA also recognizes this possible relationship, so concerns about possible adverse effects cannot be ignored. Therefore, we used changes in both HDL–C and LDL–C as a second method to quantify the effects of *trans* fat intake on CHD risk, with the noted qualification that the primary basis for the rule was the effect of *trans* fat on LDL–C (64 FR 62746 at 62769). As discussed in section V of this document, because of chemical and physiologic distinctions between saturated and *trans* fats, the agency has reconsidered the position that the two fatty acids should be declared as one combined entity. Declaration of the amount of *trans* fat on a separate line from saturated fat on the nutrition label is consistent with the possibility that the health benefits of *trans* fat labeling may be due to changes in LDL–C alone (Method 1), or to changes in both LDL–C and HDL–C (Method 2).

In response to the comment about relative risk in the prospective studies, FDA acknowledges that relative risk estimates in prospective studies will depend on the base risk used for comparisons and this dependence on base risk may result in inaccuracies when the relative risk is related to the absolute risk in other studies or in the general population. However, FDA does not agree that this difference would change the basic conclusion of the prospective studies, that the CHD risk associated with *trans* fat in the prospective studies is much greater than the CHD risk expected due to either Method 1 (LDL–C) or Method 2 (LDL–C and HDL–C). In the 14-year followup of the Nurses Health Study (Ref. 38), the increased risk of CHD associated with *trans* fat intake compared with carbohydrate intake was more than ten times the increased risk for the same amount of saturated fat compared with carbohydrate. This comparison between *trans* fat and saturated fat was in contrast to the prediction based on Method 1 (LDL–C) or Method 2 (LDL–C and HDL–C). In Method 1, *trans* fat would be predicted to be associated with about the same increased risk as saturated fat, and in Method 2, *trans* fat would be predicted to be associated with about twice as much increased risk as saturated fat, comparing both with carbohydrate. This comparison was within a single study, so the difference between the results of this study and what would have been expected due to Method 1 or 2 cannot be attributed to any differences in baseline risk between studies. Moreover, although participants in large prospective studies have different baseline risks of CHD, the increased risk associated with known risk factors is often reasonably consistent across many of the studies. For example, the increased CHD risk associated with saturated fat for female nurses from 1980 to 1994 (Ref. 38) was quite similar to that for male employees of Western Electric Co. from 1958 to 1976 (Ref. 67) (64 FR 62746 at 62771). The changes in CHD risk associated with total cholesterol and HDL–C for male physicians from 1982 to 1987 was comparable to that for men and women from Framingham, MA in the 1970s (Ref. 131).

A meta-analysis of the relative risk of CHD associated with *trans* fat intake was recently published (Ref. 102). The meta-analysis used the results of prospective observational studies in four cohorts: Women in the United States, men in the United States, men in Finland, and men in the Netherlands. The results showed a pooled variance-weighted relative risk of 1.25 (95 percent confidence interval 1.11 to 1.40) for CHD associated with 2 percent of energy intake from *trans* fat. For 0.1 percent of energy intake from *trans* fat, the meta-analysis results would predict a relative risk of 1.0112 (confidence interval 1.0052 to 1.0170). That is, for 0.1 percent of energy intake from *trans* fat, the increase in CHD risk would be 1.12 percent (confidence interval 0.52 to 1.70 percent). In comparison, the largest change in CHD risk shown in table 9, associated with 0.1 percent of energy intake from *trans* fat, is 0.162 percent using Method 1 and 0.292 percent using Method 2. Thus, the increase in CHD risk for 0.1 percent of energy intake from *trans* fat based on a meta-analysis of prospective studies is larger than the associated CHD risk estimated using either Method 1, LDL-C or Method 2, LDL-C and HDL-C. (The calculation of relative risk at different levels of *trans* fat intake is based on taking the natural logarithm. For 2 percent of energy intake from *trans* fat, the estimated relative risk was 1.25. The coefficient in the logistic regression is the natural logarithm of 1.25 = 0.223; 0.223/2 = 0.1116, the coefficient for 1 percent of energy from *trans* fat; 0.1116 x 0.1 = 0.0112, the coefficient for 0.1 percent of energy from *trans* fat; the antilogarithm of 0.0112 = 1.0112, the relative risk associated with 0.1 percent of energy from *trans* fat.)

Thus, FDA disagrees with the comment about relative risk in the prospective studies, and maintains that the prospective studies do suggest that there may be additional mechanisms, besides changes in LDL–C and HDL–C, by which *trans* fat contributes to CHD risk. However, as discussed previously in this section, and in the November 1999 proposal (64 FR 62746 at 62771), FDA did not use the results of the prospective studies in its quantitative estimate of the health benefits of *trans* fat labeling. The sole use of the prospective studies was to suggest that there may be additional mechanisms by which *trans* fat contributes to CHD. The prospective studies thus indicate the direction of the uncertainty in the benefits estimate: That the actual benefits may be higher than the benefits estimated using Methods 1 and 2.

In response to the comments about the Ascherio et al. regression equation as discussed in the IOM/NAS report (Ref. 140), FDA notes that according to the NEJM, all submissions to the journal are peer-reviewed before publication. The comments did not cite any published articles questioning the 1999 Ascherio et al. paper (Ref. 83), and did

not submit data from the unpublished work that the comments asserted could provide an alternate explanation for the Ascherio et al. results. As noted in section IV of this document, the paper by Ascherio et al. is not the only information that the IOM/NAS used in concluding that *trans* fatty acid consumption should be as low as possible while consuming a nutritionally adequate diet (see comment 3). Additionally, the Ascherio paper is not the only information in the IOM/NAS report that supports a positive linear trend for *trans* fat intake and LDL–C and risk of CHD. For example, as mentioned previously in this section (see comment 39), the study of Lichtenstein et al. (Ref. 82), using six test diets at different levels of *trans* fat intake, found a positive linear trend for *trans* fat intake and LDL–C level. In discussing *trans* fat intake and HDL–C, the IOM/NAS report references work by Zock, Mensink, and Katan (Refs. 69 and 154). These papers pertain not only to HDL–C but also to LDL–C. The work of Zock and colleagues (Refs. 62, 69, and 154) gives one regression equation showing a positive linear trend between *trans* fat intake and LDL–C and another regression equation showing a negative linear trend between *trans* fat intake and HDL–C.

As noted in section IV and in this section of this document, FDA's primary rationale for *trans* fat labeling is the effect of *trans* fat intake on LDL–C. Additionally, the economic analysis uses changes in both HDL–C and LDL–C as a second method to quantify the effects of *trans* fat intake on CHD risk, with the noted qualification that the primary basis for the rule is the effect of *trans* fat on LDL–C. Therefore, as stated in the November 1999 proposal (64 FR 62746 at 62770), for purposes of economic analysis we used the equations of Zock et al. (Refs. 62 and 69) to estimate the effects of *trans* fat on LDL–C and HDL–C separately and did not use the equation of Ascherio et al. (Ref. 83), which estimates the positive linear trend between *trans* fat intake and the lipid ratio, LDL/HDL. FDA's Method 2, using the equations of Zock et al. (Refs. 62 and 69) for changes in both LDL–C and HDL–C, is different than the method of Ascherio et al. (Ref. 83), which uses changes in the lipid ratio, LDL/HDL. However, what FDA's Method 2 and Ascherio's method have in common is that they each provide a quantitative estimate of the adverse effects of *trans* fat on CHD risk using changes in both LDL–C and HDL–C.

As stated previously in this section (see comment 39), the regression equations of Zock et al. (Ref. 69), showing a positive linear trend between *trans* fat intake and LDL–C, are consistent with newer regression equations in a study published in 2001 by Muller et al. (Ref. 130). Thus, there is a body of research, including the work of Ascherio et al. (Ref. 83), Zock et al. (Refs. 62, 69 and 154), Lichtenstein et al. (Ref. 82) and Muller et al. (Ref. 130), that supports the existence of a linear trend for *trans* fat intake and LDL–C levels, consistent with the conclusions of the IOM/NAS (Ref. 140). As discussed in the IOM/NAS report, the existence of a linear trend of saturated fat and LDL–C is very well-established, as shown by three sets of regression equations described in the IOM/NAS report (Ref. 140, Figure 8–3, pp. 8–47 to 8–48). Thus, the existence of a positive linear trend for *trans* fat intake and LDL–C, as shown by a body of research (Refs. 62, 69, 82, 83, 130, and 154) and recognized by the IOM/NAS (Ref. 140) is not unusual, considering that there is also a positive linear trend between saturated fat intake and LDL–C. Therefore, FDA is not convinced by the comments questioning the existence of linear trends between *trans* fat and lipid levels. FDA finds that, for the purposes of economic analysis, it is appropriate to quantify the health benefits of *trans* fat labeling using regression equations (Refs. 62 and 69) describing a positive linear trend between *trans* fat intake and LDL–C and a negative linear trend between *trans* fat intake and HDL–C.

(Comment 42) One comment stated that FDA's estimate of benefits of the November 1999 proposal neglected to account for the overall reductions of mortality and morbidity from heart disease that have been occurring in the United States for the past few decades. According to the comment, FDA should have projected the future reduction in heart disease that would be expected in the absence of labeling. With such a projection, the baseline for heart disease morbidity and mortality would be progressively lower over time, and the numbers of heart attacks and deaths avoided due to *trans* fat labeling would be commensurately reduced compared with FDA's estimate. One comment stated that an overall decline in CHD from 1970 to 1990 coincided with a decline in intake of fat and saturated fat. The comment stated that margarine intake (per person) was constant during this period. Therefore, the comment concluded that substituting margarine for high saturated fat and cholesterol products had proved beneficial in decreasing CHD.

FDA agrees that the rate of heart disease mortality and morbidity in the United States has been decreasing for several decades (Refs. 132 and 133). For example, the age-adjusted death rate from CHD declined from approximately 290 per 100,000 in 1979 to 190 per 100,000 in 1996 (Ref. 133). However, because the risk of CHD is greater at older ages and the U.S. population is aging, the decline in the overall (crude) CHD death rate in this period was more modest, from approximately 225 per 100,000 to 180 per 100,000. Moreover, because of the increase in the total population, the decline in annual CHD deaths in this period was even more modest, from approximately 550,000 to 500,000, about a 10 percent decrease over 17 years. The number of deaths was fairly level during the period, 1992 through 1996. Thus, the baseline number of CHD deaths, as opposed to age-specific rates, has historically declined at a modest rate, and has been fairly level in recent years. Therefore, FDA did not correct for this in its projection of heart attacks and deaths avoided due to *trans* fat labeling. In response to the comment about correcting its estimate for overall reductions in heart disease over time, FDA acknowledges that, if the actual number of CHD deaths declines in the future, omitting this correction would result in a modest overestimate of the health benefits of *trans* fat labeling.

Regarding the comment about correlations of changes in dietary intake with declines in CHD from 1970 to 1992, information on *trans* fat intake is limited, as noted in section IV of this document. Therefore, although margarine intake was approximately constant, it is not known whether overall *trans* fat intake increased, decreased or remained the same during this period. Furthermore, the causes of the decrease in CHD over this time period have not been identified. Decreases in CHD risk factors, such as serum lipids, and decreases in saturated fat intake probably played a role, but the relative contributions of decreases in various risk factors and changes in medical care for heart attack patients are not adequately explained (Ref. 132). Therefore, FDA disagrees with the comment's conclusion that time trends in CHD incidence demonstrate a beneficial effect of margarine intake on incidence of CHD.

Based on the comments received and its own re-evaluation, FDA is not making any changes in the sample calculations for changes in CHD risk (table 8) or in the factors for changes in serum lipids and the examples of changes in CHD risk and the factors for changes in serum lipids with substitution of different macronutrients

(table 9), described earlier in this section. Earlier in this section, FDA has revised its estimate of projected decreases in *trans* fat intake due to labeling (table 2) and discussed the likely substitutions of different types of fat for *trans* fat. Using this information, FDA revised the expected changes in CHD risk due to *trans* fat labeling.

As shown in table 2, a 0.0378 percent of energy decrease in *trans* fat intake is expected to occur by the effective date of the rule. Approximately 3 years will be needed for predicted changes in *trans* fat intake to result in changes in CHD risk (Ref. 137). Table 10 shows the decreases in CHD risk that would be expected, 3 years after the effective date, for different examples of macronutrient substitutions for *trans* fat. The three specific substitutions shown in table 10 are those that FDA used to represent the range of likely ingredient substitutions for *trans* fat in margarine: (1) 100 percent cis-monounsaturated fat, (2) a mixture of 50 percent cis-monounsaturated and 50 percent cis-polyunsaturated fat, or (3) a mixture of 50 percent cis-monounsaturated and 50 percent saturated fat (Ref. 73). Table 10 shows that, using one of these three substitutions, the predicted decrease in CHD risk would range from 0.027 percent to 0.061 percent for Method 1 and from 0.090 percent to 0.110 percent for Method 2.

FDA has identified these likely substitutions, but recognizes that once reformulation begins, different combinations of ingredients may emerge. In order to estimate the health effects of reformulation, however, it is less important to identify the exact formulas to be used than it is to identify the range of possible changes in CHD risk. To estimate the potential health benefits from the reformulation of margarine, FDA used a probabilistic model with a distribution of effects based on the distribution of possible changes in CHD risk associated with the three ingredient substitutions. FDA used a distribution rather than a weighted average because we did not know which combination was most likely, or what distribution of combinations would emerge. (The formal distribution we used was a BetaPERT, which uses three points: A minimum, an intermediate, and a maximum. The model used the change in CHD risk for a mixture of 50 percent cis-monounsaturated and 50 percent saturated fat as the minimum, the change with 100 percent cis-monounsaturated fat as intermediate, and the change for a mixture of 50 percent cis-monounsaturated and 50 percent cis-polyunsaturated fat as the maximum. The mean of a BetaPERT distribution = (minimum + (4 x intermediate) + maximum)/6.)

As shown in table 10, the probabilistic model of substitutions for *trans* fat predicted a decrease in CHD risk of 0.052 percent using Method 1 and 0.106 percent using Method 2.

TABLE 10.—PREDICTED CHANGES IN CHD RISK DUE TO *TRANS* FAT LABELING ACCORDING TO MACRONUTRIENT SUBSTITUTION FOR *TRANS* FAT

Time after Effective Date for Final Rule[1]	Decrease in *Trans* Fat Intake (% of Energy)	Source of Decrease	Substitution for *Trans* Fat	Percent Decrease in CHD Risk		
				Method 1, LDL	HDL	Method 2, LDL and HDL
3 years	0.0378	Consumer choice and margarine reformulation	mono	-0.056%	-0.053%	-0.108%
			mono+ poly	-0.061%	-0.049%	-0.110%
			mono+ sat	-0.027%	-0.062%	-0.090%
			Substitution from probabilistic model.	-0.052%	-0.054%	-0.106%

[1] The time after the effective date for the final rule includes 3 years for decreases in *trans* fat intake to result in changes in CHD risk.

Approximately 3 years will be needed for predicted changes in *trans* fat intake to result in changes in CHD risk (Ref. 137). Table 10 shows that the 0.0378 percent of energy decrease in *trans* fat intake expected to occur by the effective date of the rule will result, 3 years after the effective date, in a 0.052 percent decrease in CHD risk using Method 1 and a 0.106 percent decrease in CHD risk using Method 2. FDA estimated these decreases in risk using a mathematical model that accounted for the three likely substitutions for *trans* fat in reformulation of margarine and direct consumer choice, discussed previously. Table 10 shows the predicted decrease in CHD risk for each of the substitutions separately, and the overall estimate from the mathematical model.

3. Value of Changes in Health

In the previous sections, FDA presented potential changes in food markets because of this final rule and described calculations of the decreases in CHD that would result from those market changes. Uncertainties in these analyses include:

- The size of consumer substitutions among existing products;
- The amount of producer reformulation to avoid losing market shares;
- The types of ingredient substitutions producers will make to reduce the amount of *trans* fat in their products; and,
- The decrease in CHD that will result from decreased *trans* fat in the diet.

FDA used three specific substitutions to represent the range of likely ingredient substitutions for *trans* fat in margarine: (1) 100 percent *cis*-monounsaturated fat, (2) a mixture of 50 percent *cis*-monounsaturated and 50 percent *cis*-polyunsaturated fat, or (3) a mixture of 50 percent *cis*-monounsaturated and 50 percent saturated fat (Ref. 73).

FDA estimated the benefits from the final rule for two methods. The two methods give low and high estimates of the change in CHD risk brought about by changing intakes of *trans* fat. Method 1 assumes that the reduction in CHD risk associated with reduced *trans* fat intakes comes about only through the reduction in LDL–C. Method 2 assumes that the reduction in CHD risk comes about through a combination of reducing LDL–C and increasing HDL–C.

Method 2 results in higher benefit estimates than Method 1.

The reduction in CHD risk is highly uncertain primarily because of the difficulties in estimating the amount of reformulation, consumer response, and the reduction in CHD risk due to a decrease in *trans* intake. Also, these changes will occur over time and can be affected by other, unanticipated events. FDA dealt with the uncertainty by estimating a range of possible reductions in CHD risk associated with the final rule. The low and high estimated benefits can be interpreted as a range of potential effects. When we lacked direct evidence on uncertain values, we dealt with the uncertainty by choosing values that generated lower-bound estimates of benefits. This practice and the evidence in the previous section both imply that the actual realized benefits may exceed the range given by the two methods.

a. *CHD morbidity and mortality prevented*. FDA calculated the benefits from the final rule as the reduction (from the baseline) in CHD multiplied by the value of preventing both fatal and nonfatal cases of CHD. FDA assumed that the cases of CHD prevented by this rule will have the same proportions of fatal and nonfatal cases as currently exist in the population. The AHA estimates that 1.1 million heart attack cases of CHD occur annually, with 40 percent of them fatal (Ref. 134). The average years of life lost per fatal case is 13, or 8 years discounted to the present at 7 percent or 11 years discounted to the present at 3 percent. FDA used these estimates as the baseline for the estimated benefits. The number of cases varies from year to year, so FDA treated the annual number of cases as a distribution with a mean equal to 1.1 million (and a standard deviation of 110,000). FDA applied the estimated decline in the probability of CHD to the baseline to get estimates of the number of cases and fatalities prevented by the final rule. FDA used these estimates in the analysis for the proposed rule, and comments on this are discussed in the previous section on changes in health states. FDA estimated the effects using Method 1, which considers changes only in LDL–C, and using Method 2, which considers changes in both LDL–C and HDL–C.

The benefits are expected to begin 3 years after the effective date. The 3-year lag occurs because a dietary change takes several years to begin to affect the CHD risk (Ref. 137). With Method 1, FDA estimated that 3 years after the effective date, the final rule would annually prevent 600 cases of CHD and 240 deaths. Preventing 240 deaths would annually save about 1,920 discounted life years (240 deaths x 8 years) using a 7 percent discount rate, or 2,640 discounted life years (240 deaths x 11 years) using a 3 percent discount rate. With Method 2, FDA estimated that 3 years after the effective date, the final rule would annually prevent 1,200 cases of CHD and 480 deaths, saving about 3,840 discounted life years (480 deaths x 8 years) using a 7 percent discount rate, or 5,280 discounted life years (480 deaths x 11 years) using a 3 percent discount rate. Because the association between *trans* fat consumption and CHD through changes in LDL–C is more conclusive, the benefits estimated using Method 1 should be regarded as more certain than the benefits estimated using Method 2.

For nonfatal cases, FDA estimated the cost to be the sum of the medical costs, the cost of functional disability, and the cost of pain and suffering. The functional disability, and pain and suffering combine to reduce the quality of life for victims. In a recent study, Cutler and Richardson (Ref. 77) estimated from National Center for Health Statistics data that the quality adjusted life year for a CHD survivor was 0.71, which indicates that the annual loss to the victim is 0.29 quality adjusted years. This loss represents the combined effects of functional disability and pain and suffering. FDA assumed that the loss lasts for 13 years, or 8.4 discounted years. FDA did not estimate the extent to which nonfatal cases reduce life expectancy or increase other health costs. Because nonfatal cases probably do have these effects, FDA may have underestimated the health benefits from preventing nonfatal cases.

The medical costs for nonfatal CHD are also important. The American Heart Association estimates that the cost of a new event is about $22,700 and the total annual costs are $51.1 billion (Ref. 75). If 1.1 million cases lead to $22,700 per case, then all theses cases cost about $25 billion. The remaining 13.9 million cases average about $1,900 per year (($51.1 billion - $25 billion) /13.9 million). FDA, therefore, estimated medical costs per case as $22,700 in the first year and about $1,900 per year thereafter.

The total cost per nonfatal case is the sum of lost quality-adjusted life years multiplied by $100,000 per life year plus the medical costs of $22,700 plus $1,900 per year times the discounted life years. FDA estimated the morbidity cost per case to be about $282,000 ((0.29 x $100,000 x 8.4) + ($1,900 x 8.4) + $22,700).

b. *Value of CHD morbidity and mortality prevented*. In a May 30, 2003 Memorandum to the President's Management Council, OIRA Administrator John D. Graham recommended that agencies, when performing benefit cost-analysis, present results using both VSL and VSLY methods. Below we present estimates using both methods. The Memorandum also recommends that agencies present analyses with larger VSLY estimates for senior citizens. Since many of the beneficiaries of this final rule are senior citizens, larger VSLY values than the ones we have used will increase benefits further.

FDA therefore estimates the benefits of this rule using two approaches that reflect different methods used in the economics literature. First, it calculates benefits as the extensions to longevity multiplied by the value of such increases in life-years gained, plus the number of nonfatal cases prevented multiplied by the costs of nonfatal cases, plus the savings in medical costs associated with reductions in nonfatal CHD. Its second calculation is like the first, except that it values reductions in mortality risk as the number of statistical deaths prevented multiplied by the willingness to pay to reduce the risk of death (rather than the extensions to longevity multiplied by the value of increases in life-years gained), and calculates the value of reducing the number of nonfatal cases as simply the savings in medical costs. This section presents these two approaches in turn, beginning with benefits as the extensions to longevity multiplied by the value of such increases in life-years gained, plus the prevented costs of nonfatal cases and medical costs.

Under the first approach, FDA estimated the costs of nonfatal cases to be the sum of the medical costs, the cost of functional disability, and the cost of pain and suffering. The functional disability, and pain and suffering combine to reduce the quality of life for victims. In a recent study, Cutler and Richardson (Ref. 77) estimated from National Center for Health Statistics data that the quality adjusted life year for a CHD survivor was 0.71, which indicates that the annual loss to the victim is 0.29 quality adjusted years. This loss represents the combined effects of functional disability and pain and suffering. FDA assumed that the loss lasts for 13 years, or 8.4 discounted years (discounted at 7 percent) and 10.6 discounted years (discounted at 3 percent). FDA did not estimate the extent to which nonfatal cases reduce life expectancy or increase other health costs. Because nonfatal cases probably do have these effects, FDA may have

underestimated the health benefits from preventing nonfatal cases.

There are also medical costs for nonfatal cases of CHD. The American Heart Association estimates that the cost of a new CHD case is about $22,700 and the total annual costs are $51.1 billion (Ref. 75). If 1.1 million cases lead to $22,700 per case, then all these cases cost about $25 billion. The remaining 13.9 million cases average about $1,900 per year (($51.1 billion - $25 billion) /13.9 million). FDA, therefore, estimated medical costs per case as $22,700 in the first year and about $1,900 per year thereafter.

Under the first approach, the total cost per nonfatal case is the sum of lost quality-adjusted life years multiplied by a value per life year plus the medical costs of $22,700 plus $1,900 per year times the discounted life years. FDA estimates the morbidity cost per case to be about $282,000 ((0.29 x $100,000 x 8.4) + ($1,900 x 8.4) + $22,700), assuming a value of $100,000 per quality-adjusted life year (VSLY).

In the first approach, FDA uses a range to estimate the value of an additional year of life to reflect the uncertainty in the literature. As a lower bound, FDA uses $100,000 per (quality-adjusted) statistical life year. Cutler and Richardson (Ref. 77) use a similar estimate, and Garber and Phelps (Ref. 157) conclude that estimates of the value of a life year are about twice the level of income, though they present a broad range to reflect uncertainty associated with risk aversion and discount rates. Updating Garber and Phelps' estimates suggests that $100,000 per life year is a reasonable estimate, given that median family income in 2002 was about $51,000 (Ref. 158). Moreover, this estimate is close to the estimate used in FDA's economic analysis of the regulations implementing the 1990 amendments. FDA received no public comments on that estimate. To reflect other underlying literature, and following suggestions from other Federal agencies, we begin with an estimate of the value of a statistical life (VSL) of $6.5 million. This estimate is consistent with the survey by Viscusi and Aldy (Ref. 159) on the premium for risk observed in labor markets. Annuitizing this value over 35 years at 3 percent and at 7 percent discount rates, as is consistent with OMB guidance, implies estimates of a value of an additional year of life of about $300,000 and $500,000. Therefore, table 11a shows estimated benefits for three estimates of VSLYs: $100,000, $300,000 and $500,000, for both of the methods of estimating gains in life years. Total benefits differ from mortality-related benefits by including the value of reduced morbidity and health care costs.

TABLE 11A.—BENEFITS FOR DIFFERENT VALUES OF STATISTICAL LIFE YEARS

Value of Statistical Life Years Gained	Discount Rate	Number of Discounted Life Years Gained		Mortality Related Benefits Estimated In Year 3 After the Effective Date and Annually Thereafter (in millions)		Total Benefits (in millions)	
		Method 1	Method 2	Method 1	Method 2	Method 1	Method 2
$100,000	7 percent	1,920	3,840	$192	$384	$234	$477
$300,000	3 percent	2,640	5,280	$792	$1,584	$968	$1,973
$500,000	7 percent	1,920	3,840	$960	$1,920	$1,127	$2,295

In applying the second approach to calculating benefits, FDA assumes values of a statistical life of $5 million and $6.5 million. These values represent reasonable central tendencies for a larger range of VSL estimates reported in the literature: $1 million to $10 million (Ref. 159). The two values FDA uses here are also consistent with one reasonable interpretation of studies of willingness to pay to reduce mortality risks (Refs. 159 and 160). FDA uses the lower value to reflect the fact that many of the estimates of willingness to pay to reduce mortality risk from papers not surveyed by Viscusi and Aldy are relatively low. Table 11B shows the annual benefits estimated in this way for the two different VSLs using both a 3 and 7 percent discount rate. The totals in the final 2 columns of the table are discounted, so direct multiplication of the previous columns does not give the totals in the final columns.

TABLE 11B.—BENEFITS FOR DIFFERENT VALUES OF STATISTICAL LIFE AND DISCOUNT RATES

VSL and Discount Rate	Expected Deaths Averted		Average Medical Costs per Nonfatal Case	Expected Nonfatal Cases Averted		Total Benefits Estimated in Year 3 After the Effective Date and Annually Thereafter (in millions)	
	Method 1	Method 2		Method 1	Method 2	Method 1	Method 2
$5,000,000 (3%)	240	480	$43,000	360	720	$1,112	$2,225
$6,500,000 (3%)			$43,000			$1,442	$2,884
$5,000,000 (7%)			$39,000			$991	$1,982
$6,500,000 (7%)			$39,000			$1,285	$2,570

F. Overview of Benefits and Costs

To provide an overview of this analysis, we can compare the estimated total benefits and costs and summarize the sources of information used in making these estimates.

1. Summary of Benefits and Costs

Table 12 shows the timing of the discounted benefits and costs estimated for this rule, as well as the totals. The

benefits reported in table 12 are based on a VSLY of $300,000 and a discount rate of 3 percent. The effectiveness of this final rule can also be seen in the relatively low cost per life year saved. For example, if we express the one time costs as annualized cost over 20 years (discounted at 3 percent), the medium cost estimate in table 12 comes to about $12 million per year. With Method 1, the cost per life year saved would be about $4,500 ($12 million/2,600 life years). These ratios would be even lower if we included the quality-adjusted life years associated with nonfatal cases. The deaths prevented alone demonstrate the effectiveness of this final rule.

TABLE 12.—SUMMARY OF COSTS AND BENEFITS BY YEAR AFTER PUBLICATION, DISCOUNTED TO EFFECTIVE DATE, IN MILLIONS OF DOLLARS

		Effective Date							
	Years After Publication	2	3	4	5	6	7		Cummulative Total as of Year 20
Costs									
Low		$139	none	none	none	none	none	...	$139
Medium		$185	none	none	none	none	none	...	$185
High		$275	none	none	none	none	none	...	$275
Benefits									
Method 1	Annual	none	none	none	$968	$940	$913	...	
	Cumulative				$968	$1,908	$2,821	...	$13,130
Method 2	Annual	none	none	none	$1,973	$1,916	$1,860	...	
	Cumulative				$1,973	$3,889	$5,784	...	$26,757

2. Summary of Information Sources

Table 12A summarizes the inputs, data sources, and assumptions used in the Final Regulatory Impact Analysis for this final rule.

TABLE 12A.—SUMMARY OF INPUTS, DATA SOURCES, AND ASSUMPTIONS

Name of Input	Value or Distribution Used	Type of Estimate	Source of Data or Assumption
Current trans fat intake.	Total intake, 2.55% of energy; intake from hydrogenated fat, 2.03% of energy (table 1 of this document).	FDA's best estimate from available data.	USDA trans fat food composition database, (Ref. 40); USDA food group data from CSFII. 1994-96, (Ref. 115).
Adjustment of trans fat intake for current level of margarine reformulation.	0.063% of energy, decrease in current amount of trans fat intake from margarine (table 2 of this document).	FDA's best estimate from available data.	15% decrease in current amount of trans fat intake from margarine based on industry comments on proposed rule.
Change in trans fat intake due to margarine reformulation.	0.0359% of energy decrease (table 2 of this document).	Low assumption based on uncertainty.	Assume 10% decrease in remaining trans fat from margarine.
Change in trans fat intake due to consumer choice.	0.0019% of energy decrease (table 2 of this document).	Low assumption based on uncertainty.	Assume 0.1% decrease in remaining trans fat intake from hydrogenated fat after margarine reformulation.
Overall change in trans fat intake due to labeling.	0.0378% of energy decrease (tables 2 and 10 of this document).	Low assumption based on uncertainty. Excludes possible reformulation of products other than margarine.	Sum of two previous values.
Number of products to be tested.	154,000 (table 3 of this document).	High estimate based on uncertainty. Includes many products that have already been tested.	Main data sources: RTI labeling cost model (Ref. 129) for number of products likely to be affected and our judgement about what categories of products are likely to be affected.
Per product cost of testing.	$261 to $371 (table 4 of this document).	Data.	RTI labeling cost model, Ref. 129.

TABLE 12A.—SUMMARY OF INPUTS, DATA SOURCES, AND ASSUMPTIONS—Continued

Name of Input	Value or Distribution Used	Type of Estimate	Source of Data or Assumption
Percent of SKU label changes that can be coordinated with scheduled labeling changes.	84% of branded SKUs, 50% of private label SKUs.	FDA interpolation of information on 24 and 36 month compliance period proportions.	RTI labeling cost model, Ref. 129.
Per product category cost of relabeling.	Varies (table 5 of this document).	Data.	RTI labeling cost model, Ref. 129.
Number of margarines reformulated.	30 (table 6 of this document).	Low assumption based on uncertainty.	Assume 10% of margarine products reformulate.
Per product cost of reformulation.	$440,000 (table 6 of this document).	Data.	Industry supplied information (64 FR 62745 at 62782, November 17, 1999).
Overall change in CHD risk per change in trans fat intake.	0.147% decrease in CHD risk per 0.1% of energy decrease in trans fat intake. Method 1 (table 8 of this document).	Low estimate, assuming change in CHD risk is entirely through effect of trans fat on LDL-C.	Multiply change in trans fat intake by factors below: -0.1% x 1.5 x 0.7 x 1.4 = -0.147%, decrease in CHD risk.
Overall change in CHD risk per change in trans fat intake.	0.287% decrease in CHD risk per 0.1% of energy decrease in trans fat intake. Method 2 (table 8 of this document).	Intermediate estimate, assuming change in CHD risk is through effect of trans fat on both LDL-C and HDL-C. Excludes other possible mechanisms linking trans fat to CHD risk.	Multiply change in trans fat intake by factors below: -0.1% x -0.4 x -2.5 x 1.4 = -0.140%, decrease in CHD risk due to change in HDL-C. Add to result from Method 1: -0.147% + (-0.140%) = -0.287%, decrease in CHD risk, Method 2.
Change in LDL-C with change in trans fat intake.	1.5 mg/dL per 1% of energy from trans fat substituted for cis-monounsaturated fat (table 8 of this document).	Data.	Published meta-analyses, Refs. 62 and 69.
Change in HDL-C with change in trans fat intake.	-0.4 mg/dL per 1% of energy from trans fat substituted for cis-monounsaturated fat (table 8 of this document).	Data.	Published meta-analyses, Refs. 62 and 69.
Changes in LDL-C and HDL-C with substitutions of other macronutrients for trans fat.	Various coefficients shown in table 9 of this document.	FDA's best estimate from available data.	Published meta-analyses, Ref. 65, combined with meta-analyses in Refs. 62 and 69.
Changes in CHD risk with changes in LDL-C.	0.7% increase per 1 mg/dL increase in LDL-C (table 8 of this document).	Data.	Published meta-analyses, Refs. 59, 60, and 61.
Changes in CHD risk with changes in HDL-C.	2.5% increase per 1 mg/dL decrease in HDL-C (table 8 of this document).	Data.	Published meta-analyses, Refs. 59, 60, and 61.
Adjustment for regression dilution.	Factor of 1.4 increase in relationship of change in CHD risk with changes in LDL-C and HDL-C (table 8 of this document).	Data.	Published data, Ref. 64.
Overall change in CHD risk due to labeling.	-0.052%, Method 1;-0.106%, Method 2 (table 10 of this document).	Factors above combined with probabilistic model to account for macronutrient substitutions.	BetaPERT distribution, using the change in CHD risk for a mixture of 50% cis-monounsaturated and 50% saturated fat as the minimum, the change with 100% cis-monounsaturated fat as intermediate, and the change for a mixture of 50% cis-monounsaturated and 50% cis-polyunsaturated fat as the maximum. The mean of a BetaPERT distribution = (minimum + (4 x intermediate) + maximum)/6.

TABLE 12A.—SUMMARY OF INPUTS, DATA SOURCES, AND ASSUMPTIONS—Continued

Name of Input	Value or Distribution Used	Type of Estimate	Source of Data or Assumption
Time lag between effective date of labeling and first health benefits.	3 years (table 10 of this document).	Data.	3 years for serum lipid changes from dietary change. Ref. 137.
Heart attacks per year.	Mean 1.1 million cases, std. dev. 110,000 cases.	Data for mean. Assumption for std. dev.	Published data, Ref. 134.
Percent of heart attacks per year that are fatal.	40%.	Data.	Published data, Ref. 134.
Life-years saved.	13, or 8.4 years discounted to the present at 7% (table 10 of this document).	FDA's best estimate from available data.	Published data, Refs. 75, 76, and 134.
Life-years saved.	13, or 10.6 years discounted to the present at 3% (table 10 of this document).	FDA's best estimate from available data.	Published data, Refs. 75, 76, and 134.
Medical Costs saved per non-fatal case.	$39,000 at 7% discount rate; $43,000 at 3% discount rate (table 11 of this document).	FDA's best estimate from data and life expectancy calculations.	Published data, Ref. 134.
Value of Statistical Life Year (VSLY).	$100,000; $300,000; $500,000 (table 11 of this document).	Data and FDA's best estimate from available data.	$100,000 from Refs. 77 and 68; $300,000 from $6.5 million for value of statistical life discounting 35 remaining years at 3%; $500,000 from $6.5 million for value of statistical life discounting 35 remaining years at 7% (Ref. 159).
Value of Statistical Life (VSL).	$5 million; $6,5 million (table 11 of this document).	Data.	General VSL literature (Ref. 159).

G. Peer Review

FDA submitted this economic analysis to the Interagency Economic Peer Review (IEPR) for peer review. The IEPR is a voluntary review process composed of, but not limited to, Federal economists and analysts who review Regulatory Impact Analyses and Regulatory Flexibility Analyses prior to OMB clearance to improve the quality of economic analysis.

Two Federal economists reviewed this analysis. Their specific comments and FDA's responses are detailed in Ref. 155. FDA made the following changes to the analysis in response to the comments of the reviewers:

- Added several sections to repeat information contained in the analysis that accompanied the proposal to provide more background and context for the reader,
- Made some style changes for clarity,
- Added explanations for how some numbers were calculated,
- Added references for the European market experience with margarine reformulation,
- Addressed the comments on costs more explicitly,
- Explained why the costs of reformulation are included in the analysis,
- Added an introduction describing the plan of the benefits model and the linkages between the various parts of the model,
- Corrected our description of study subjects in the 1994–1996 Diet and Health Knowledge Survey (DHKS) in discussing Ref. 119.

X. Final Regulatory Flexibility Analysis

A. Introduction

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

B. Economic Effects on Small Entities

1. Number and Type of Small Entities Affected

FDA used data from the 1999 County Business Patterns (Ref. 136) to estimate the number of small businesses affected by this rule. Table 13 shows the number of small businesses affected by the North American Industry Classification System (NAICS). The final rule will affect almost all manufacturers of packaged, labeled food sold in the United States, with the exception of exempt manufacturers. The criteria for exemption are: (1) Annual sales of fewer than 100,000 units; (2) no claims or other nutrition information on product labels, labeling, or advertising; (3) fewer than 100 full-time employees; and (4) filing of a notice with the Office of Food Labeling (§ 101.9(j)(18) 2002). FDA has previously estimated that the exemption for all foods would affect about 1.8 percent of FDA regulated foods by volume (see 58 FR 2927 at 2928, January 6, 1993). FDA estimated the effects of exemptions only for the total costs to small businesses.

TABLE 13.—NUMBER OF SMALL ESTABLISHMENTS BY NAICS CODE

Category Description	NAICS Code	No. of Establishments
Rice	311212	60
Refined or Blended Fats and Oils	311225	140
Breakfast Cereals and Related Products	311230	60
Chocolate and Confectionery Products Made from Cacao Beans	311320	150
Nonchocolate Confectionery Products	311340	590
Frozen Fruits and Vegetables	311411	230
Frozen Specialties, NEC	311412	380
Specialty Canned Food	311422	140
Dried and Dehydrated Foods	311423	180
Fluid Milk	311511	570
Creamery Butter	311512	30
Cheese	311513	520
Dry, Condensed and Evaporated Milk	311514	210
Ice Cream and Frozen Desserts	311520	420
Fresh and Frozen Seafood	311712	660
Commercial Bakery Products	311812	2760
Frozen Bakery Products	311813	230
Cookies and Crackers	311821	390
Flour Mixes and Dough Made from Purchased Powder	311822	230
Other Snack Foods	311919	400
Mayonnaise, Dressings and Other Prepared Sauces	311941	340
Spices and Extracts	311942	280
Perishable Prepared Food	311991	480
All Other Miscellaneous Food Preparations	311999	850
Pharmaceutical Preparations (NAICS classification for dietary supplements	325412	880
Total		11,180

2. Costs to Small Entities

FDA calculated the costs to small businesses with the same basic model that we used in section IX.D of this document to estimate the total costs. Although the basic model is the same for large and small firms, the individual components of costs differ for large and small firms. On average, small firms produce fewer products, and market fewer labels. FDA assumes that the estimated margarine reformulation will be done by large producers.

FDA estimated the total costs of the final rule to small business by estimating the individual categories of costs and summing them. The first category is testing costs. Small businesses would need to test their products to determine the amounts of *trans* fats. FDA did not have direct estimates of the number of products produced by the small businesses affected by the final rule. FDA estimated the number of products produced by small businesses by using a sample from the Enhanced Establishment Database (EED) and assuming that the proportion of all products produced by small businesses was the same as the sample proportion (85 percent). FDA then multiplied the 60,000 products estimated to be tested (table 3 of this document) by the proportion of products produced by small businesses (85 percent) to estimate that 51,000 products will be tested by small businesses. Table 14 shows the range of testing costs for all small businesses.

TABLE 14.—RANGE OF PER PRODUCT AND TOTAL TESTING COSTS FOR SMALL BUSINESSES

	Low	Medium	High
Cost per Product	$261	$291	$371
Total Testing Cost	$13,311,000	$14,841,000	$18,921,000

Under this final rule many more labels will have to be changed than under the proposed rule. FDA has used the new Labeling Cost Model to re-estimate the relabeling costs of this final rule. FDA estimated reprinting costs for information panels on a per label (SKU) basis. FDA assumed that the proportion of SKUs from small businesses as a whole equaled the proportion in the EED (73 percent). Across product categories the average low relabeling cost per SKU is about $1,100 and the average high relabeling cost per SKU is $2,600. The reported estimated costs of changing labels varies within a product category because different packaging converters and food manufacturers reported different costs to RTI International. Table 15 shows the total estimated costs of relabeling per product category and for all small businesses affected.

TABLE 15.—RANGE OF RELABELING COSTS FOR SMALL BUSINESSES BY PRODUCT CATEGORY

Product Categories	SKUs Changed	Low	Medium	High
Baked Goods	9,100	$7,987,000	$11,870,000	$19,879,000
Baking Ingredients	1,200	$1,179,000	$1,737,000	$2,846,000
Baby Foods	100	$120,000	$182,000	$295,000
Selected Beverages	6,600	$8,666,000	$12,161,000	$18,569,000
Breakfast Foods	700	$585,000	$903,000	$1,492,000
Selected Candy	3,000	$3,505,000	$5,091,000	$7,819,000
Selected Condiments, Dips and Spreads	2,700	$2,939,000	$4,358,000	$6,777,000
Dairy Foods	6,400	$7,843,000	$11,698,000	$18,273,000
Desserts	2,600	$2,016,000	$3,112,000	$5,141,000
Dietary Supplements	5,900	$9,818,000	$14,680,000	$24,850,000
Selected Dressings and Sauces	2,000	$2,123,000	$3,177,000	$4,933,000
Eggs	1,800	$1,448,000	$2,114,000	$3,713,000
Entrees	1,800	$1,469,000	$2,247,000	$3,673,000
Fats and Oils	600	$554,000	$847,000	$1,349,000
Fruits and Vegetables	5,500	$5,421,000	$7,968,000	$13,054,000
Seafood	1,000	$1,264,000	$1,855,000	$2,764,000
Side Dishes and Starches	3,000	$2,454,000	$3,741,000	$6,201,000
Snack Foods	2,600	$2,631,000	$3,860,000	$6,204,000
Soups	500	$591,000	$872,000	$1,353,000
Weight Control Foods	100	$143,000	$207,000	$357,000
Total	57,200	$62,754,000	$92,590,000	$149,640,000

Table 16 of this document shows the total costs to small businesses of the final rule. The adjusted total costs of the final rule equal the unadjusted total minus 1.8 percent of the total cost of the rule to all businesses (see 58 FR 2927 at 2928, January 6, 1993). The average cost per small business is about $12,000.

TABLE 16.—TOTAL COSTS FOR SMALL BUSINESSES

Cost Category	Low	Medium	High
Testing	$34,713,000	$38,703,000	$49,343,000
Relabeling	$62,754,000	$92,590,000	$137,891,000
Total	$97,467,000	$131,293,000	$187,234,000
Adjustment for Exemption	-$1,754,000	-$ 2,363,000	-$3,370,000
Adjusted Total	$96,000,000	$129,000,000	$195,000,000

FDA has attempted to place the burden that these costs will place on small businesses in the context of the entire environment in which small businesses exist. Eastern Research Group under contract with FDA has developed a model for estimating the impact of regulatory costs on the survival of small businesses. (Reference: Eastern Research Group, ''Model for Estimating the Impacts of Regulatory Costs on the Survival of Small Businesses and Its Applications to Four FDA-Regulated Industries,'' 2002.) This model does not cover the entire range of products covered by this final rule, so it is not possible to estimate the burden of this rule. However, table 16a gives a sense of the impact that this rule may have on three industry categories that have many small businesses. The model estimates the additional number of small businesses that will have negative cash flow as a result of the costs of complying with a regulation. These estimates are likely to be larger than the actual effects because the model is neither able to take into account the exemption from nutrition labeling that is available to some small businesses, nor can it take into account the compliance period of over 2 years which allows small businesses to budget and plan ahead for the expense of the label change.

TABLE 16A.—ILLUSTRATIONS OF IMPACTS ON SMALL BUSINESS

Product Category	NAICS Code	Total Number of Small Businesses	Average Number SKUs Changed Early per Firm	Range of Costs per Firm	Standard Number of Small Businesses Lost Regardless of Regulation	Additional Small Businesses Lost Due to Compliance Costs of This Rule
Nonchocolate Confectionery Products	311340	590	6	$8,700–$18,100	30–80	0–30
Cheese	311513	520	6	$7,500–$16,300	40–90	0–20
Commercial Bakery Products	311812	2,760	4	$4,200–$9,800	560	10–60

C. Regulatory Options

The Regulatory Flexibility Act requires that FDA consider options for regulatory relief for small entities.

1. Exemption for Small Businesses

The exemption of small businesses from the provisions of the final rule would provide regulatory relief. Table 16 of this document shows that small businesses are expected to bear total costs of about $130 million as a result of the final rule, an average of $12,000 per small business. As a first approximation, then, exempting small businesses would reduce the burden by an average of $12,000 per small business.

FDA believes that this option would not be desirable. On the one hand, because so many of the businesses in the food processing industry are classified as small by the Small Business Administration, if small businesses are exempted, most of the potential benefits from the final rule would not be realized. On the other hand, exempt businesses may be forced by market pressures to adopt the final label in any case. In addition, under section 403(q)(5)(E) of the act and implementing regulations, very small producers (those with fewer than 100 full-time employees) that: (1) File a notice with the Office of Nutritional Products, Labeling, and Dietary Supplements; (2) make very low volume products (fewer than 100,000 units annually); and (3) place no claims or other nutrition information on product labels, labeling, or advertising would already be exempt from this final rule.

2. Longer Compliance Period for Small Businesses

Longer compliance periods provide regulatory relief for small businesses. Some comments requested that the compliance period be extended several years (e.g., 4 to 7 years) for small businesses. These comments stated that it was important for small businesses to be able to phase in the cost associated with the new label requirements so that they have extra time to absorb the costs of these changes. Some small manufacturers reported that they have significant inventories of labels. Also, smaller manufacturers indicated that they would incur costs, including, loss and disposal of obsolete packaging inventories, product in obsolete packages, and new printing plates. These small businesses believe that a longer compliance period would allow them to more easily manage their inventories and phase in the *trans* fat labeling requirements along with other scheduled labeling revisions. This will help minimize unnecessary labeling costs and costs passed on to consumers.

To minimize the need for multiple labeling changes and to provide additional time for compliance by small businesses to allow them to use current label inventories and phase in label changes, the agency is setting the effective date at January 1, 2006, the

next uniform effective date following publication of this rule. This allows firms more than 2 years to implement this final rule providing some regulatory relief and economic savings for small businesses. This should be long enough for most small businesses to coordinate the label change for this rule with other label changes and reprinting. However, in this final rule, FDA has decided not to extend the compliance period for small businesses beyond what is given for all businesses. Because this final rule does not affect nutrient content or health claims, no small businesses will have to change the principal display panels or marketing of their products, which could be very costly.

With small businesses producing 85 percent of the products and 73 percent of the SKUs, extending the compliance period for small businesses to the uniform effective date after January 1, 2006, would leave most labels not listing *trans* fat for almost 5 years after publication. This could result in significant confusion for consumers looking for *trans* fat content on labels and would make the Nutrition Facts panel inconsistent across product categories. This inconsistency would be contrary to the intent of the 1990 amendments. It also would undermine the policy goal of providing consistent nutrition information to consumers. Also, extending the effective date for products containing *trans* fat would delay the benefits of this rule to the public health.

3. Exemptions for Small Entities

FDA has chosen not to exempt small entities because consumption of *trans* fat results in consequences to the consumer. Consumers may increase or decrease their risk of CHD based on the level of *trans* fat in their diets. Thus, the presence or absence of *trans* fat in a food product is a material fact under section 201(n) of the act.

Consumers must know the amount of *trans* fat in food products that they select as part of their total daily diet to choose products that would allow them to reduce their intake of *trans* fat, and thus, reduce the risk of CHD. Section IV of this document discusses the scientific evidence for why *trans* fat consumption places consumers at risk for CHD. Absent mandatory labeling, consumers would not be able to understand the relative contribution that foods make to their total daily intake of *trans* fat. First, because polyunsaturated and monounsaturated fats are not subject to mandatory labeling, simply including *trans* fat as part of the total fat contribution would not allow consumers to calculate the *trans* fat content by finding the difference between the sum total of all the mandatory fats listed on the label and the total fat content. Second, even if all component fats were required to be listed, it would not be realistic to expect consumers to do such calculations on each product to compare the relative *trans* fat contribution of each. Further, the fact that an individual food product may contain zero gram *trans* fat, and thus, not contain a level of *trans* fat that would contribute to CHD risk, does not prevent the absence of that fact on the label to no longer be considered a ''material fact'' for that food. In the context of mandatory labeling of nutrients in a nutrition facts panel, the relative contribution of various food products to the total day's consumption of a heart unhealthy fat is important for consumers ''to readily observe and comprehend the information and to understand the relative significance of that information in the context of the total daily diet'' (section 2(b)(1)(A) of Public Law 101–535).

Further, section 403(q)(2)(A) of the act provides that mandatory labeling would be appropriate when information about a nutrient would assist consumers to maintain healthy dietary practices. Information on the *trans* fat content of food would assist consumers in this way. Consumers need the information on *trans* fat content of all foods that they consume so that they can reduce their intake of *trans* fat. The fact that a food may have no *trans* fat or a small amount of *trans* fat is useful information to the consumer so that food choices can be made and the consumer can put that product, along with many other products consumed as part of the daily diet, into the context of the total daily diet to maintain healthy dietary practices. There is ample discussion in section IV of this document about the heart unhealthy effects of consuming *trans* fat and strong consensus among the scientific community for reducing *trans* fat intake.

Survey data show that consumers rely on the Nutrition Facts label as a guide to choosing foods that meet their dietary objectives. As consumers learn more about the dietary significance of *trans* fat and the dietary advice to limit its consumption, the Nutrition Facts panel is where label users will expect to find this information. If they cannot find information on *trans* fat content there or if it is only there when claims are made about fatty acids or cholesterol, they will be hampered in their ability to implement the most recent dietary guidance, and are likely to be misled about a food's basic characteristics.

Consumers need the *trans* fat information on products in order to determine how each product fits into their individual health goal for reducing *trans* fat intake in the context of their total daily diet. Thus, the agency is requiring *trans* fat labeling, regardless of whether claims are made or the levels of other fats are declared, to prevent products from being misleading under sections 403(a)(1) and 201(n) of the act. Therefore, as described in section III of this document, in this rulemaking FDA is relying on its authority under those sections as well as its authority under section 403(q)(2)(A) of the act to require that information on *trans* fat be included in nutrition labeling to assist consumers in maintaining healthy dietary practices. Not requiring such information on labels, whether or not voluntary nutrients are listed or claims are made about fatty acids or cholesterol, would be inconsistent with statutory directives for nutrition labeling in section 403(q) of the act.

Furthermore, the benefits of covering products made by small businesses exceed the costs that would be saved by exempting them. The medium estimated cost of covering small businesses is a one time cost of $129 million dollars (table 16). If we assume no benefits from small businesses reformulating, then the benefits associated only with changing labels on all food products is $48 million per year using Method 1 ($99 million using Method 2). If small businesses produce at least 22 percent of food consumed annually, then benefits of covering products made by small businesses will exceed the costs that would be saved by exempting them after 20 years discounted at 3 percent. Using Method 2 for calculating benefits, small businesses would only need to account for production of at least 11 percent of food consumed. Since the Small Business Administration definition of small business includes the vast majority of food firms, products, and SKUs, even the 22 percent amount is quite plausible.

D. Recordkeeping and Reporting Requirements

The Regulatory Flexibility Act requires FDA to include a description of the recordkeeping and reporting required for compliance with this final rule. This final rule does not require the preparation of a report or a record.

E. Summary

FDA finds that under the Regulatory Flexibility Act (5 U.S.C. 605(b)) this final rule will have a significant economic impact on a substantial number of small entities. Approximately

10,300 small businesses could be affected by the rule. The total burden on small entities is estimated to be between $96 and $184 million, or about $9,300 to $17,900 per entity.

XI. Unfunded Mandates

The Unfunded Mandates Reform Act of 1995 (Public Law 104–4) requires cost-benefit and other analyses for rules that would cost more than $100 million in 1 single year. The final rule qualifies as a significant rule under the statute. FDA has carried out the cost- benefit analysis in sections IX.C and IX.D of this document. The other requirements under the Unfunded Mandates Act of 1995 include assessing the rule's effects on the following:

1. Future costs;
2. Particular regions, communities, or industrial sectors;
3. National productivity and economic growth;
4. Full employment and job creation; and,
5. Exports.

A. Future Costs

Most of the costs of this rule will be incurred during the compliance period. Future costs beyond that period would likely be small, because the food industry would have adjusted to the new requirements by that time.

B. Particular Regions, Communities, or Industrial Sectors

The final rule applies to the food industry and would, therefore, affect that industry disproportionately. Any long run increase in the costs of food production would largely be passed on to the entire population of consumers.

C. National Productivity and Economic Growth

The final rule is not expected to substantially affect productivity or economic growth. It is possible that productivity and growth in certain sectors of the food industry could be slightly lower than otherwise because of the need to divert research and development resources to compliance activities. The diversion of resources to compliance activities would be temporary. Moreover, FDA anticipates that, because the health benefits are estimated to be significant, both productivity and economic growth would be higher than in the absence of the rule. In section IX.C.3 of this document, FDA estimated benefits from the reduction in functional disability associated with a reduction in nonfatal CHD. A reduction of functional disability would result in an increase in productivity. The increased health of the population and the reduction in direct and indirect health costs could increase both productivity and economic growth.

D. Full Employment and Job Creation

The human resources devoted to producing certain foods would be redirected by the final rule. The final rule could lead to some short-run unemployment as a result of the structural changes within the food industry, the rise of some product lines and decline of others. The growth of employment (job creation) could also be temporarily slower.

E. Exports

Because the final rule does not mandate any changes in products, current export products will not be required to change in any way. Food processors, however, do not necessarily distinguish between production for export and production for the domestic market. The effect of the final rule on U.S. food exports depends on how foreign consumers react to information about *trans* fats and to product formulations that contain lower amounts of partially hydrogenated oils. The new label and possible new formulations could either increase or decrease exports. Products in Germany and certain other European countries, for example, currently use partially hydrogenated oils to a lesser degree than in the United States, so the final rule could make U.S. exports of margarine more attractive to consumers in those countries than they have been. However, it could also make U.S. exports of unreformulated products that reveal the presence of *trans* fat less attractive to consumers in those countries than they have been.

XII. Environmental Impact

The agency has previously considered the environmental effects of this rule as announced in the proposed rule (64 FR 62746, November 17, 1999). No new information or comments have been received that would affect the agency's previous determination that there is no significant impact on the human environment and that an environmental impact statement is not required.

XIII. Paperwork Reduction Act

This final rule contains information collection provisions that are subject to review by 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 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: Food Labeling; *Trans* Fatty Acids in Nutrition Labeling, Nutrient Content Claims and Health Claims.

Description: Section 403(q)(1)(A) and (q)(1)(B) of the act requires that the label or labeling of a food bear nutrition information on the amount of nutrients present in the product. Under these provisions of the act and section 2(b) of the 1990 amendments, FDA has issued regulations in § 101.9(c)(2) that require that the Nutrition Facts panel disclose information on the amounts of fat and certain fatty acids in the food product. This final rule establishes § 101.9(c)(2)(ii) to require that the Nutrition Facts panel disclose information on the amount of *trans* fat in the food product. Similarly, under the provisions of section 403(q)(5)(F) of the act, FDA has issued regulations in § 101.36(b)(2) that specify the nutrition information that must be on the label or labeling of dietary supplements. This final rule establishes § 101.36(b)(2) (21 CFR 101.36(b)(2)) to specify that when nutrition information is declared on the label and in labeling, it must include the amount of *trans* fat.

The regulations set forth in this final rule require that *trans* fat be declared in the nutrition label of conventional foods and dietary supplements on a separate line immediately under the line for the declaration of saturated fat.

Description of Respondents: Persons and businesses, including small businesses.

FDA estimates the burden of this collection of information as follows:

TABLE 17.—ESTIMATED REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Responses per Respondent	Total No. of Responses	Hours per Response	Total Hours	Operating Costs (in thousands)
101.9(c)(2)(ii)	10,490	27	278,100	2	556,200	$155,200
101.36(b)(2)	910	32	29,500	2	59,000	$16,500
Totals					615,200	$171,700

[1] There are no capital costs and or maintenance costs associated with this collection of information.

The impact of these requirements concerning *trans* fatty acids would be largely a one-time burden created by the need for firms to revise food and dietary supplement labels. FDA used data from the 1999 County Business Patterns to estimate the number of respondents. The total number of responses is equal to the total number of SKUs being changed (table 3 of this document). Based upon its knowledge of food and dietary supplement labeling, FDA estimates that firms would require less than 2 hours per SKU (hours per response) to comply with the nutrition labeling requirements in this final rule. This 2 hour per SKU estimate is based on assumptions about the amount of time required per SKU to test a product for *trans* fat, to redesign the label as needed, and to order the change for the label. FDA received no comments objecting to this estimate.

Multiplying the total number of responses by the hours per response gives the total hours. FDA has estimated operating costs by combining the medium testing and relabeling costs from table 7 of this document ($44.9 million + $126.8 million for relabeling) to get the total operating cost. This total was then apportioned between §§ 101.9 and 101.36 according to the proportion of responses for each section. Based on the labeling cost model, FDA expects that, with a compliance period of over 2 years, 75 percent of firms will coordinate labeling revisions required by this final rule with other planned labeling changes for their products.

The information collection provisions of this final rule have been submitted to OMB for review. Prior to the effective date of this final rule, FDA will publish a document in the **Federal Register** announcing OMB's decision to approve, modify, or disapprove the information collection provisions in this final rule. 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.

XIV. Federalism

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule has a preemptive effect on State law. Section 4(a) of the Executive order requires agencies to ''construe * * * a Federal Statute to preempt State law only where the statute contains an express preemption provision, or there is some other clear evidence that the Congress intended preemption of State law, or where the exercise of State authority conflicts with the exercise of Federal authority under the Federal statute.'' Section 403A of the act (21 U.S.C. 343–1) is an express preemption provision. That section provides that ''no State or political subdivision of a State may directly or indirectly establish under any authority or continue in effect as to any food in interstate commerce'' certain food labeling requirements, unless an exemption is provided by the Secretary (and, by delegation, FDA). Relevant to this final rule, one such requirement that States and political subdivisions may not adopt is ''any requirement for nutrition labeling of food that is not identical to the requirement of section 403(q) * * * '' (act section 403A(a)(4), 21 U.S.C. 343–1(a)(4)). Prior to the effective date of this rule, this provision operated to preempt States from imposing nutrition labeling requirements concerning trans fat because no such requirements had been imposed by FDA under section 403(q) of the act. Once this rule becomes effective, States will be preempted from imposing any nutritional labeling requirements for trans fat that are not identical to those required by this rule.

Section 403A(a)(4) of the act (21 U.S.C. 343–1(a)(4)) displaces both state legislative requirements and state common-law duties. *Medtronic* v. *Lohr*, 518 U.S. 470, 503 (1996) (Breyer, J., concurring in part and concurring in the judgment); *id.* at 510 (O'Connor, J., joined by Rehnquist, C. J., Scalia, J., and Thomas, J., concurring in part and dissenting in part); *Cippollone* v. *Liggett Group, Inc.*, 505 U.S. 504, 521 (1992) (plurality opinion); *id.* at 548–49 (Scalia, J., joined by Thomas, J., concurring in part in the judgment and dissenting in part). Although this rule has preemptive effect in that it would preclude States from adopting statutes, issuing regulations, or adopting or enforcing any requirements that are not identical to the *trans* fat labeling required by this final rule, including State tort-law imposed requirements, this preemptive effect is consistent with what Congress set forth in section 403(A) of the act.

Section 4(c) of the Executive order further requires that any ''regulatory preemption of State law shall be restricted to the minimum level necessary'' to achieve the regulatory objective. The agency is exercising its discretion under section 403(q)(2)(A) of the act, in a manner that is consistent with such section, to require that the amount of *trans* fat be listed in the label or labeling of food. This action is the minimum level necessary to achieve the agency regulatory objective. Further, section 4(e) of the Executive order provides that ''when an agency proposes to act through adjudication or rulemaking to preempt State law, the agency shall provide all affected State and local officials notice and an opportunity for appropriate participation in the proceedings.'' FDA sought input from all stakeholders through publication of the proposed rule in the **Federal Register**. Eight comments from State and local governmental entities were received; all supported the proposal. In addition, one supportive comment was received from a municipal health agency in response to the reopening of the comment period relating to the proposed footnote.

In conclusion, FDA has determined that the preemptive effects of the final rule are consistent with Executive Order 13132.

XV. References

The following references have been placed in the Dockets Management Branch (see **ADDRESSES**) and may be seen by interested persons between 9

a.m. and 4 p.m., Monday through Friday.

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List of Subjects in 21 CFR 101

Food labeling, Nutrition, Reporting and recordkeeping requirements.

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

PART 101—FOOD LABELING

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

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

■ 2. Section 101.9 is amended by:

a. Redesignating paragraphs (c)(2)(ii) and (c)(2)(iii) as (c)(2)(iii) and (c)(2)(iv),

b. Adding new paragraph (c)(2)(ii), and

c. Revising paragraphs (c)(2)(i), (d)(1)(ii)(A), the first sentence of paragraph (f), the first sentence of paragraph (g)(5), the second sentence of paragraph (g)(6), and the sample labels in paragraphs (d)(11)(iii), (d)(12), (d)(13)(ii), (e)(5), (j)(13)(ii)(A)(*1*), and (j)(13)(ii)(A)(*2*).

■ The revisions and additions are to read as follows:

§ 101.9 Nutrition labeling of food.

* * * * *

(c) * * *

(2) * * *

(i) ''Saturated fat,'' or ''Saturated'': A statement of the number of grams of saturated fat in a serving defined as the sum of all fatty acids containing no double bonds, except that label declaration of saturated fat content information is not required for products that contain less than 0.5 gram of total fat in a serving if no claims are made about fat, fatty acid, or cholesterol content, and if ''calories from saturated fat'' is not declared. Except as provided for in paragraph (f) of this section, if a statement of the saturated fat content is not required and, as a result, not declared, the statement ''Not a significant source of saturated fat'' shall be placed at the bottom of the table of nutrient values. Saturated fat content shall be indented and expressed as grams per serving to the nearest 0.5 gram (1/2) gram increment below 5 grams and to the nearest gram increment above 5 grams. If the serving contains less than 0.5 gram, the content shall be expressed as zero.

(ii) ''*Trans* fat'' or ''*Trans*'': A statement of the number of grams of *trans* fat in a serving, defined as the sum of all unsaturated fatty acids that contain one or more isolated (i.e., nonconjugated) double bonds in a *trans* configuration, except that label declaration of *trans* fat content information is not required for products that contain less than 0.5 gram of total fat in a serving if no claims are made about fat, fatty acid or cholesterol content. The word ''*trans*'' may be italicized to indicate its Latin origin. *Trans* fat content shall be indented and expressed as grams per serving to the nearest 0.5 (1/2)-gram increment below 5 grams and to the nearest gram increment above 5 grams. If the serving contains less than 0.5 gram, the content, when declared, shall be expressed as zero. Except as provided for in paragraph (f) of this section, if a statement of the *trans* fat content is not required and, as a result, not declared, the statement ''Not a significant source

of *trans* fat'' shall be placed at the bottom of the table of nutrient values.

* * * * *

(d)(1) * * *

(ii) * * *

(A) Except as provided for in paragraph (c)(2)(ii) of this section, a single easy-to-read type style,

* * * * *

(11) * * *

(iii) * * *

Nutrition Facts

Serving Size 2 slices (56g)
Servings Per Container 10

Calories 140
Calories from Fat 15

Amount/serving	% Daily Value*	Amount/serving	% Daily Value*
Total Fat 1.5g	**2%**	**Total Carbohydrate** 26g	**9%**
Saturated Fat 0.5g	**3%**	Dietary Fiber 2g	**8%**
Trans Fat 0.5g		Sugars 1g	
Cholesterol 0mg	**0%**	**Protein** 4g	
Sodium 280mg	**12%**		

Vitamin A 0% • Vitamin C 0% • Calcium 6% • Iron 6%
Thiamin 15% • Riboflavin 8% • Niacin 10%

* Percent Daily Values are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs:

	Calories:	2,000	2,500
Total Fat	Less than	65g	80g
Sat Fat	Less than	20g	25g
Cholesterol	Less than	300mg	300mg
Sodium	Less than	2,400mg	2,400mg
Total Carbohydrate		300g	375g
Dietary Fiber		25g	30g

(12) * * *

Nutrition Facts

Serving Size 1 cup (228g)
Servings Per Container 2

Amount Per Serving

Calories 260 Calories from Fat 120

	% Daily Value*
Total Fat 13g	**20%**
Saturated Fat 5g	**25%**
Trans Fat 2g	
Cholesterol 30mg	**10%**
Sodium 660mg	**28%**
Total Carbohydrate 31g	**10%**
Dietary Fiber 0g	**0%**
Sugars 5g	
Protein 5g	

Vitamin A 4% • Vitamin C 2%
Calcium 15% • Iron 4%

* Percent Daily Values are based on a 2,000 calorie diet. Your Daily Values may be higher or lower depending on your calorie needs:

	Calories:	2,000	2,500
Total Fat	Less than	65g	80g
Sat Fat	Less than	20g	25g
Cholesterol	Less than	300mg	300mg
Sodium	Less than	2,400mg	2,400mg
Total Carbohydrate		300g	375g
Dietary Fiber		25g	30g

Calories per gram:
Fat 9 • Carbohydrate 4 • Protein 4

(13) * * *

(ii) * * *

Nutrition Facts	Wheat Squares Sweetened		Corn Flakes Not Sweetened		Mixed Grain Flakes Sweetened	
Serving Size 1 Box	(35g)		(19g)		(27g)	
Servings Per Container	1		1		1	
Amount Per Serving						
Calories	130		70		100	
Calories from Fat	0		0		0	
		% Daily Value*		**% Daily Value***		**% Daily Value***
Total Fat	0g	**0%**	0g	**0%**	0g	**0%**
Saturated Fat	0g	**0%**	0g	**0%**	0g	**0%**
Trans Fat	0g		0g		0g	
Cholesterol	0mg	**0%**	0mg	**0%**	0mg	**0%**
Sodium	0mg	**0%**	200mg	**8%**	120mg	**5%**
Potassium	125mg	**4%**	25mg	**1%**	30mg	**1%**
Total Carbohydrate	29g	**10%**	17g	**6%**	24g	**8%**
Dietary Fiber	3g	**12%**	1g	**4%**	1g	**4%**
Sugars	8g		6g		13g	
Protein	4g		1g		1g	
Vitamin A	0%		10%		10%	
Vitamin C	0%		15%		90%	
Calcium	0%		0%		0%	
Iron	10%		6%		20%	
Thiamin	30%		15%		20%	
Riboflavin	30%		15%		20%	
Niacin	30%		15%		20%	
Vitamin B_6	30%		15%		20%	

* Percent Daily Values are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs:

	Calories:	2,000	2,500
Total Fat	Less than	65g	80g
Sat Fat	Less than	20g	25g
Cholesterol	Less than	300mg	300mg
Sodium	Less than	2,400mg	2,400mg
Potassium		3,500mg	3,500mg
Total Carbohydrate		300g	375g
Dietary Fiber		25g	30g

* * * * *

(e) * * *

(5) * * *

Nutrition Facts

Serving Size 1/12 package
(44g, about 1/4 cup dry mix)
Servings Per Container 12

Amount Per Serving	Mix	Baked
Calories	190	280
Calories from Fat	45	140
	% Daily Value**	
Total Fat 5g*	8%	24%
Saturated Fat 2g	10%	13%
Trans Fat 1g		
Cholesterol 0mg	0%	23%
Sodium 300mg	13%	13%
Total Carbohydrate 34g	11%	11%
Dietary Fiber 0g	0%	0%
Sugars 18g		
Protein 2g		
Vitamin A	0%	0%
Vitamin C	0%	0%
Calcium	6%	8%
Iron	2%	4%

* Amount in Mix

** Percent Daily Values are based on a 2,000 calorie diet. Your Daily Values may be higher or lower depending on your calorie needs:

	Calories:	2,000	2,500
Total Fat	Less than	65g	80g
Sat Fat	Less than	20g	25g
Cholesterol	Less than	300mg	300mg
Sodium	Less than	2,400mg	2,400mg
Total Carbohydrate		300g	375g
Dietary Fiber		25g	30g

(f) The declaration of nutrition information may be presented in the simplified format set forth herein when a food product contains insignificant amounts of eight or more of the following: Calories, total fat, saturated fat, *trans* fat, cholesterol, sodium, total carbohydrate, dietary fiber, sugars, protein, vitamin A, vitamin C, calcium, and iron; * * *

* * * * *

(g) * * *

(5) A food with a label declaration of calories, sugars, total fat, saturated fat, *trans* fat, cholesterol, or sodium shall be deemed to be misbranded under section 403(a) of the act if the nutrient content of the composite is greater than 20 percent in excess of the value for that nutrient declared on the label. * * *

(6) * * * Reasonable deficiencies of calories, sugars, total fat, saturated fat, *trans* fat, cholesterol, or sodium under labeled amounts are acceptable within current good manufacturing practice.

* * * * *

(j) * * *

(13) * * *

(ii) * * *

(A) * * *

(*1*) * * *

Nutrition Facts

Serving Size 1/3 cup (56g)
Servings about 3
Calories 90
Fat Cal. 20

*Percent Daily Values (DV) are based on a 2,000 calorie diet.

Amount/serving	%DV*	Amount/serving	%DV*
Total Fat 2g	3%	**Total Carb.** 0g	0%
Sat. Fat 1g	5%	Fiber 0g	0%
Trans Fat 0.5g		Sugars 0g	
Cholest. 10mg	3%	**Protein** 17g	
Sodium 200mg	8%		

Vitamin A 0% • Vitamin C 0% • Calcium 0% • Iron 6%

(*2*) * * *

Nutrition Facts Serv. Size: 1 package, Amount Per Serving:
Calories 45, Fat Cal. 10, **Total Fat** 1g (2% DV), Sat. Fat 0.5g (3% DV), *Trans* Fat 0.5g, **Cholest.** 0mg (0% DV), **Sodium** 50mg (2% DV), **Total Carb.** 8g (3% DV), Fiber 1g (4% DV), Sugars 4g, **Protein** 1g, Vitamin A (8% DV), Vitamin C (8% DV), Calcium (0% DV), Iron (2% DV). Percent Daily Values (DV) are based on a 2,000 calorie diet.

* * * * *

■ 3. Section 101.36 is amended by revising paragraph (b)(2)(i) to read as follows:

§ 101.36 Nutrition labeling of dietary supplements.

* * * * *

(b) * * *

(2) * * *

(i) The (b)(2)-dietary ingredients to be declared, that is total calories, calories from fat, total fat, saturated fat, *trans* fat,

cholesterol, sodium, total carbohydrate, dietary fiber, sugars, protein, vitamin A, vitamin C, calcium and iron, shall be declared when they are present in a dietary supplement in quantitative amounts by weight that exceed the amount that can be declared as zero in nutrition labeling of foods in accordance with § 101.9(c) of this part. * * *

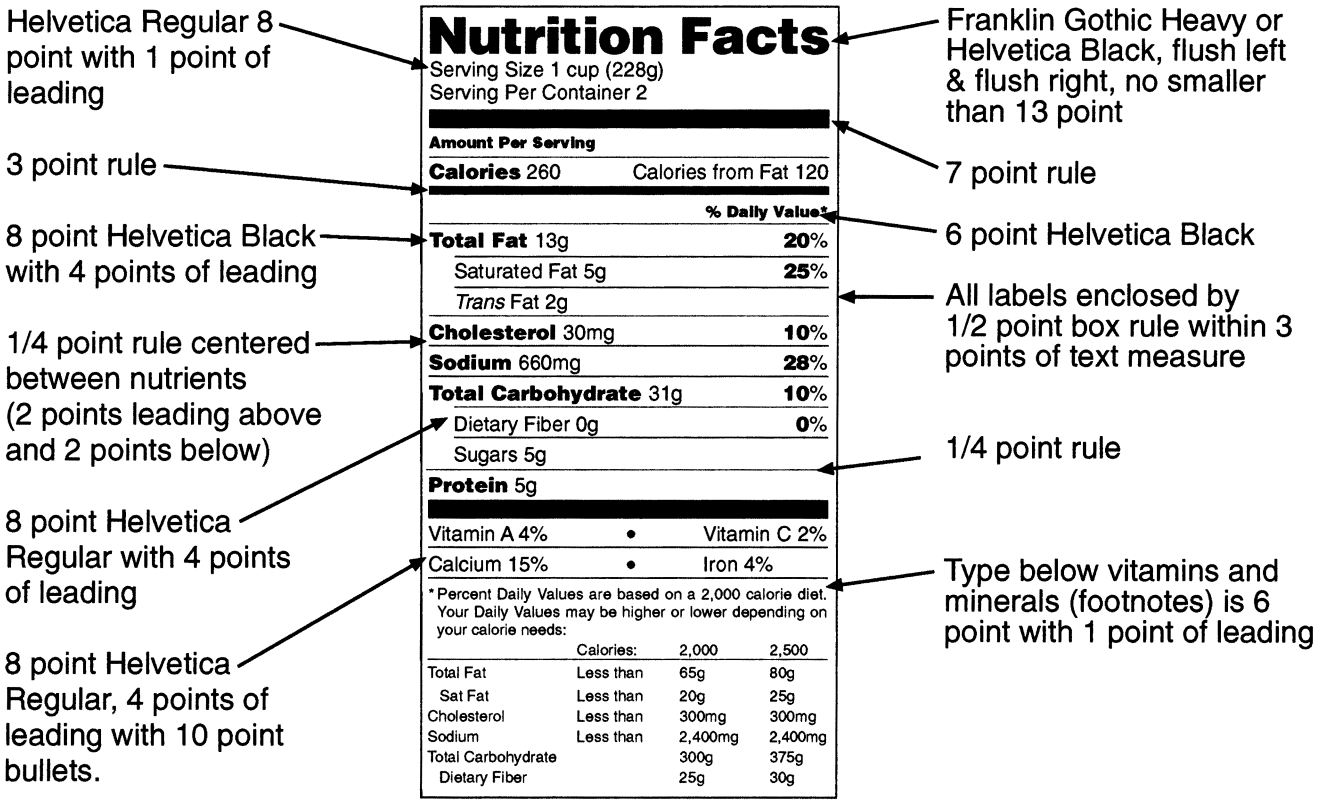
* * * * *

■ 4. Appendix B to Part 101 is amended by revising the sample label following the list of examples to read as follows:

Appendix B to Part 101—Graphic Enhancements Used by the FDA

* * * * *

Examples of Graphic Enhancements used by the FDA



Dated: May 7, 2003.

Mark B. McClellan,

Commissioner of Food and Drugs.

Dated: July 2, 2003.

Tommy G. Thompson,

Secretary of Health and Human Services.

[FR Doc. 03–17525 Filed 7–9–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. 03N–0076]

RIN 0910–AC50

Food Labeling: *Trans* Fatty Acids in Nutrition Labeling; Consumer Research to Consider Nutrient Content and Health Claims and Possible Footnote or Disclosure Statements

AGENCY: Food and Drug Administration, HHS.

ACTION: Advance notice of proposed rulemaking.

SUMMARY: The Food and Drug Administration (FDA) is issuing this advance notice of proposed rulemaking (ANPRM) to solicit information and data that potentially could be used to establish new nutrient content claims about *trans* fatty acids (*trans* fat); to establish qualifying criteria for *trans* fat in current nutrient content claims for saturated fatty acids (saturated fat) and cholesterol, lean and extra lean claims, and health claims that contain a message about cholesterol-raising lipids; and, in addition, to establish disclosure and disqualifying criteria to help consumers make heart-healthy food choices. The agency is also requesting comments on whether it should consider statements about *trans* fat, either alone or in combination with saturated fat and cholesterol, as a footnote in the Nutrition Facts panel or as a disclosure statement in conjunction with claims to enhance consumers' understanding about such cholesterol-raising lipids and how to use the information to make healthy food choices. Information and data obtained from comments and from consumer studies that will be conducted by FDA also may be used to help draft a proposed rule that would establish criteria for certain nutrient content or health claims or require the use of a footnote, or other labeling approach, about one or more cholesterol-raising lipids in the Nutrition Facts panel to assist consumers in maintaining healthy dietary practices. Elsewhere in this issue of the **Federal Register**, FDA is amending its regulations on nutrition labeling to require that *trans* fat be declared in the nutrition label of conventional foods and dietary supplements on a separate line under the line for the declaration of saturated fat.

DATES: Submit written or electronic comments by October 9, 2003.

ADDRESSES: Submit written or electronic comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*.

FOR FURTHER INFORMATION CONTACT: Julie Schrimpf, Center for Food Safety and Applied Nutrition (HFS–800), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–2373.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of November 17, 1999 (64 FR 62746) (the November 1999 proposal), FDA (we) proposed, among other things, to: (1) Amend our regulations on nutrition labeling to require that the amount of *trans* fat present in a food, including dietary supplements, be included in the amount and percent of Daily Value (% DV) declared for saturated fat with a footnote indicating the amount of *trans* fat in a serving of the product when the product contains 0.5 or more grams (g) per (/) serving, (2) establish a nutrient content claim for ''*trans* fat free,'' and (3) revise existing nutrient content and health claims that have limits on levels of saturated fat to include a criterion for *trans* fat. In that proposal, FDA concluded that dietary *trans* fat, like saturated fat, has adverse effects on blood cholesterol measures that are predictive of coronary heart disease (CHD) risk (64 FR 62746 at 62754).

Comments received in response to the November 1999 proposal were very diverse. Many comments strongly opposed the inclusion of *trans* fat as part of the amount and % DV for saturated fat (see ''Food Labeling: *Trans* Fatty Acids in Nutrition Labeling, Nutrient Content Claims, and Health Claims'' (the *trans* fat final regulation) found elsewhere in this issue of the **Federal Register**) and supported the declaration of *trans* fat on a separate line immediately under that for saturated fat. Comments relating to claims were equally diverse and indicated strongly opposing views. Comments objecting to proposed definitions for nutrient content claims were based on scientific, legal, and economic arguments with some comments stating that the agency was acting in advance of scientific justification. Moreover, comments encouraged the agency to wait for the soon-to-be published report on macronutrients by the Institute of Medicine of the National Academy of Sciences (IOM/NAS) before finalizing the proposal. The comments explained that the IOM/NAS was expected to review the available science on *trans* fat and might establish a dietary reference intake (DRI) level from which FDA could establish a daily reference value (DRV) that would assist it in providing other information on the nutrition label, such as a % DV for *trans* fat.

In September of 2002, the IOM/NAS issued the report entitled ''Dietary Reference Intakes for Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein and Amino Acids'' (the IOM/NAS macronutrient report) and found that, similar to saturated fat, there is ''a positive linear trend'' between *trans* fat intake and low density lipoprotein-cholesterol (LDL-C) concentration, and therefore increased risk of CHD (Ref. 1). Although the IOM/NAS macronutrient report recommended that the intake of *trans* fat be as low as possible while maintaining a nutritionally balanced diet, it did not provide a DRI for *trans* fat or information that the agency needs to establish a DRV for nutrition labeling purposes.

Dietary guidance for the general population similar to that in the IOM/NAS macronutrient report was included in the *Dietary Guidelines for Americans* (2000, 5th ed.) (Ref. 2), which recommended cutting back on saturated and *trans* fats when reducing total fat intake. Moreover, the National Cholesterol Education Program's Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults recommended that individuals at high risk for CHD keep their intake of *trans* fat low (Ref. 3).

In light of recommendations in the IOM/NAS macronutrient report, the agency published in the **Federal Register** of November 15, 2002 (67 FR 69171) a document reopening the comment period of the November 1999 proposal (November 2002 reopening of the comment period) to solicit comments on a proposed footnote statement that would be used in place of a % DV for *trans* fat on the nutrition label. In that document, the agency recognized the importance of providing information on the *trans* fat content of foods on food labels and set forth its thinking that the proposed footnote statement would provide guidance to consumers when using the quantitative information to help maintain healthy dietary practices. Thus, in the absence of a basis on which to establish a DV, the agency proposed to require an asterisk (or other symbol) in the % DV column for *trans* fat, when it is listed,

that is tied to a similar symbol at the bottom of the Nutrition Facts box and the statement that ''Intake of *trans* fat should be as low as possible.'' The agency asked for comments on the proposed footnote statement.

A few comments to the November 2002 reopening of the comment period supported the proposed footnote statement, ''Intake of *trans* fat should be as low as possible,'' with or without some modification to the statement. However, the majority of comments strongly opposed the proposed footnote statement and recommended that FDA drop the footnote and finalize the quantitative (gram/serving) label declaration of *trans* fat on a separate line below saturated fat with no % DV. A more thorough review of the comments can be seen in comment 17 of the *trans* fat final regulation found elsewhere in this issue of the **Federal Register**.

The dominant concern, from both industry and consumers, was that the footnote would create a goal of achieving a ''zero'' *trans* fat intake level so that the market (that is, manufacturer reformulations and consumer preferences) would be driven toward products that were devoid of *trans* fat, regardless of the level of saturated fat. One comment submitted two consumer surveys that suggest the proposed footnote statement may lead consumers to identify foods with much higher levels of saturated fat but no *trans* fat as ''more healthful'' than those containing lesser amounts of saturated fat and *trans* fat combined (see comment 17 in the *trans* fat final regulation found elsewhere in this issue of the **Federal Register**).

Another concern expressed in comments was that the proposed footnote statement was inconsistent with the IOM/NAS report (Ref. 1) and other dietary guidelines. The comments argued that the footnote statement implies that intake of *trans* fat should be zero, in other words, a de facto DV of ''zero'' whereas the IOM/NAS macronutrient report states that the intake of *trans* fat is unavoidable in ordinary diets. Moreover, the report states that eliminating them from an ordinary diet would require significant changes in dietary intake patterns that may result in unknown and unquantifiable health risks. The IOM recommendation was that intake of *trans* fat should be as low as possible ''while consuming a nutritionally adequate diet.'' The comments noted that the IOM/NAS macronutrient report makes similar recommendations for saturated fat and cholesterol, which also have adverse effects on LDL–C.

Thus, the comments expressed the belief that the proposed footnote statement could mislead consumers into selecting foods with more saturated fat in an effort to avoid foods containing *trans* fat. Virtually all comments conveyed that *trans* fat and saturated fat (and perhaps cholesterol) need to be viewed in tandem—not one at the exclusion of the other(s).

Comments also raised concerns about the absence of consumer studies to determine how the proposed footnote would be perceived. As noted previously, industry comments perceived it as a warning label for consumers to avoid *trans* fat-containing foods at all costs, resulting in an increased intake of saturated fat and negating years of government health messages to limit saturated fat intake. Comments also indicated concerns about an additional footnote adding clutter to the label and thereby discouraging consumers from reading it. The comments strongly supported consumer research on the proposed and other possible footnote statements to determine consumers' understanding of *trans* fat in light of such statements and how *trans* fat may be perceived relative to other cholesterol-raising lipids in a food, as well as how consumers would react to the footnote.

In the *trans* fat final regulation, found elsewhere in this issue of the **Federal Register**, we amend regulations on nutrition labeling to require that *trans* fat be declared in the nutrition label of conventional foods and dietary supplements on a separate line immediately under the line for the declaration of saturated fat but without a % DV or the proposed nutrient content claims or footnote statement. In that document, we concurred with the comments that support consumer testing to ensure that any claim or footnote statement about *trans* fat, alone or in combination with other nutrients, such as saturated fat and cholesterol, provides meaningful guidance to consumers and drives the market in a nutritionally beneficial direction. However, we concluded that based on information and arguments presented in the comments, it is premature to establish new or revised definitions for nutrient content claims or require the use of the proposed footnote statement in the nutrition label. Instead, we decided to issue this ANPRM and solicit comment and consumer research on: (1) An appropriate basis for establishing qualifying criteria for *trans* fat in *trans* fat nutrient content claims and current nutrient content claims for saturated fat and cholesterol, lean and extra lean claims, and health claims that contain a message about cholesterol-raising lipids as well as disclosure and disqualifying levels; (2) whether such claims mislead consumers about the total fatty acid profile if levels of all cholesterol-raising lipids are not addressed, and if so, whether qualifiers or disclosure statements would remedy this problem; (3) the use of a footnote, (4) the language that may be appropriate for use in a footnote, and (5) the impact of nutrient content or health claims or a footnote or disclosure statement on consumers' food selections.

II. Agency Request for Information

A. Nutrient Content Claims, Health Claims, Disclosure, and Disqualifying Levels

FDA has a mandate to provide nutrition information on food labels to assist consumers in maintaining healthy dietary practices. As explained in the *trans* fat final regulation, published elsewhere in this issue of the **Federal Register**, although the science now supports a relationship between *trans* fat intake and risk of CHD, the agency believes that the current level of scientific evidence does not provide the type of quantitative information that the agency would need to support the establishment of a DRV for *trans* fat. In 1993, when the agency established a DRV for saturated fat (58 FR 2206, January 6, 1993), it based the DRV on quantitative guidelines set forth by the National Academy of Science 1989 report ''Diet and Health, Implications for Reducing Chronic Disease Risk'' (Ref. 4) and a report from the National Cholesterol Education Program (National Heart, Lung, and Blood Institute of the National Institutes of Health) (Ref. 5) that stated that saturated fat should provide less than 10 percent of total calories. The agency derived a DRV of 20 grams for saturated fat (rounded) as the amount of saturated fat that would provide approximately 10 percent of the reference caloric intake (i.e., 2,000 calories/day) (55 FR 29476 at 29483, July 19, 1990). There is no such quantitative recommendation at this time for *trans* fat, either as an absolute amount or as a percentage of caloric intake. The IOM/NAS report recommended keeping *trans* fat intake as low as possible while recognizing that *trans* fat is unavoidable in ordinary, nonvegan diets and that trying to eliminate *trans* fat from the diet entirely would require significant changes in eating patterns that may introduce undesirable effects. In the absence of a DRV for *trans* fat, the agency is providing for mandatory *trans* fat labeling, without a % DV, to provide

consumers with information they need to help them make healthy food choices in the context of their total daily diet.

In addition to the information on the Nutrition Facts panel, nutrient content and health claims are important tools for providing consumers with information about the level of one or more nutrients in a food product. Because the level of scientific evidence does not currently support the establishment of an appropriate reference value for daily consumption of *trans* fat, such as a DRI level, from which the agency could derive a DRV for *trans* fat, the agency decided, in the *trans* fat final regulation, to withdraw those provisions of the proposed *trans* fat rule pertaining to the establishment of a definition of ''*trans* fat free,'' consideration of ''reduced *trans* fat'' and ''reduced saturated fat and *trans* fat'' claims and limits on the amounts of *trans* fat wherever saturated fat limits are placed on nutrient content claims, health claims, and disclosure and disqualifying levels. However, the agency plans to continue to evaluate the emerging science and revisit the need for establishing nutrient content claims related to *trans* fat, and limits on *trans* fat in certain nutrient content claims, health claims, and disclosure and disqualifying levels through a new rulemaking once the scientific evidence has evolved to a point at which the agency believes the scientific evidence would support such a rulemaking. If a company wants to make a statement about the fat content of a product that is demonstrably true, balanced, adequately substantiated, and not misleading, FDA would have to consider the exercise of its enforcement discretion.

The agency is concerned about ensuring that consumers obtain the best possible information related to *trans* fat and other cholesterol-raising lipids on the food label. Therefore, we are interested in receiving information from scientific bodies concerning recommended or upper intake levels of *trans* fat. We are also requesting interested persons to submit, as part of their comments on this ANPRM, scientific information and data, including consumer research data and analyses of risk inherent in selecting specific levels of *trans* fat, that would assist the agency in establishing qualifying criteria for *trans* fat in *trans* fat nutrient content claims, current nutrient content claims for saturated fat and cholesterol, lean and extra lean claims, and health claims that contain a message about cholesterol-raising lipids, and, in addition, as disclosure and disqualifying levels. Alternatively, in the absence of evidence to support the establishment of such qualifying criteria, the agency is interested in receiving any available data to support the usefulness of or need for a disclosure statement, in conjunction with nutrient content or health claims, concerning levels of saturated fat, *trans* fat, or cholesterol in a food or in the diet or a message about the role of such cholesterol-raising lipids in increasing the risk of CHD.

The agency is also interested in comments on the impact on consumers' shopping choices of a qualifying criterion for *trans* fat in saturated fat, cholesterol, lean and extra lean nutrient content claims and in health claims that contain a message about cholesterol-raising lipids. What kinds of products would consumers buy more or less of because of such claims and a *trans* fat criterion?

B. Footnote Statements

We are asking interested persons and those with expertise in consumer research to submit, as part of their comments on the ANPRM, information and consumer research data on any of the following footnote statements:

- Intake of saturated fat and *trans* fat should be kept low while maintaining a nutritionally adequate diet;
- Intake of *trans* fat should be kept low while maintaining a nutritionally adequate diet;
- Intake of saturated fat, *trans* fat, and cholesterol should be kept low while maintaining a nutritionally adequate diet;
- As part of a nutritionally balanced diet, intake of saturated fat, *trans* fat, and cholesterol should be kept low;
- Healthy diets start with diets low in saturated fat, *trans* fat, and cholesterol; and
- Nutritionally adequate diets include diets low in saturated fat, *trans* fat, and cholesterol.

Other footnote statements may also be considered.

In particular, we are interested in information about whether a footnote about *trans* fat, alone or in combination with saturated fat and cholesterol, would be helpful to consumers and what kinds of footnote statements are likely to be helpful to consumers to achieve the goal of conveying information about *trans* fat and/or other cholesterol-raising lipids in a manner which ''enables the public to readily observe and comprehend such information and to understand its relative significance in the context of a total daily diet.'' (Section 2(b) of Public Law 101–535). Such information might consist of tests of the ability of various footnotes to assist consumers in making product choices or to draw correct inferences about product characteristics. It might also be useful to know how different footnote statements are comprehended by consumers and whether they are: (1) Seen as credible, (2) understood as statements of dietary guidance or as product warning statements, or (3) seen as confusing. As always, we will take into account the adequacy of the sample, sample size, response rates, study design, and the representativeness of the products and product comparisons used in the study when we evaluate and/or design a study.

We intend to conduct consumer research of this kind in the near future.

C. Specific Questions to be Considered

Comments are also requested on the following questions:

- How will nutrient content or health claims or a footnote or disclosure statement about *trans* fat, either alone or in combination with saturated fat and cholesterol, change, if at all, the way consumers are likely to respond to the required declaration of the amount of saturated and *trans* fats in the Nutrition Facts panel?
- Will a claim or a footnote or disclosure statement have an impact on consumers' shopping choices, and, if so, what kinds of products will consumers buy more of and less of?
- Is there any information, other than claims or a footnote or disclosure statement, that FDA should consider requiring in labeling that would be more helpful to consumers with respect to cholesterol-raising lipids in maintaining a healthy diet and in getting accurate and reliable nutrition information, or that would help consumers make better use of the information about cholesterol-raising lipids on the label?
- Since the amount of *trans* fat will be listed in the Nutrition Facts panel right below the amount and % DV of saturated fat, what additional effect will claims or a footnote or disclosure statement about *trans* fat, either alone or in combination with saturated fat and cholesterol, have on the line of products that manufacturers choose to make?
- What kinds of existing products will manufacturers reformulate because of claims or a footnote or disclosure statement?
- What kinds of new products will manufacturers develop because of claims or a footnote or disclosure statement?
- What kinds of products will manufacturers stop producing because of claims or a footnote or disclosure statement?

• What First Amendment issues, if any, would be raised by establishing qualifying criteria for *trans* fat in *trans* fat claims and other nutrient content or health claims with existing criteria for saturated fat and by requiring a footnote or disclosure statement?

• How will manufacturers weigh the consumer concerns about both saturated and *trans* fats with the functional properties of those fats in the food. For example, if, as some manufacturers have claimed, functional considerations may sometimes cause *trans* fat to be replaced with equal or greater amounts of saturated fat, then how will consumers react to a potentially unhealthful substitution where a product lists fewer grams of *trans* fat, but lists more grams of saturated fat and reports a higher % DV for saturated fat? At what ratio of substitution of saturated fat for *trans* fat would it not be advantageous to a manufacturer to make such a substitution, even with a claim or footnote or disclosure statement? What steps could FDA take to encourage more healthful reformulation?

• In order to comply with the Small Business Regulatory Enforcement Fairness Act of 1996, what options for regulatory relief should we consider giving to small businesses?

III. References

The following references have been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen between 9 a.m. and 4 p.m., Monday through Friday, except on Federal government holidays. FDA has verified the Web site addresses, but is not responsible for subsequent changes to the Web sites after this document publishes in the **Federal Register**.

1. IOM/NAS, ''Dietary Reference Intakes for Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein and Amino Acids,'' National Academy Press, Washington, DC, pp. S1–S17, 8–1 to 8–97, and 11–1 to 11–48, 2002 (Internet address: *http://www.nap.edu/books/0309085373/html/*).

2. U.S. Department of Agriculture and U.S. Department of Health and Human Services, *Nutrition and Your Health: Dietary Guidelines for Americans*, 5th ed., Washington DC; Home and Garden Bulletin No. 232, 2000 (Internet address: *http://www.health.gov*).

3. Third Report of the National Cholesterol Education Program (NCEP) Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel III), chapter II, ''Rationale for Intervention'' and Chapter V ''Adopting Healthful Lifestyle Habits to Lower LDL Cholesterol and Reduce CHD Risk,'' 2001, (Internet address: *http://www.NHLBI.nih.gov/guidelines/cholesterol/index.htm*).

4. Committee on Diet and Health, Food and Nutrition Board, National Research Council, ''Diet and Health: Implications for Reducing Chronic Disease Risk,'' chapter 28, Washington, DC, National Academy Press, 1989.

5. Population Panel, National Cholesterol Education Program, National Heart, Lung, and Blood Institute, National Institutes of Health, ''Report of the Expert Panel on Population Strategies for Blood Cholesterol Reduction, Executive Summary'' Bethesda, MD, NIH Publication No. 90–3047, November 1990.

IV. How to Submit Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments to *http://www.fda.gov/dockets/ecomments* or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

This ANPRM is issued under sections 201, 403, and 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 343, and 371) and under the authority of the Commissioner of Food and Drugs.

Dated: June 26, 2003.

Mark B. McClellan,

Commissioner of Food and Drugs.

[FR Doc. 03–17526 Filed 7–9–03; 8:45 am]

BILLING CODE 4160–01–S

Federal Register

Friday,
July 11, 2003

Part IV

Department of Labor

Office of the Secretary

29 CFR Part 35

Nondiscrimination on the Basis of Age in Programs or Activities Receiving Federal Financial Assistance From the Department of Labor; Proposed Rule

DEPARTMENT OF LABOR

Office of the Secretary

29 CFR Part 35

RIN 1291–AA21

Nondiscrimination on the Basis of Age in Programs or Activities Receiving Federal Financial Assistance From the Department of Labor

AGENCY: Office of the Secretary, Labor.

ACTION: Notice of proposed rulemaking.

SUMMARY: This Notice of Proposed Rulemaking sets out the Department of Labor's (''DOL'' or ''the Department'') proposed rules for implementing the Age Discrimination Act of 1975, as amended (''Age Act''). The Age Act prohibits discrimination on the basis of age in programs or activities receiving Federal financial assistance. The Age Act also contains certain exceptions that permit, under limited circumstances, use of age distinctions or factors other than age that might have a disproportionate effect on the basis of age. The Age Act applies to persons of all ages.

DATES: Comments must be received by September 9, 2003.

ADDRESSES: Address all comments about this proposed rule to Annabelle T. Lockhart, Director, Civil Rights Center (''CRC''), Frances Perkins Building, 200 Constitution Ave., NW., Room N–4123, Washington, DC 20210. Brief comments (maximum five pages) may be submitted by facsimile machine (FAX) to 202/693–6505. Comments by electronic mail may be sent to *CivilRightsCenter@dol.gov.* Receipt of submissions, whether by mail, FAX transmittal or by e-mail, will not be acknowledged; however, the sender may request confirmation that a submission has been received, by telephoning the Civil Rights Center at (202) 693–6500 (VOICE) or (202) 693–6515, (800) 326–2577 (TTY/TDD).

Comments that CRC receives will be available for public inspection at DOL during normal business hours. Appropriate aids are available on request to persons needing assistance to review the comments. In addition, copies of this proposed rule are available, upon request, in large print and electronic file on computer disk. Other formats will be considered upon request. To schedule an appointment to review the comments and/or to obtain the proposed rule in an alternate format, contact CRC at the telephone number or address listed above.

FOR FURTHER INFORMATION CONTACT: Annabelle T. Lockhart, Director, Civil Rights Center (CRC), Frances Perkins Building, 200 Constitution Ave. NW., Room N–4123, Washington, DC 20210, *CivilRightsCenter@dol.gov,* (202) 693–6500 (VOICE) or (202) 693–6515, (800) 326–2577 (TTY/TDD).

SUPPLEMENTARY INFORMATION:

I. Background Information

The Age Discrimination Act of 1975, 42 U.S.C. 6101 *et seq.*, prohibits discrimination on the basis of age in programs or activities receiving Federal financial assistance. The Age Act applies to discrimination at all age levels. The Age Act also contains specific exceptions that permit the use of certain age distinctions and factors other than age that meet the Age Act's requirements.

The Age Act required the former Department of Health, Education, and Welfare (HEW) to issue general, government-wide regulations setting standards to be followed by all Federal agencies implementing the Age Act. These government-wide regulations, which were issued on June 12, 1979 (45 CFR part 90; 44 FR 33768), and became effective on July 1, 1979, require each Federal agency providing financial assistance to any program or activity to publish final regulations implementing the Age Act, and to submit final agency regulations to HEW (now the Department of Health and Human Services (HHS)), before publication in the **Federal Register**. (*See* 45 CFR 90.31.)

II. Rulemaking History

On December 29, 1998, DOL published its first NPRM to implement the Age Act. *See* 63 FR 71714 (1998). No comments were received by DOL regarding the proposal. A second NPRM (NPRM II) was published on June 10, 2002, to address changes in statutory and case law that occurred subsequent to publication of the first NPRM. *See* 67 FR 39830 (2002). No comments were received by DOL regarding the second proposal.

As part of the clearance process required by the government-wide Age Act regulations, DOL submitted its draft final rule to the Department of Health and Human Services (HHS) for review prior to publication as required by 45 CFR 90.31(c). HHS raised concerns about consistency between the draft DOL final Age Act rule and the government-wide Age Act regulations, as well as a few additional minor matters. The purpose of this NPRM is to address the HHS concerns and to propose minor technical corrections to the rule. These changes are discussed below in the section-by-section review of the proposed rule.

III. Section-by-Section Review of the NPRM

The NPRM published today is identical to NPRM II with five exceptions. The proposed language in sections 35.2(b), 35.3, 35.13, 35.15 and 35.37 is different from the language proposed for these sections in NPRM II. The differences between today's proposal and NPRM II are discussed below. Individuals interested in information about those sections of the proposed rule not discussed below are referred to the December 29, 1998, NPRM (63 FR 71714) and the June 10, 2002, NPRM II (67 FR 39830) for additional information.

Section 35.2(b)

NPRM II proposed that Section 35.2(b) state that ''[c]ompliance with Section 188 of the Workforce Investment Act of 1998 (WIA) (29 U.S.C. 2938) and implementing regulations at 29 CFR part 37, will satisfy the obligations of recipients of Federal financial assistance from DOL under WIA to comply with this part. CRC will use the legal standards in Subpart B of this part when evaluating whether a WIA recipient has engaged in unlawful age discrimination.'' Today the Department is proposing not to include this language in the rule.

Compliance with the implementing regulations for section 188 of WIA will not satisfy recipient obligations under the Age Act. The definition of ''WIA Title I-funded program or activity'' found in the WIA regulations is not consistent with the definition of ''program or activity'' found in the Age Act, which was amended by the Civil Rights Restoration Act of 1987 (CRRA). The effect of the CRRA on the Age Act was to define ''program or activity'' to encompass all parts of the recipient's operations; *i.e.*, the scope of coverage is institution-wide. The regulation implementing section 188 of WIA does not contain as broad a scope of coverage. The scope of coverage of WIA is limited to the specific program or activity that receives financial assistance and not the entire institution. Additionally, the regulation implementing section 188 of WIA does not contain the exemptions to the rules against age discrimination that are part of the government-wide rule at 45 CFR 91.13 and 91.14. Accordingly, to make the Department's Age Act rule correspond to the government-wide Age Act rule, the Department proposes to delete section 35.2(b) and renumber this section.

Section 35.3

Section 35.3 would contain definitions applicable to the Age Act regulations. The definition for ''program or activity'' has been modified in two respects in today's NPRM: the modified definition contains an updated statutory citation to the definition of ''local educational agency,'' and the definition is now proposed to match the definition used in the Civil Rights Restoration Act of 1987. As discussed above, the CRRA amended the definition of ''program or activity'' in the Age Act to encompass all parts of the recipient's operations. The definition proposed today is the same as the definition proposed for the Department of Justice common rule which will amend the definition of ''program or activity'' for various Executive branch agencies' Title VI, Section 504 of the Rehabilitation Act, and Age Act regulations. (For more information on this change, *see* 65 FR 76460, December 6, 2000.)

Section 35.13

Section 35.13 is proposed to contain certain exemptions to the rules against age discrimination. Today's proposal differs from NPRM II in that the word ''reasonable'' has been deleted from the text of this section to conform its language to that of the government-wide Age Act regulation.

Section 35.15

Section 35.15 is proposed to allow recipients to take steps to overcome the effects of conditions that result in a limited participation on the basis of age. Today's NPRM proposes to revise the title of this section and to clarify that this section does not allow recipients to take actions that would permit any otherwise prohibited use of age distinctions in any program or activity receiving Federal financial assistance from DOL.

Section 35.37

In NPRM II DOL proposed to use its procedures for conducting hearings, issuing decisions, and conducting post-termination proceedings under Section 188 of the Workforce Investment Act to conduct such proceedings under the Age Act as well. Differences between the Age Act and WIA coverage, discussed above, make it more appropriate to propose use of DOL Title VI enforcement procedures for Age Act cases. Section 37.37 of today's proposal would accomplish that end.

IV. Regulatory Procedures

Executive Order 12866

These proposed Age Discrimination Act regulations have been drafted and reviewed in accordance with Executive Order 12866, section 1(b), Principles of Regulation. The Department has determined that this proposed rule is a ''significant regulatory action'' under Executive Order 12866, section 3(f), Regulatory Planning and Review, yet is not economically significant as defined in section 3(f)(1), and, therefore, the information enumerated in section 6(a)(3)(C) of the order is not required. Pursuant to Executive Order 12866, this proposed rule has been reviewed by the Office of Management and Budget.

Unfunded Mandates Reform

Executive Order 12875—This proposed rule would not create an unfunded Federal mandate on any State, local or tribal government.

Unfunded Mandates Reform Act of 1995—This proposed rule would not include any Federal mandate that might result in increased expenditures by State, local and tribal governments, in the aggregate, of $100 million or more, or increased expenditures by the private sector of $100 million or more.

Regulatory Flexibility Act

This proposed rule clarifies existing requirements for entities receiving financial assistance from DOL. The requirements prohibiting age discrimination by recipients of Federal financial assistance that are in the Age Act and the government-wide regulations have been in effect since 1979. In addition, entities receiving financial assistance from DOL under WIA have been expressly informed of their obligations to comply with the Age Act by both WIA statutory language and by the DOL regulations implementing the civil rights provisions of WIA. Because this proposed rule will not substantively change existing obligations on recipients, but merely clarifies such duties, the Department certifies that the proposed rule would not have a significant economic impact on a substantial number of small entities. Consequently, a regulatory flexibility analysis is not required.

Paperwork Reduction Act

Section 35.31(c)(1) of the proposed rule allows a complainant to file a complaint by submitting a written statement that identifies the parties involved and the date the complainant first had knowledge of the alleged violation, describes generally the action or practice complained of, and is signed by the complainant. Section 35.40(b)(3)(iii) of the proposed rule requires a complainant to give 30 days notice to the Secretary of Labor, the Secretary of Health and Human Services, the Attorney General of the United States, and the recipient, before commencing a civil action in the event that CRC issues a finding in favor of the recipient or fails to make a finding within 180 days. Based on the history of the program, the Department projects that fewer than 9 persons per year will either file a complaint with CRC or give notice that a civil action is being pursued. Accordingly, the Department believes the Paperwork Reduction Act is inapplicable to this rule. The Department invites the public to comment on its Paperwork Reduction Act analysis.

Executive Order 13132

This proposed rule has been reviewed in accordance with Executive Order 13132 regarding Federalism. This proposed 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. Therefore, the requirements of section 6 of Executive Order 13132 do not apply to this rule.

List of Subjects in 29 CFR Part 35

Administrative practice and procedure, Age discrimination, Children, Civil rights, Elderly, Grant programs—Labor.

Signed at Washington, DC this 7th day of July, 2003.

Elaine L. Chao,

Secretary of Labor.

For the reasons set out in the preamble, 29 CFR subtitle A is proposed to be amended by adding a new part 35 to read as follows:

PART 35—NONDISCRIMINATION ON THE BASIS OF AGE IN PROGRAMS OR ACTIVITIES RECEIVING FEDERAL FINANCIAL ASSISTANCE FROM THE DEPARTMENT OF LABOR

Subpart A—General

Sec.

35.1 What is the purpose of the Department of Labor (DOL) age discrimination regulations?
35.2 To what programs or activities do these regulations apply?
35.3 What definitions apply to these regulations?

Subpart B—Standards for Determining Age Discrimination

35.10 Rules against age discrimination.

35.11 Definitions of the terms ''normal operation'' and ''statutory objective.''
35.12 Exceptions to the rules against age discrimination: normal operation or statutory objective of any program or activity.
35.13 Exceptions to the rules against age discrimination: reasonable factors other than age.
35.14 Burden of proof.
35.15 Remedial action.
35.16 Special benefits for children and the elderly.
35.17 Age distinctions in DOL regulations.

Subpart C—Duties of DOL Recipients

35.20 General responsibilities.
35.21 Recipient responsibility to provide notice.
35.22 Information requirements.
35.23 Assurances required.
35.24 Designation of responsible employee.
35.25 Complaint procedures.
35.26 Recipient assessment of age distinctions.

Subpart D—Investigation, Conciliation, and Enforcement Procedures

35.30 Compliance reviews.
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35.32 Mediation.
35.33 Investigations.
35.34 Effect of agreements on enforcement effort.
35.35 Prohibition against intimidation or retaliation.
35.36 Enforcement.
35.37 Hearings, decisions, and post-termination proceedings.
35.38 Procedure for disbursal of funds to an alternate recipient.
35.39 Remedial action by recipient.
35.40 Exhaustion of administrative remedies.

Authority: 42 U.S.C. 6101 *et seq.;* 45 CFR part 90.

Subpart A—General

§ 35.1 What is the purpose of the Department of Labor (DOL) age discrimination regulations?

The purpose of this part is to set out the DOL rules for implementing the Age Discrimination Act of 1975, as amended. The Act prohibits discrimination on the basis of age by recipients of Federal financial assistance and in federally assisted programs or activities, but permits the use of certain age distinctions and factors other than age that meet the requirements of the Act and this part.

§ 35.2 To what programs or activities do these regulations apply?

(a) *Application.* This part applies to any program or activity that receives Federal financial assistance, directly or indirectly, from DOL.

(b) *Limitation of application.* This part does not apply to:

(1) An age distinction contained in that part of a Federal, State, or local statute or ordinance adopted by an elected, general purpose legislative body that:

(i) Provides persons with any benefits or assistance based on age; or

(ii) Establishes criteria for participation in age-related terms; or

(iii) Describes intended beneficiaries or target groups in age-related terms.

(2) Any employment practice of any employer, employment agency, labor organization, or any labor-management joint apprentice training, except any program or activity receiving Federal financial assistance under the Workforce Investment Act of 1998 (29 U.S.C. 2801 *et seq.*).

§ 35.3 What definitions apply to these regulations?

As used in this part:

Act means the Age Discrimination Act of 1975, as amended (42 U.S.C. 6101 *et seq.*).

Action means any act, activity, policy, rule, standard, or method of administration, or the use of any policy, rule, standard, or method of administration.

Age means how old a person is, or the number of years from the date of a person's birth.

Age distinction means any action using age or an age-related term.

Age-related term means a word or words that necessarily imply a particular age or range of ages (*e.g.*, ''child,'' ''adults,'' ''older persons,'' but not ''student'').

Applicant for Federal financial assistance means the individual or entity submitting an application, request, or plan required to be approved by a DOL official or recipient as a condition to becoming a recipient or subrecipient.

Beneficiary means the person(s) intended by Congress to receive benefits or services from a recipient of Federal financial assistance from DOL.

CRC means the Civil Rights Center, Office of the Assistant Secretary for Administration and Management, United States Department of Labor.

Director means the Director of CRC.

Department means the United States Department of Labor.

DOL means the United States Department of Labor.

Federal financial assistance means any grant, entitlement, loan, cooperative agreement, contract (other than a procurement contract or a contract of insurance or guaranty), or any other arrangement by which DOL provides or otherwise makes available assistance in the form of:

(1) Funds;

(2) Services of Federal personnel; or

(3) Real and personal property or any interest in or use of property, including:

(i) Transfers or leases of property for less than fair market value or for reduced consideration; and

(ii) Proceeds from a subsequent transfer or lease of property if the Federal share of its fair market value is not returned to the Federal Government.

Program or activity means all of the operations of any entity described in paragraphs (1) through (4) of this section, any part of which is extended Federal financial assistance:

(1)(i) A department, agency, special purpose district, or other instrumentality of a State or of a local government; or

(ii) The entity of such State or local government that distributes such assistance and each such department or agency (and each other State or local government entity) to which the assistance is extended, in the case of assistance to a State or local government;

(2)(i) A college, university, or other postsecondary institution, or a public system of higher education; or

(ii) A local educational agency (as defined in section 7801 of title 20), system of vocational education, or other school system;

(3)(i) An entire corporation, partnership, or other private organization, or an entire sole proprietorship—

(A) If assistance is extended to such corporation, partnership, private organization, or sole proprietorship as a whole; or

(B) Which is principally engaged in the business of providing education, health care, housing, social services, or parks and recreation; or

(ii) The entire plant or other comparable, geographically separate facility to which Federal financial assistance is extended, in the case of any other corporation, partnership, private organization, or sole proprietorship; or

(4) Any other entity which is established by two or more of the entities described in paragraph (1), (2), or (3) of this section.

Recipient means any State or its political subdivision, any instrumentality of a State or its political subdivision, any public or private agency, institution, organization, or other entity, or any person to which Federal financial assistance from DOL is extended, directly or through another recipient, but excludes the ultimate beneficiary of the assistance. Recipient includes any subrecipient to which a recipient extends or passes on Federal

financial assistance, and any successor, assignee, or transferee of a recipient.

Secretary means the Secretary of Labor, or his or her designee.

State means the individual States of the United States, the Commonwealth of Puerto Rico, the District of Columbia, Guam, the Virgin Islands, American Samoa, Wake Island and the Commonwealth of the Northern Mariana Islands.

Subpart B—Standards for Determining Age Discrimination

§ 35.10 Rules against age discrimination.

The rules stated in this section are subject to the exceptions contained in §§ 35.12 and 35.13.

(a) *General rule.* No person in the United States shall be, on the basis of age, excluded from participation in, denied the benefits of or subjected to discrimination under, any program or activity receiving Federal financial assistance from DOL.

(b) *Specific rules.* A recipient may not, directly or through contractual, licensing, or other arrangements, use age distinctions or take any other actions that have the effect of, on the basis of age:

(1) excluding individuals from, denying them the benefits of, or subjecting them to discrimination under, a program or activity receiving Federal financial assistance from DOL; or

(2) denying or limiting individuals in their opportunity to participate in any program or activity receiving Federal financial assistance from DOL.

(c) *Other forms of age discrimination.* The listing of specific forms of age discrimination in paragraph (b) of this section is not exhaustive and does not imply that any other form of age discrimination is permitted.

§ 35.11 Definitions of the terms ''normal operation'' and ''statutory objective.''

As used in this part, the term:

(a) *Normal operation* means the operation of a program or activity without significant changes that would impair the ability of the program or activity to meet its objectives.

(b) *Statutory objective* means any purpose of a program or activity expressly stated in any Federal statute, State statute, or local statute or ordinance adopted by an elected, general purpose legislative body.

§ 35.12 Exceptions to the rules against age discrimination: normal operation or statutory objective of any program or activity.

A recipient is permitted to take an action otherwise prohibited by § 35.10 if the action reasonably takes age into account as a factor necessary to the normal operation or the achievement of any statutory objective of a program or activity. An action reasonably takes age into account as a factor necessary to the normal operation or the achievement of any statutory objective of a program or activity if:

(a) Age is used as a measure or approximation of one or more other characteristics;

(b) The other characteristic(s) must be measured or approximated in order for the normal operation of the program or activity to continue, or to achieve any statutory objective of the program or activity;

(c) The other characteristic(s) can reasonably be measured or approximated by the use of age; and

(d) The other characteristic(s) are impractical to measure directly on an individual basis.

§ 35.13 Exceptions to the rules against age discrimination: reasonable factors other than age.

A recipient is permitted to take an action otherwise prohibited by § 35.10, if that action is based on a factor other than age, even though the action may have a disproportionate effect on persons of different ages. An action is based on a factor other than age only if the factor bears a direct and substantial relationship to the normal operation of the program or activity or to the achievement of a statutory objective.

§ 35.14 Burden of proof.

The recipient has the burden of proving that an age distinction or other action falls within the exceptions outlined in §§ 35.12 and 35.13.

§ 35.15 Remedial action.

Even in the absence of a finding of discrimination, a recipient, in administering a program, may take steps to overcome the effects of conditions that resulted in a limited participation on the basis of age. Nothing in this section will permit any otherwise prohibited use of age distinctions that have the effect of excluding individuals from, denying them benefits of, subjecting them to discrimination under, or limiting them in their opportunity to participate in any program or activity receiving federal financial assistance from DOL.

§ 35.16 Special benefits for children and the elderly.

If a recipient is operating a program or activity that provides special benefits to the elderly or to children, the use of such age distinctions is presumed to be necessary to the normal operation of the program or activity, notwithstanding the provisions of § 35.12.

§ 35.17 Age distinctions in DOL regulations.

Any age distinction in regulations issued by DOL is presumed to be necessary to the achievement of a statutory objective of the program or activity to which the regulations apply, notwithstanding the provisions of § 35.12.

Subpart C—Duties of DOL Recipients

§ 35.20 General responsibilities.

Each DOL recipient has primary responsibility for ensuring that its programs or activities are in compliance with the Act and this part and for taking appropriate steps to correct any violations of the Act or this part.

§ 35.21 Recipient responsibility to provide notice.

(a) *Notice to other recipients.* Where a recipient of Federal financial assistance from DOL passes on funds to other recipients, that recipient shall notify such other recipients of their obligations under the Act and this part.

(b) *Notice to beneficiaries.* A recipient shall notify its beneficiaries about the provisions of the Act and this part and their applicability to specific programs or activities. The notification must also identify the responsible employee designated under § 35.24 by name or title, address, and telephone number.

§ 35.22 Information requirements.

Each recipient shall:

(a) Keep such records as CRC determines are necessary to ascertain whether the recipient is complying with the Act and this part;

(b) Upon request, provide CRC with such information and reports as the Director determines are necessary to ascertain whether the recipient is complying with the Act and this part; and

(c) Permit reasonable access by CRC to books, records, accounts, reports, other recipient facilities and other sources of information to the extent CRC determines is necessary to ascertain whether the recipient is complying with the Act and this part.

§ 35.23 Assurances required.

A recipient or applicant for Federal financial assistance from DOL shall sign a written assurance, in a form specified by DOL, that the program or activity will be operated in compliance with the Act and this part. In subsequent applications to DOL, an applicant may incorporate this assurance by reference.

§ 35.24 Designation of responsible employee.

Each recipient shall designate at least one employee to coordinate its compliance activities under the Act and this part, including investigation of any complaints that the recipient receives alleging any actions that are prohibited by the Act or this part.

§ 35.25 Complaint procedures.

Each recipient shall adopt and publish complaint procedures providing for prompt and equitable resolution of complaints alleging any action that would be prohibited by the Act or this part.

§ 35.26 Recipient assessment of age distinctions.

(a) In order to assess a recipient's compliance with the Act and this part, as part of a compliance or monitoring review, or a complaint investigation, CRC may require a recipient employing the equivalent of 15 or more full-time employees to complete a written self-evaluation, in a manner specified by CRC, of any age distinction imposed in its program or activity receiving Federal financial assistance from DOL.

(b) Whenever such an assessment indicates a violation of the Act or this part, the recipient shall take prompt and appropriate corrective action.

Subpart D—Investigation, Conciliation, and Enforcement Procedures

§ 35.30 Compliance reviews.

(a) CRC may conduct such compliance reviews, pre-award reviews, and other similar procedures as permit CRC to investigate and correct violations of the Act and this part, irrespective of whether a complaint has been filed against a recipient. Such reviews may be as comprehensive as necessary to determine whether a violation of the Act or this part has occurred.

(b) Where a review conducted pursuant to paragraph (a) of this section indicates a violation of the Act or this part, CRC will attempt to achieve voluntary compliance. If voluntary compliance cannot be achieved, CRC will begin enforcement proceedings, as described in § 35.36.

§ 35.31 Complaints.

(a) *Who may file.* Any person, whether individually, as a member of a class, or on behalf of others, may file a complaint with CRC alleging discrimination in violation of the Act or these regulations, based on an action occurring on or after July 1, 1979.

(b) *When to file.* A complainant must file a complaint within 180 days from the date the complainant first had knowledge of the alleged act of discrimination. The Director may extend this time limit for good cause shown.

(c) *Complaint procedure.* A complaint is considered to be complete on the date CRC receives all the information necessary to process it, as provided in paragraph (c)(1) of this section. CRC will:

(1) Accept as a complete complaint any written statement that identifies the parties involved and the date the complainant first had knowledge of the alleged violation, describes generally the action or practice complained of, and is signed by the complainant;

(2) Freely permit a complainant to add information to the complaint to meet the requirements of a complete complaint;

(3) Notify the complainant and the recipient of their rights and obligations under the complaint procedure, including the right to have a representative at all stages of the complaint procedure; and

(4) Notify the complainant and the recipient (or their representatives) of their right to contact CRC for information and assistance regarding the complaint resolution process.

(d) *No jurisdiction.* CRC will return to the complainant any complaint outside the jurisdiction of this part, with a statement indicating why there is no jurisdiction.

§ 35.32 Mediation.

(a) *Referral to mediation.* CRC will promptly refer to the Federal Mediation and Conciliation Service or the mediation agency designated by the Secretary of Health and Human Services under 45 CFR part 90, all complaints that:

(1) Fall within the jurisdiction of the Act or this part, unless the age distinction complained of is clearly within an exemption under § 35.2(c); and

(2) Contain all information necessary for further processing, as provided in § 35.31(c)(1).

(b) *Participation in mediation process.* Both the complainant and the recipient shall participate in the mediation process to the extent necessary to reach an agreement or to make an informed judgment that an agreement is not possible. The recipient and the complainant do not need to meet with the mediator at the same time, and a meeting may be conducted by telephone or other means of effective dialogue if a personal meeting between the party and the mediator is impractical.

(c) *When agreement is reached.* If the complainant and the recipient reach an agreement, the mediator shall prepare a written statement of the agreement, have the complainant and recipient sign it, and send a copy of the agreement to CRC.

(d) *Confidentiality.* The mediator shall protect the confidentiality of all information obtained in the course of the mediation process. No mediator may testify in any adjudicative proceeding, produce any document, or otherwise disclose any information obtained in the course of the mediation process, unless the mediator has obtained prior approval of the head of the mediation agency.

(e) *Maximum time period for mediation.* The mediation shall proceed for a maximum of 60 days after a complaint is filed with CRC. This 60-day period may be extended by the mediator, with the concurrence of the Director, for not more than 30 days, if the mediator determines that agreement is likely to be reached during the extended period. In the absence of such an extension, mediation ends if:

(1) 60 days elapse from the time the complaint is filed; or

(2) prior to the end of the 60-day period, either

(i) an agreement is reached; or

(ii) the mediator determines that agreement cannot be reached.

(f) *Unresolved complaints.* The mediator shall return unresolved complaints to CRC.

§ 35.33 Investigations.

(a) *Initial investigation.* CRC will investigate complaints that are unresolved after mediation or reopened because the mediation agreement has been violated.

(1) As part of the initial investigation, CRC will use informal fact-finding methods, including joint or separate discussions with the complainant and recipient to establish the facts and, if possible, resolve the complaint to the mutual satisfaction of the parties. CRC may seek the assistance of any involved State, local, or other Federal agency.

(2) Where agreement between the parties has been reached pursuant to paragraph (a)(1) of this section, the agreement shall be put in writing by DOL, and signed by the parties and an authorized official of DOL.

(b) *Formal findings, conciliation, and hearing.* If CRC cannot resolve the complaint during the early stages of the investigation, CRC will complete the investigation of the complaint and make formal findings. If the investigation indicates a violation of the Act or this part, CRC will attempt to achieve voluntary compliance. If CRC cannot obtain voluntary compliance, CRC will

begin appropriate enforcement action, as provided in § 35.36.

§ 35.34 Effect of agreements on enforcement effort.

An agreement reached pursuant to either § 35.32(c) or § 35.33(a) shall have no effect on the operation of any other enforcement effort of DOL, such as compliance reviews and investigations of other complaints, including those against the recipient.

§ 35.35 Prohibition against intimidation or retaliation.

A recipient may not engage in acts of intimidation or retaliation against any person who:

(a) Attempts to assert a right protected by the Act or this part; or

(b) Cooperates in any mediation, investigation, hearing or other part of CRC's investigation, conciliation, and enforcement process.

§ 35.36 Enforcement.

(a) DOL may enforce the Act and this part through:

(1) Termination of, or refusal to grant or continue, a recipient's Federal financial assistance from DOL under the program or activity in which the recipient has violated the Act or this part. Such enforcement action may be taken only after a recipient has had an opportunity for a hearing on the record before an administrative law judge.

(2) Any other means authorized by law, including, but not limited to:

(i) Referral to the Department of Justice for proceedings to enforce any rights of the United States or obligation of the recipient created by the Act or this part; or

(ii) Use of any requirement of, or referral to, any Federal, State, or local government agency that will have the effect of correcting a violation of the Act or this part.

(b) Any termination or refusal under paragraph (a)(1) of this section will be limited to the particular recipient and to the particular program or activity found to be in violation of the Act or this part. A finding with respect to a program or activity that does not receive Federal financial assistance from DOL will not form any part of the basis for termination or refusal.

(c) No action may be taken under paragraph (a) of this section until:

(1) DOL has advised the recipient of its failure to comply with the Act or with this part and has determined that voluntary compliance cannot be obtained; and

(2) Thirty days have elapsed since DOL sent a written report of the circumstances and grounds of the action to the committees of Congress having jurisdiction over the program or activity involved.

(d) *Deferral.* DOL may defer granting new Federal financial assistance to a recipient when termination proceedings under paragraph (a)(1) of this section are initiated.

(1) New Federal financial assistance from DOL includes all assistance for which DOL requires an application or approval, including renewal or continuation of existing activities, or authorization of new activities, during the deferral period. New Federal financial assistance from DOL does not include increases in funding as a result of changed computation of formula awards or assistance approved prior to the initiation of a hearing under paragraph (a)(1) of this section.

(2) DOL may not defer a grant until the recipient has received notice of an opportunity for a hearing under paragraph (a)(1) of this section. A deferral may not continue for more than 60 days unless a hearing has begun within the 60-day period or the recipient and DOL have mutually agreed to extend the time for beginning the hearing. If the hearing does not result in a finding against the recipient, the deferral may not continue for more than 30 days after the close of the hearing.

§ 35.37 Hearings, decisions, and post-termination proceedings.

Certain DOL procedural provisions applicable to Title VI of the Civil Rights Act of 1964 apply to DOL enforcement of these regulations. They are found at 29 CFR 31.9 through 31.11.

§ 35.38 Procedure for disbursal of funds to an alternate recipient.

(a) If funds are withheld from a recipient under this part, the Secretary may disburse the funds withheld directly to an alternate recipient.

(b) The Secretary will require any alternate recipient to demonstrate:

(1) The ability to comply with the Act and this part; and

(2) The ability to achieve the goals of the Federal statute authorizing the Federal financial assistance.

§ 35.39 Remedial action by recipient.

Where CRC finds discrimination on the basis of age in violation of this Act or this part, the recipient shall take any remedial action that CRC deems necessary to overcome the effects of the discrimination. In addition, if a recipient funds or otherwise exercises control over another recipient that has discriminated, both recipients may be required to take remedial action.

§ 35.40 Exhaustion of administrative remedies.

(a) A complainant may file a civil action under the Act following the exhaustion of administrative remedies. Administrative remedies are exhausted if:

(1) One hundred eighty days have elapsed since the complainant filed the complaint with CRC, and CRC has made no finding with regard to the complaint; or

(2) CRC issues any finding in favor of the recipient.

(b) If CRC fails to make a finding within 180 days, or issues a finding in favor of the recipient, CRC will promptly:

(1) Notify the complainant;

(2) Advise the complainant of his or her right to bring a civil action for injunctive relief; and

(3) Inform the complainant that:

(i) The complainant may bring a civil action only in a United States district court for the district in which the recipient is found or transacts business;

(ii) A complainant who prevails in a civil action has the right to be awarded the costs of the action, including reasonable attorney's fees, but that the complainant must demand these costs in the complaint filed with the court;

(iii) Before commencing the action, the complainant must give 30 days notice by registered mail to the Secretary, the Secretary of Health and Human Services, the Attorney General of the United States, and the recipient;

(iv) The notice required by paragraph (b)(3)(iii) of this section must state the alleged violation of the Act, the relief requested, the court in which the complainant is bringing the action, and whether or not attorney's fees are demanded in the event that the complainant prevails; and

(v) The complainant may not bring an action if the same alleged violation of the Act by the same recipient is the subject of a pending action in any court of the United States.

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