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Presidential Documents

Title 3—

The President

Executive Order 13285 of January 29, 2003

President's Council on Service and Civic Participation

By the authority vested in me as President by the Constitution and the laws of the United States of America, and in order to encourage the recognition of volunteer service and civic participation by all Americans, and especially America's youth, it is hereby ordered as follows:

Section 1. *The President's Council on Service and Civic Participation.* (a) There is hereby established within the Corporation for National and Community Services (CNCS) the President's Council on Service and Civic Participation (Council).

(b) The Council shall be composed of up to 25 members, including representatives of America's youth, appointed by the President. Each member shall serve for a term of 2 years and may continue to serve after the expiration of their term until a successor is appointed. The President shall designate one member to serve as Chair and one member to serve as Vice Chair. Subject to the direction of the Chief Executive Officer of the CNCS, the Chair, and in the Chair's absence the Vice Chair, shall convene and preside at the meetings of the Council, determine its agenda, and direct its work.

Sec. 2. *Mission and Functions of the Council.*

(a) The mission of the Council shall be to:

(i) encourage the recognition of outstanding volunteer service and civic participation by individuals, schools, and organizations and thereby encourage more such activity, especially on the part of America's youth; and

(ii) facilitate awareness of the ways in which Americans throughout our history have helped to meet the vital needs of their communities and Nation through volunteer service and civic participation.

(b) In carrying out its mission, the Council shall:

(i) design and recommend programs to recognize individuals, schools, and organizations that excel in their efforts to support volunteer service and civic participation, especially with respect to students in primary schools, secondary schools, and institutions of higher learning;

(ii) exchange information and ideas with interested individuals and organizations on ways to expand and improve programs developed pursuant to subsection 2(b)(i) of this order;

(iii) advise the Chief Executive Officer of the CNCS on broad dissemination, especially among schools and youth organizations, of information regarding recommended practices for the promotion of volunteer service and civic participation, and other relevant educational and promotional materials;

(iv) monitor and advise the Chief Executive Officer of the CNCS on the need for the enhancement of materials disseminated pursuant to subsection 2(b)(iii) of this order; and

(v) make recommendations from time to time to the President, through the Director of the USA Freedom Corps, on ways to promote and recognize outstanding volunteer service and civic participation by individuals, schools, and organizations and to promote awareness of the ways in which Americans throughout our history have helped to meet the vital needs of their communities and Nation through volunteer service and civic participation.

Sec. 3. *Administration.* (a) Each Federal agency, to the extent permitted by law and subject to the availability of appropriations, shall furnish such information and assistance to the Council as the Council may, with the approval of the Director of the USA Freedom Corps, request.

(b) The members of the Council shall serve without compensation for their work on the Council. Members of the Council who are not officers or employees of the United States may receive travel expenses, including per diem in lieu of subsistence, as authorized by law for persons serving intermittently in the Government (5 U.S.C. 5701–5707).

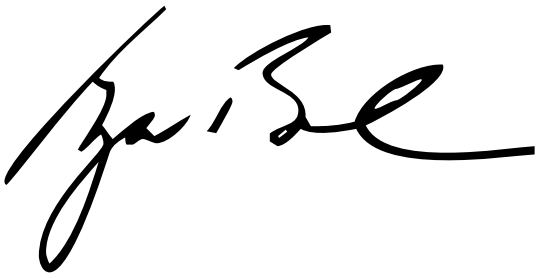
(c) To the extent permitted by law, the Chief Executive Officer of the CNCS shall furnish the Council with necessary staff, supplies, facilities, and other administrative services and shall pay the expenses of the Council.

(d) The Chief Executive Officer of the CNCS shall appoint an Executive Director to head the staff of the Council.

(e) The Council, with the approval of the Chief Executive Officer of the CNCS, may establish subcommittees of the Council, consisting exclusively of members of the Council, as appropriate to aid the Council in carrying out its mission under this order.

Sec. 4. *General Provisions.* (a) Insofar as the Federal Advisory Committee Act, as amended (5 U.S.C. App.) (Act), may apply to the administration of any portion of this order, any functions of the President under the Act, except that of reporting to the Congress, shall be performed by the Chief Executive Officer of CNCS in accordance with the guidelines and procedures issued by the Administrator of General Services.

(b) Unless extended by the President, this order shall expire 2 years from the date of this order.



THE WHITE HOUSE,
January 29, 2003.

[FR Doc. 03–2606
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Rules and Regulations

Federal Register
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Monday, February 3, 2003

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

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DEPARTMENT OF AGRICULTURE

Commodity Credit Corporation

7 CFR Part 1413

RIN 0560–AG71

Hard White Wheat Incentive Program

AGENCY: Commodity Credit Corporation, USDA.

ACTION: Final rule.

SUMMARY: This rule implements the Hard White Wheat Incentive Program (HWWIP). This program provides incentive payments to eligible hard white wheat producers in the amount of $0.20 per bushel, with a maximum of 60 bushels of hard white wheat production eligible for payment on each acre planted. Planting certified hard white wheat seed is not an eligibility requirement to receive payment under HWWIP; however, an additional incentive payment in the amount of $2.00 per acre is provided to hard white wheat producers who plant certified hard white wheat seed for any of the 2003 through 2005 crops of hard white wheat. The purpose of the program is to increase the production of both spring and winter varieties of hard white wheat during the 2003 through 2005 crop years.

DATES: Effective January 29, 2003.

FOR FURTHER INFORMATION CONTACT: Helen Smith, Production, Emergencies, and Compliance Division, FSA/USDA, Stop 0517, 1400 Independence Ave., SW., Washington, DC 20250–0512; telephone (202) 720–7641; facsimile (202) 690–3610; e-mail: *HSmith@wdc.usda.gov.* Persons with disabilities who require alternative means for communication (Braille, large print, audio tape, etc.) should contact the USDA Target Center at (202) 720–2600 (voice and TDD).

SUPPLEMENTARY INFORMATION:

Notice and Comment

Section 1601(c) of the Farm Security and Rural Investment Act of 2002 (Pub. L. 107–171) requires that the regulations necessary to implement these provisions be promulgated without regard to the notice and comment provisions of 5 U.S.C. 553 or the Statement of Policy of the Secretary of Agriculture (the Secretary) effective July 24, 1971 (36 FR 13804) relating to notices of proposed rulemaking and public participation in rulemaking. These provisions are thus issued as final and are effective immediately.

Executive Order 12866

This rule is issued in conformance with Executive Order 12866 and has been determined to be significant and has been reviewed by the Office of Management and Budget. A cost-benefit assessment was completed and is summarized after the background section.

Federal Assistance Programs

The titles and numbers of the Federal assistance programs, as found in the Catalog of Federal Domestic Assistance, to which this final rule applies are: Commodity Loans and Loan Deficiency Payments, 10.051.

Regulatory Flexibility Act

It has been determined that the Regulatory Flexibility Act is not applicable to this rule because the Commodity Credit Corporation (CCC) is not required by 5 U.S.C. 553 or any other provision of law to publish a notice of proposed rulemaking with respect to the subject matter of this rule.

Commodity Loans and Loan Deficiency Payments, 10.051.

Environmental Evaluation

The environmental impacts of this final rule have been considered in accordance with the provisions of the National Environmental Policy Act of 1969 (NEPA), 42 U.S.C. 4321 *et seq.*, the regulations of the Council on Environmental Quality (40 CFR parts 1500–1508), and the FSA regulations for compliance with NEPA, 7 CFR parts 799, and 1940, subpart G. FSA completed an environmental evaluation and concluded the rule requires no further environmental review. No extraordinary circumstances or other unforeseeable factors exist which would require preparation of an environmental assessment or environmental impact statement. A copy of the environmental evaluation is available for inspection and review upon request.

Executive Order 12988

This final rule has been reviewed in accordance with Executive Order 12988. The provisions of this final rule preempts State laws to the extent such laws are inconsistent with the provisions of this rule. Before any judicial action may be brought concerning provisions of this rule, administrative remedies must be exhausted.

Executive Order 12372

This program is not subject to the provisions of Executive Order 12372, which requires intergovernmental consultation with State and local officials. See the notice related to 7 CFR part 3015, subpart V, published at 48 FR 29115 (June 24, 1983).

Unfunded Mandates Reform Act of 1995

This rule contains no Federal mandates under the regulatory provisions of Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) for State, local, and tribal governments or the private sector. Thus, this rule is not subject to the requirements of section 202 and 205 of UMRA.

Small Business Regulatory Enforcement Fairness Act of 1996

Section 1601(c) requires that authority in section 808 of the Small Business Regulatory Enforcement Fairness Act of 1996, (SBREFA), be used which allows an agency to forgo SBREFA's usual 60-day Congressional Review delay of the effective date of a major regulation if the agency finds that there is a good cause to do so. Accordingly, this rule is effective upon the date of filing for public inspection by the Office of the Federal Register.

Paperwork Reduction Act

Section 1601(c) of the 2002 Act provides that the promulgation of regulations and the administration of Title I of the 2002 Act shall be made without regard to chapter 5 of title 44 of the United States Code (the Paperwork Reduction Act). Accordingly, these regulations and the information collection activities needed to

administer the program authorized by these regulations, are not subject to review by the Office of Management and Budget under the Paper Reduction Act.

Government Paperwork Elimination Act

The Farm Service Agency (FSA) is committed to compliance with the Government Paperwork Elimination Act (GPEA) and the Freedom to E-File Act, which require Government agencies in general and FSA in particular to provide the public the option of submitting information or transacting business electronically to the maximum extent possible. The forms and other information collection activities required by participation in the Hard White Wheat Incentive Payment Program are not yet fully implemented for the public to conduct business with FSA electronically.

Applications for all programs may be submitted at the FSA county offices by mail or fax. At this time, electronic submission is not available. Full implementation of electronic submission is underway.

Executive Order 12612

It has been determined that this rule does not have sufficient Federalism implications to warrant the preparation of a Federalism Assessment. The provisions contained in this rule will not have a substantial direct effect on States or their political subdivisions, or on the distribution of power and responsibilities among the various levels of government.

Background

Section 1616 of the Farm Security and Rural Investment Act of 2002, (the 2002 Act), provides that a total of $20,000,000 of CCC funds be used during the 2003 through 2005 crop years, to provide incentive payments to producers of hard white wheat. The 2002 Act also mandates that this program shall be implemented on not more than 2,000,000 acres or equivalent volume of production for the 2003 through the 2005 crop years. An equivalent volume of production has been determined to be 120,000,000 bushels, which is the product of 2,000,000 acres times 60 bushels per acre.

In the event that the 2,000,000 acre limitation is reached under this program before the $20 million authorized for the program is distributed, the 120,000,000 million bushels shall become the cap for implementing the program.

The purpose of this program is to create an incentive for producers to plant hard white wheat of winter and for spring varieties, which would subsequently increase production for both domestic and export markets. Payments under this program are available to producers in every State.

The Hard White Wheat Incentive Program (HWWIP) will provide two payments to producers: An incentive payment of $0.20 for each bushel of eligible hard white wheat production, with a maximum of 60 bushels per acre eligible for payment, and (2) a payment of $2.00 per acre for certified seed. Producers do not have to plant certified seed to receive the production incentive payment.

With respect to the first payment, the reason for the 60 bushel per acre cap is to provide consistent payments to producers in the various geographic regions of the United States that have disparate hard white wheat production capabilities. Two payment options were considered. One, a direct payment per acre of production; and two, a direct payment for each bushel of production. Traditionally, hard white wheat yields in the Northwest growing region are significantly higher than in the Plains States. Accordingly, a per acre payment is not an equitable solution, nor does a payment based on production, with no limitation on the production eligible for payment, provide equitable assistance. Therefore, it was determined that a $0.20 per bushel payment, with a 60 bushel per acre cap, will most equitably distribute payments and address production disparities across the hard white wheat growing areas. Also, it was determined that a bushel-based payment system would likely result in the production of more bushels of hard white wheat than will an acre-based payment system because it will attract more productive land. This incentive payment will be issued only if hard white wheat is actually produced and after production is verified by means of a settlement sheet or other similar documentation delivered to CCC.

In order to encourage purity and yield potential of the hard white wheat production, an additional incentive payment is provided in the amount of $2.00 per acre for each acre a producer plants to 2003 through 2005 crops of hard white wheat with certified seed. Producers utilizing this option will be required to show proof that certified seed was planted on the reported acres. This additional payment is provided to help offset the added cost of the certified seed, and should increase the purity of the hard white wheat produced, decreasing the possibility that the seed used to plant the hard white wheat contains other types of wheat. This payment may be issued even if the crop subsequently fails and no hard white wheat production is realized from the acreage planted to the certified seed.

Minimum quality standards have been determined to be U.S. #2 Hard White Wheat or better, as established by Federal Grain Inspection Service. A settlement sheet or other similar documentation is required before incentive payments may be issued and must indicate at a minimum: That the wheat accounted for on the document is hard white wheat; the grade of the hard white wheat; name and address of person the hard wheat was purchased from; net bushels; and name and address of purchasing facility. The settlement sheet shall be subject to verification by CCC.

Cost Benefit Assessment Summary

Hard White Winter Wheat Incentive Payments

Increased plantings of hard white wheat varieties are expected to be offset by lower plantings of other classes of wheat. Thus, the incentive payments will not measurably affect total wheat production. On the demand side, millers are likely to use hard white wheat for domestic food use at the expense of other wheat classes. The net impact on the estimated annual quantity of wheat used for food is negligible.

Currently, U.S. hard white wheat exports are small, partly due to an inadequate supply of consistent quality. Target markets are predominantly in southeast Asia, where hard white wheat varieties are used to produce Chinese noodles. Incentives to grow hard white wheat should increase supplies of consistent quality so exporters can compete in this export market.

Federal outlays are expected to increase by the amount of CCC funds that must be made available for the incentive payments, or $20 million. Timing of these payments depends on producer participation. About $6 million will likely be expended for the 2003 crop, $12 million for the 2004 crop, and the remaining $2 million for the 2005 crop. Because of the potential for hard white wheat payment requests to exceed available funds during the 2004 and 2005 crops, procedures will allow factoring of payment levels to avoid expending more than the $20 million provided by the law.

For further information, contact: Phil Sronce at 202–720–2711, or *phil_sronce@usda.gov.*

List of Subjects in 7 CFR 1413

Agricultural commodities, Feed grains, Grains.

Accordingly, 7 CFR Chapter XIV is amended by adding part 1413 is set forth below.

1. Part 1413 is added to read as follows:

PART 1413—HARD WHITE WHEAT INCENTIVE PROGRAM

Sec.

1413.101 Applicability.
1413.102 Administration.
1413.103 Definitions.
1413.104 Signup and application process.
1413.105 Eligibility.
1413.106 Quality.
1413.107 Availability of funds and maximum eligible acreage and production.
1413.108 Applicant's maximum payment quantity.
1413.109 Calculation of assistance.
1413.110 Offsets and withholdings.
1413.111 Assignments.
1413.112 Appeals.
1413.113 Other regulations

Authority: 7 U.S.C. 7999; 15 U.S.C. 714b and 714c.

§ 1413.101 Applicability.

(a) These regulations in this part set forth the terms and conditions of the Hard White Wheat Incentive Program. The Farm Security and Rural Investment Act of 2002 provides that $20,000,000 of the funds of CCC shall be available during the 2003 through the 2005 crop years for producers to produce and market hard white wheat limits this program to not more than a total of 2,000,000 acres or an equivalent volume of 120,000,000 bushels of production for the 2003 through 2005 crop years.

(b) A production payment incentive shall be available only for hard white winter wheat that grades U.S. # 2 grade or higher, established by the Federal Grain Inspection Service, that is produced and harvested in the United States.

(c) A certified seed incentive payment shall be available for each acre planted to certified hard white wheat seed, as approved by CCC. Producers are eligible to receive incentive payments for the production incentive or the certified seed incentive, or both. Each incentive payment is independent of the other.

§ 1413.102 Administration.

(a) The program is administered under the general supervision of the Executive Vice-President, CCC, and shall be carried out by the Farm Service Agency (FSA) State and county committees (State and county committees).

(b) State and county committees, their representatives and employees, have no authority to modify or waive any of the provisions of the regulations of this part, except as provided in paragraph (e) of this section.

(c) The State committee shall take any action required by the regulations of this part that the county committee has not taken. The State committee shall also:

(1) Correct, or require a county committee to correct any action taken by such county committee that is not in accordance with the regulations of this part; or

(2) Require a county committee to withhold taking any action that is not in accordance with the regulations of this part.

(d) No provision or delegation of this part to a State or county committee shall preclude the Executive Vice President, CCC, or a designee, from determining any question arising under the program or from reversing or modifying any determination made by the State or county committee.

(e) The Deputy Administrator, Farm Programs, FSA, may authorize State and county committees to waive or modify deadlines and other program requirements in cases where lateness or failure to meet such other requirements do not adversely affect the operation of this program and does not violate statutory limitations on the program.

(f) Any payment applications not executed in accordance with the terms and conditions determined and announced by CCC, including any purported execution prior to the dates authorized by the Executive Vice President, CCC, is null and void and shall not be considered to be a contract between CCC and any person executing the contract.

§ 1413.103 Definitions.

The definitions set forth in this section shall be applicable for all purposes of administering the Hard White Wheat Incentive Program established by this part.

Application period means the date established by the Deputy Administrator for producers of hard white wheat to apply for program benefits.

CCC means the Commodity Credit Corporation.

Certified seed means hard white wheat seed grown from acceptable seedstock and sold, according to rules imposed by a State's Certified Seed Board, as determined acceptable by the Deputy Administrator.

County committee means the FSA county committee.

County office means the FSA office.

Department or USDA means the United States Department of Agriculture.

Deputy Administrator means the Deputy Administrator for Farm Programs (DAFP), Farm Service Agency or a designee.

Eligible bushels means hard white wheat bushels that were produced in the United States anytime during the 2003 through 2005 crop years, and for which an acceptable settlement sheet has been provided to the county committee.

Farm Service Agency or FSA means the Farm Service Agency of the United States Department of Agriculture.

Payment means the bushels of wheat or seed production for which an operation is eligible to be paid under this part.

Settlement sheet means a document provided to a seller of hard white wheat upon delivery of hard white wheat to a CCC-approved warehouse, or other hard white wheat purchasing facility determined acceptable by CCC, with information which includes, but is not limited to: the name and address of buyer and seller; gross quantity; net quantity; price per bushel; and type and grade of the delivered hard white wheat.

§ 1413.104 Signup and application process.

(a) Signup for the Hard White Wheat Incentive Program shall be conducted by CCC for each of the 2003 through 2005 crop years during the application period announced by the Deputy Administrator. Applications are available from any county FSA office. Applicants must submit a complete application to FSA during the application period.

(b) The producer shall submit one application for all farms within in a particular county. On the application, the applicant must certify to: The total number and location of acres planted to hard white wheat and the number of eligible bushels sold. Applicants must also provide a settlement sheet, to FSA upon disposal of the production certified to on the application.

(c) Each applicant for a certified seed incentive payment must submit an acceptable seed receipt for the certified seed to FSA, and certify to the number and location of acres planted with certified seed.

(d) Producers requesting benefits under this part must certify to the accuracy and truthfulness of the information provided in their application. All information provided is subject to verification by FSA.

§ 1413.105 Eligibility.

(a) The certified seed incentive payment and the production incentive payments are available to eligible producers under § 1413.101(b) and (c) for any or all of the years 2003 through

2005. Producers are eligible to receive both the certified seed and production incentive in the same year. Where an acre of land receives both the certified seed incentive and production incentive payment in the same year, only one acre shall be counted under the total 2,000,000 acreage limitation of § 1413.101(a).

(b) To be eligible to receive the certified seed incentive payment, a producer must:

(1) Submit a complete application during the application period.

(2) Submit a receipt for the purchase of certified seed to FSA.

(c) To be eligible to receive the production incentive payment, a producer must:

(1) Submit a complete application during the application period.

(1) Produce hard white wheat of the quality required under § 1413.106;

(2) Have an interested buyer with the intent to use the wheat for all purposes except for feed use.

§ 1413.106 Quality.

The hard white wheat must be grade #2 or higher under the grading standards, established by the Federal Grain Inspection Service (FGIS).

§ 1413.107 Availability of funds and maximum eligible acreage and production.

The total available program funds for the 2003 through 2005 crop years is $20 million. To ensure that funds are available for each of the 2003 through 2005 crop years, payments may be factored based on total eligible producers for any year the eligible payments exceed the total funds available to be spent. The maximum hard white wheat acreage and production for which payments may be issued for the 2003 through 2005 crop year is to total 2,000,000 acres, or 120,000 bushels, whichever is greater. The certified seed incentive may be discontinued, as determined by the Deputy Administrator, in any year sufficient funds are determined to be unavailable.

§ 1413.108 Applicant's maximum payment quantity.

(a) The maximum payment quantity of hard white wheat for which an applicant may be approved under the production incentive payment for any year shall be the smaller of:

(1) The actual number of bushels harvested from the acres certified on the application; or

(2) The product of:

(i) The number of acres certified on the application;

(ii) Times 60 bushels per acre.

(b) [Reserved]

§ 1413.109 Calculation of assistance.

(a) Payment for the production incentive shall be the product of:

(1) The bushels determined in accordance with § 1413.108

(2) Times $0.20.

(b) Payment for the certified hard white wheat planting incentive shall be the product of:

(1) The number of acres certified on the application;

(2) Times $2.00 per acre.

§ 1413.110 Offsets and withholdings.

CCC may offset or withhold payments approved under this part in accordance with part 1403 of this chapter.

§ 1413.111 Assignments.

Persons entitled to a HWWIP payment may assign their rights to such payments in accordance with part 1404 of this chapter.

§ 1413.112 Appeals.

Any producer who is dissatisfied with a determination made pursuant to this part may request reconsideration or appeal such determination in accordance with parts 11 and 780 of this title.

§ 1413.113 Other regulations.

(a) The provisions of part 12 of this title, and the controlled substance provisions of part 718 of this title apply to payments made under this part.

(b) The payment limitation provisions of part 1400 of this title shall not be applicable to payments made under this part.

(c) The provisions of part 707 of this title relating to the making of payments in the event of the death of a program participant or and in the event of other special circumstances shall apply to payments made under this part.

Signed in Washington, DC, on January 28, 2003.

James R. Little,

Executive Vice President, Commodity Credit Corporation.

[FR Doc. 03–2359 Filed 1–29–03; 11:56 am]

BILLING CODE 3410–05–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 25

[Docket No. NM243; Special Conditions No. 25–226–SC]

Special Conditions: Bombardier Model BD–100–1A10 Airplanes; High-Intensity Radiated Fields (HIRF).

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final special conditions; request for comments.

SUMMARY: These special conditions are issued for Bombardier Model BD–100–1A10 airplanes. These airplanes will have a novel or unusual design feature when compared to the state of technology envisioned in the airworthiness standards for transport category airplanes. The airplane design includes four large liquid crystal display (LCD) electronic displays, an integrated electronic standby system, and full authority digital engine controls (FADEC) all of which perform critical functions. The applicable airworthiness regulations do not contain adequate or appropriate safety standards for the protection of these systems from the effects of high-intensity-radiated fields (HIRF). These special conditions contain the additional safety standards that the Administrator considers necessary to establish a level of safety equivalent to that established by the existing airworthiness standards.

DATES: The effective date of these special conditions is January 9, 2003. Comments must be received on or before March 5, 2003.

ADDRESSES: Comments on these special conditions may be mailed in duplicate to: Federal Aviation Administration, Transport Airplane Directorate, Attention: Rules Docket (ANM–113), Docket No. NM243, 1601 Lind Avenue SW., Renton, Washington 98055–4056; or delivered in duplicate to the Transport Airplane Directorate at the above address. All comments must be marked: Docket No. NM243.

FOR FURTHER INFORMATION CONTACT: Greg Dunn, FAA, Airplane and Flight Crew Branch, ANM–111, Transport Airplane Directorate, Aircraft Certification Service, 1601 Lind Avenue SW., Renton, Washington 98055–4056; telephone (425) 227–2799; facsimile (425) 227–1149.

SUPPLEMENTARY INFORMATION:

Comments Invited

The FAA has determined that notice and opportunity for public comment in

accordance with 14 CFR 11.38 are unnecessary, because the FAA has provided previous opportunities to comment on substantially identical special conditions and has fully considered and addressed all the substantive comments received. Based on a review of the comment history and the comment resolution, the FAA is satisfied that new comments are unlikely. The FAA, therefore, finds that good cause exists for making these special conditions effective upon issuance.

However, the FAA invites interested persons to participate in this rulemaking by submitting written comments, data, or views. The most helpful comments reference a specific portion of the special conditions, explain the reason for any recommended change, and include supporting data. We ask that you send us two copies of written comments.

We will file in the docket all comments we receive, as well as a report summarizing each substantive public contact with FAA personnel concerning these special conditions. The docket is available for public inspection before and after the comment closing date. If you wish to review the docket in person, go to the address in the **ADDRESSES** section of this preamble between 7:30 a.m. and 4 p.m., Monday through Friday, except Federal holidays.

We will consider all comments we receive on or before the closing date for comments. We will consider comments filed late if it is possible to do so without incurring expense or delay. We may change these special conditions based on the comments we receive.

If you want the FAA to acknowledge receipt of your comments on these special conditions, include with your comments a pre-addressed, stamped postcard on which the docket number appears. We will stamp the date on the postcard and mail it back to you.

Background

On March 26, 1999, Bombardier Inc. submitted an application to Transport Canada for FAA type certification of its new Model BD–100–1A10 airplane. The BD–100–1A10 airplane is a business jet powered by two Honeywell AS907 High Bypass turbo-fan engines. The airplane has a two-pilot cockpit and interior seating for sixteen passengers. The overall length of the Model BD–100–A10 is 68.7 feet, the height is 20.25 feet, and the wing span is 63.8 feet. The airplane has a maximum takeoff weight of 37,500 pounds, a maximum landing weight of 33,750 pounds, a maximum operating altitude of 45,000 feet, and a design range of 3,100 nautical miles at Mach 0.8 or 2,780 nautical miles at Mach 0.82. The Model BD–100–1A10 airplane will include four large LCD electronic displays, an integrated electronic standby system, and FADEC, all of which perform critical functions. These systems may be vulnerable to HIRF external to the airplane.

Type Certification Basis

Under the provisions of 14 CFR 21.17, Bombardier Inc. must show that Model BD–100–1A10 airplanes meet the applicable provisions in effect on the date of application for the type certificate or applicable provisions of 14 CFR part 25, as amended by Amendments 25–1 through 25–98. Subsequent changes have been made to § 21.101 as part of Amendment 21–77, but those changes do not become effective until June 10, 2003.

If the Administrator finds that the applicable airworthiness regulations (*i.e.*, part 25, as amended) do not contain adequate or appropriate safety standards for Bombardier Model BD–100–1A10 airplanes because of a novel or unusual design feature, special conditions are prescribed under the provisions of § 21.16.

In addition to the applicable airworthiness regulations and special conditions, Model BD–100–1A10 airplanes must comply with the fuel vent and exhaust emission requirements of 14 CFR part 34 and the noise certification requirements of 14 CFR part 36, and the FAA must issue a finding of regulatory adequacy pursuant to § 611 of Public Law 92–574, the ''Noise Control Act of 1972.''

Special conditions, as defined in 14 CFR 11.19, are issued in accordance with § 11.38 and become part of the type certification basis in accordance with § 21.101(a)(2).

Special conditions are initially applicable to the model for which they are issued. Should the type certificate for that model be amended later to include any other model that incorporates the same novel or unusual design feature, these special conditions would also apply to the other model under the provisions of § 21.101(a)(1), Amendment 21–69, effective September 16, 1991.

Novel or Unusual Design Features

As noted earlier, Model BD–100–1A10 airplanes will incorporate four LCD electronic displays, an integrated electronic standby system, and FADEC that will perform critical functions. These systems may be vulnerable to HIRF external to the airplane. The current airworthiness standards of part 25 do not contain adequate or appropriate safety standards for the protection of this equipment from the adverse effects of HIRF. Accordingly, these systems are considered to be novel or unusual designs.

Discussion

There is no specific regulation that addresses protection requirements for electrical and electronic systems from HIRF. Increased power levels from ground-based radio transmitters and the growing use of sensitive avionics/electronics and electrical systems to command and control airplanes have made it necessary to provide adequate protection.

To ensure that a level of safety is achieved equivalent to that intended by the regulations incorporated by reference, special conditions are needed for Model BD–100–1A10 airplanes. These special conditions require that avionic/electronic and electrical systems that perform critical functions be designed and installed to preclude component damage and interruption of function due to both the direct and indirect effects of HIRF.

High-Intensity Radiated Fields (HIRF)

With the trend toward increased power levels from ground-based transmitters and the advent of space and satellite communications, coupled with electronic command and control of the airplane, the immunity of critical avionic/electronic and electrical systems to HIRF must be established.

It is not possible to precisely define the HIRF to which the airplane will be exposed in service. There is also uncertainty concerning the effectiveness of airframe shielding for HIRF. Furthermore, coupling of electromagnetic energy to cockpit-installed equipment through the cockpit window apertures is undefined. Based on surveys and analysis of existing HIRF emitters, an adequate level of protection exists when compliance with the HIRF protection special condition is shown with either paragraph 1 or 2 below:

1. A minimum threat of 100 volts rms (root-mean-square) per meter electric field strength from 10 KHz to 18 GHz.

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

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

2. A threat external to the airframe of the field strengths identified in the table below for the frequency ranges indicated. Both peak and average field strength components from the table are to be demonstrated.

Frequency	Field strength (volts per meter)	
	Peak	Average
10 kHz–100 kHz ...	50	50
100 kHz–500 kHz	50	50
500 kHz–2 MHz	50	50
2 MHz–30 MHz	100	100
30 MHz–70 MHz ...	50	50
70 MHz–100 MHz	50	50
100 MHz–200 MHz	100	100
200 MHz–400 MHz	100	100
400 MHz–700 MHz	700	50
700 MHz–1 GHz ...	700	100
1 GHz–2 GHz	2000	200
2 GHz–4 GHz	3000	200
4 GHz–6 GHz	3000	200
6 GHz–8 GHz	1000	200
8 GHz–12 GHz	3000	300
12 GHz–18 GHz ...	2000	200
18 GHz–40 GHz ...	600	200

The field strengths are expressed in terms of peak of the root-mean-square (rms) over the complete modulation period.

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

Applicability

As discussed above, these special conditions are applicable to Bombardier BD–100–1A10 airplanes. Should Bombardier apply at a later date for a change to the type certificate to include another model incorporating the same novel or unusual design feature, these special conditions would apply to that model as well, under the provisions of § 21.101(a)(1), Amendment 21–69, effective September 16, 1991.

Conclusion

This action affects only certain novel or unusual design features on Bombardier Model BD–100–1A10 airplanes. It is not a rule of general applicability, and affects only the applicant which applied to the FAA for approval of these features on the airplane. The FAA has determined that notice and opportunity for public comment are unnecessary, because the FAA has provided previous opportunities to comment on substantially identical special conditions and has fully considered and addressed all the substantive comments received. The FAA is satisfied that new comments are unlikely and finds, therefore, that good cause exists for making these special conditions effective upon issuance.

List of Subjects in 14 CFR Part 25

Aircraft, Aviation safety, Reporting and recordkeeping requirements.

The authority citation for these special conditions is as follows:

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

The Special Conditions

Accordingly, pursuant to the authority delegated to me by the Administrator, the following special conditions are issued as part of the type certification basis for the Bombardier Model BD–100–1A10 airplane.

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

2. For the purpose of these special conditions, the following definition applies: *Critical Functions:* Functions whose failure would contribute to or cause a failure condition that would prevent the continued safe flight and landing of the airplane.

Issued in Renton, Washington, on January 9, 2003.

Ali Bahrami,

Assistant Director, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 03–2422 Filed 1–31–03; 8:45 am]

BILLING CODE 4910–13–P

SOCIAL SECURITY ADMINISTRATION

20 CFR Parts 404 and 416

[Regulations Nos. 4 and 16]

RIN 0960–AE97

Federal Old-Age, Survivors and Disability Insurance and Supplemental Security Income for the Aged, Blind, and Disabled; Administrative Review Process; Video Teleconferencing Appearances Before Administrative Law Judges of the Social Security Administration

AGENCY: Social Security Administration (SSA).

ACTION: Final rules with request for comment.

SUMMARY: We are revising our rules to allow us to conduct hearings before administrative law judges (ALJs) at which a party or parties to the hearing and/or a witness or witnesses may appear before the ALJ by video teleconferencing (VTC). The revised rules provide that if we schedule your hearing as one at which you would appear by VTC, rather than in person, and you object to use of that procedure, we will reschedule your hearing as one at which you may appear in person before the ALJ. These revisions will provide us with greater flexibility in scheduling and holding hearings, improve hearing process efficiency, and extend another service delivery option to individuals requesting a hearing. Although we are issuing these rules as final rules, we are also requesting comments on a provision of the rules that involves a significant change from the proposed rules we previously published concerning our use of VTC.

DATES: These rules are effective March 5, 2003. To be sure your comments are considered, we must receive them by April 4, 2003.

ADDRESSES: You may give us your comments by using our Internet site facility (*i.e.*, Social Security Online) at *http://www.ssa.gov/regulations;* by e-mail to *http://www.regulations@ssa.gov;* by telefax to (410) 966–2830; or by letter to the Commissioner of Social Security, PO Box 17703, Baltimore, MD 21235–7703. You may also deliver them to the Office of Process and Innovation Management, Social Security Administration, L2109 West Low Rise Building, 6401 Security Boulevard, Baltimore, MD 21235–6401 between 8 a.m. and 4:30 p.m. on regular business days. Comments are posted on our internet site, or you may inspect them physically on regular business days by making arrangements with the contact person shown below.

FOR FURTHER INFORMATION CONTACT: Martin Sussman, Regulations Officer, Social Security Administration, Office of Regulations, 100 Altmeyer Building, 6401 Security Boulevard, Baltimore, MD 21235–6401, (410) 965–1767 or TTY 1–800–966–5906, for information about this notice. For information on eligibility or filing for benefits, call our national toll-free number, 1–800–772–1213 or TTY 1–800–325–0778, or visit our Internet site, Social Security Online, at *http://www.ssa.gov.*

SUPPLEMENTARY INFORMATION:

Background

Nationally, over 500,000 requests for a hearing before an ALJ are filed with us each year. Hearings have traditionally been held with all participants (the party(ies) to the hearing, the ALJ, any representative(s) appointed by the party(ies), any witness(es), any translator(s), and any other persons whom the ALJ considers necessary or proper to the hearing) present at the same location: either a hearing office or a remote hearing site. ALJs hold

hearings at remote hearing sites, which are generally at least 75 miles from a hearing office, to accommodate those individuals who do not live near a hearing office.

Approximately 40 percent of hearings are held at remote hearing sites.

To make travel to remote hearing sites as cost effective as possible, hearing offices wait until they have a sufficient number of requests for hearing to schedule a full day or, if travel to a remote hearing site requires an overnight stay, several days of hearings. Because of the need to accrue a docket, ALJs travel to some remote hearing sites infrequently. Because many remote hearing sites are in less-populous areas, it can be difficult to find a needed medical and/or vocational expert witness(es) to travel to these sites, and this difficulty may further delay scheduling a hearing. ALJs also travel from their assigned hearing offices to assist other hearing offices when the need arises.

Whether to conduct hearings at remote sites or assist other hearing offices, the time ALJs spend traveling could be used to perform other adjudicatory responsibilities.

In 1996 we published Social Security Ruling (SSR) 96–10p, Electronic Service Delivery (61 FR 68808, December 30 1996). In SSR 96–10p, we explained that we planned to explore ways for claimants to interact with us electronically. We also explained that we would not require claimants to work with us electronically, but that we would use technology to provide options for different service deliveries. VTC was one of the technologies we identified as having the potential to improve claimant service. VTC provides real-time transmission of audio and video between two or more locations and permits individuals to see, hear, and speak with each other as though they were at the same location.

As we explained in the Notice of Proposed Rulemaking (NPRM) that we published concerning these rules (66 FR 1059, January 5, 2001), we decided to propose conducting hearings by VTC based on testing conducted in the State of Iowa that demonstrated that VTC procedures can be effectively used where large scale, high quality VTC networks exist and claimants want to participate in VTC procedures because doing so reduces the distances they must travel to their hearings. In reaching that decision, we considered and discounted the results at two other test sites, Albuquerque-El Paso and Huntington-Prestonburg, because the tests at those sites offered no travel benefits to the claimants and resulted in low participation rates.

In the testing of VTC that we have been conducting since 1996 in the State of Iowa, which has a large VTC network, no one electing use of VTC procedures has had to travel more than about 20 miles from his or her home to have a hearing, and the travel typically required of claimants currently is only about 5 miles. The rate of claimant participation in the Iowa test currently exceeds 95 percent; that is, over 95 percent of the claimants offered a hearing using VTC procedures agree to the use of those procedures.

In a survey of participants in the Iowa test, a large percentage of the respondents rated hearings using VTC procedures as ''convenient'' or ''very convenient,'' and overall service as either ''good'' or ''very good.'' Test data showed that processing time for these hearings was substantially less than for hearings conducted in person at remote sites during the same time period, and that the ratio of hearings held to hearings scheduled was significantly higher for hearings using VTC procedures than for hearings conducted in person. Being able to hold hearings as scheduled increases our efficiency because we do not have to recontact the individual to determine why he or she did not appear at a scheduled hearing nor reschedule the hearing (which can be time consuming, especially when an expert witness(es) has been scheduled to testify). Further, an ALJ does not spend time waiting for someone who does not appear, as would be the case in a hearing conducted in person at a remote site.

Based on all these factors—claimant satisfaction, ability to provide more timely hearings, savings in ALJ travel time, faster case processing, and higher ratio of hearings held to hearings scheduled—we decided that conducting hearings by VTC is an efficient service delivery alternative. We also decided that scheduling a hearing for use of VTC, rather than asking someone to elect a hearing using VTC, as we have been doing in our testing of VTC, would improve hearing office efficiency and would permit us to provide faster access to a hearing for some individuals.

We plan to begin using VTC facilities in the servicing area of a hearing office when the Associate Commissioner for Hearings and Appeals determines that appearances at hearings conducted in the area can be conducted more efficiently by VTC than in person. We foresee initially scheduling VTC appearances where absent use of VTC:

- We would need to accrue a docket for a remote hearing site.
- An ALJ would need to travel to assist another hearing office.
- An expert witness(es) or appropriate medical specialist(s) would not be available for a hearing site. (In such a case, all participants could be at different locations; for example, the ALJ at a hearing office, the individual at a remote hearing site or another hearing office, and the expert witness(es) at a third location.)

At first, we plan to locate most remote sites for using VTC to conduct appearances either in space where we have a long-term lease or in another federal building. We are investigating sharing VTC facilities with other federal agencies and states, and, if we can ensure privacy, we may eventually rent commercial space to expand use of VTC as a service delivery option. Calling into SSA's VTC network from private facilities, such as facilities owned by a law firm, may also be possible. Regardless of the type of facility, we will make certain that:

- The individual has the same access to the hearing record when appearing by VTC as he or she would have if appearing in person before the ALJ.
- There is a means of transmitting and receiving additional evidence between all locations and all participants.
- An assistant is present at the VTC site to operate the equipment and provide other help, as required.
- The audio/video transmission is secure and the individual's privacy is protected.

We will follow the same procedures for audiotaping hearings that we conduct using VTC that we do for hearings where all the participants appear in person. We have no plans to videotape hearings in which a party or a witness appears by VTC. Should there be a problem with the VTC equipment, before or during a hearing, we will reschedule the hearing as we do now when unforeseen circumstances require us to reschedule a hearing: at the earliest time possible based on the request for hearing filing date.

We reserve the right not to schedule an appearance by VTC for someone who asks to appear by VTC. In many locations, especially in the near term, we may not have the capability to accommodate the request, and the ALJ may determine that an appearance must be conducted in person even where VTC capability exists. As access to VTC expands, we will generally accommodate requests to appear by VTC as space and time permit.

Despite the fact that conducting hearings by VTC has the potential to improve service, we will not require any

individual to appear at his or her hearing by VTC if the individual objects to that procedure at the earliest possible opportunity before the time scheduled for the hearing. Under these final rules, if a party so objects to making his or her appearance by VTC, we will reschedule the hearing as one at which the individual may appear in person.

When we reschedule a hearing because a party objects to making his or her appearance by VTC, we will reschedule the hearing at the earliest time possible based on the request for hearing filing date. Where necessary, to expedite the rescheduling, we will give the party the opportunity to appear in person at the hearing office or any other hearing site within the service area of the hearing office at which we are first able to schedule a hearing. The party's travel expenses to the remote site or to the hearing office, and the travel expenses of his or her appointed representative, if any, and the travel expenses of any unsubpoenaed witnesses we determine to be reasonably necessary, will be reimbursed in accordance with the provisions of 20 CFR 404.999a–404.999d and 416.1495–416.1499.

To ensure that a party fully understands the right to decline to appear by VTC, a notice scheduling an individual to appear at his or her hearing by VTC will clearly state:

- What it means to appear by VTC;
- That we have scheduled the individual's appearance to be by VTC;
- That we will schedule a hearing at which the individual may appear in person if the individual tells us that he or she does not want to appear by VTC; and
- How to tell us that.

We will evaluate hearings using VTC procedures to ensure that there is no significant difference in the outcome of hearings conducted using VTC and those conducted in person and that we maintain a high degree of accuracy in decisions made based on hearings using VTC. We will also ensure that individuals:

- Understand that they are not required to appear at their hearings by VTC;
- Know how to tell us if they do not want to appear by VTC;
- Receive a full and fair hearing; and
- Are satisfied with the VTC process in relation to their appearance and the appearances of any witnesses.

The Final Regulations

We are revising 20 CFR 404.929 and 416.1429 to state that you may appear at your hearing in person or by VTC. We are revising 20 CFR 404.936 and 416.1436 to state that we may schedule your appearance or that of any individual appearing at the hearing to be by VTC and that, if we schedule you to appear by VTC and you tell us that you want to appear in person, we will schedule a hearing at which you may appear in person. We are revising 20 CFR 404.938 and 416.1438 to state that if we schedule you or anyone to appear at your hearing by VTC, the notice of hearing will tell you that and provide information about VTC appearances and about how you can tell us that you do not want to appear by VTC. Finally, we are revising 20 CFR 404.950(a) and (e) and 416.1450(a) and (e) to state that a party or a witness may appear at a hearing in person or by VTC.

Public Comments

We published these regulatory provisions in the **Federal Register** as an NPRM on January 5, 2001 (66 FR 1059). We provided the public with a 60-day comment period. In response to the NPRM, we received seven comment letters from the following sources: the Railroad Retirement Board (RRB), the Disability Law Center, the National Organization of Social Security Claimants Representatives, the Association of Administrative Law Judges, and seven ALJs commenting as individuals.

Because some of the comments were detailed, we have condensed, summarized, or paraphrased them below. However, we have tried to summarize commenters' views accurately and to respond to all of the significant issues raised by the commenters that were within the scope of the proposed rules.

Based on our consideration of the comments received, we have made a number of changes in the rules as proposed in the NPRM. We have also made a number of decisions about administrative practices we will follow in using VTC procedures. We discuss our response to each of the comments below.

In the NPRM we spoke of ''VTC hearings'' and ''in-person hearings'' as a way of distinguishing easily between hearings at which VTC procedures are used and those at which all the participants are at the same location. The public comments received reflected our use of that language (see below) without raising any specific issue about it. However, from our general consideration of the comments and further evaluation of the use of VTC procedures, we have concluded that we should not rely on language that could erroneously suggest that there are two types of hearings and should instead use language that reflects the fact that all claimants are afforded an opportunity for one type of hearing—*i.e.*, a hearing at which the claimant's rights to procedural due process, including the right to appear and present evidence, are fully protected. Speaking of hearings as either ''in-person'' or ''VTC'' hearings would also not accurately reflect the circumstances of hearings in which some of the participants appear before the ALJ in person and some appear by VTC.

The distinctions between hearings at which all of the participants are at the same location and hearings at which some or all of the involved individuals participate by VTC are secondary distinctions. The distinctions involve the manner in which the parties and the witnesses make their appearances before the ALJ (*i.e.*, in person or by VTC), not fundamental differences that cause the hearings to be of different types. We reflect that view in the description of the final rules set forth above, in the discussion of our responses to the comments, and in specific changes we are making in the final rules. However, our comment summaries are couched in the terms we used in the NPRM.

We further discuss these revisions, and other changes in the final rules that are not in direct response to the comments, following the discussion of our responses to the comments. *See* below under the heading, *Additional Changes*.

Comment: The RRB commented that it was very pleased to see SSA's proposal. The RRB also indicated that it would be interested in determining the feasibility of its hearing officers using the VTC facilities of SSA on a fee basis to conduct some of its hearings—to reduce the significant travel in which the RRB is required to engage to conduct its hearings.

Response: As we noted above and in the NPRM, we are investigating whether we can share facilities with other federal agencies and states. We will pursue discussions with the RRB in that regard.

Comment: One organization commented that when claimants who need hearings at a remote site want to exercise their right to an in-person hearing, they will probably face even longer waits for their hearings, and that SSA must take steps to minimize the delays these claimants will face.

Response: In considering this comment, we have concluded that frequent use of VTC procedures in a remote area could delay the hearings of individuals in that area who do not want to appear by VTC. That is the case because the participation of other individuals in VTC procedures will

eliminate some or most of the pending hearings that could go to make up a complete docket for an ALJ trip to the affected remote site.

To ensure claimants in areas of high VTC usage a meaningful option to appear in person, we will make it our practice in those areas to afford claimants who do not want to appear by VTC the opportunity to appear in person either at the hearing office (where hearings are held without need to accumulate ALJ travel dockets), or at any remote site in the hearing office's service area (including, but not limited to, the designated remote site for the claimant's place of residence). We will schedule a hearing where the claimant may appear in person at the earliest possible time based on the filing date of the claimant's request for hearing; election of the option to appear in person will not cause the claimant to lose his or her place in the queue of individuals awaiting entry into the process for scheduling hearings.

In following these practices, we will apply our normal rules for reimbursing the travel expenses that claimants, their representatives, and any unsubpoenaed witnesses incur in traveling to the hearing office or to any remote site in the service area for hearings (*see* §§ 404.999a–404.999d and 416.1495–416.1499). A claimant's decision not to accept a scheduled appearance by VTC will not prevent reimbursement of travel expenses under §§ 404.999c(d)(4) and 416.1498(d)(4).

Comment: An organization commented that choice of hearing sites should be explained at an early, informal conference, and that the choice should be deferred where a claimant wants to appoint a representative. The commenter noted that ensuring that claimants make an informed choice of hearing site would further SSA's goal of reducing the rescheduling of hearings.

Response: In areas in which the Associate Commissioner for Hearings and Appeals has determined that hearings can be conducted more efficiently using VTC than by having appearances made in person, it will be our practice in our pre-hearing activities to provide claimants with information about VTC procedures and an opportunity to ask questions about and to state a preference for or against use of those procedures.

When the ALJ determines that a case is ready to be scheduled for hearing and sets the time and place of the hearing, the ALJ will also decide whether the claimant's appearance should be scheduled to occur by VTC or in person. In doing that, the ALJ will consider any stated preference of the claimant or the representative for or against appearing by VTC, as well as the availability of VTC technology and any other factors, such as a claimant's loss of visual and auditory capacities, that may affect how the appearance should be conducted.

When we issue a notice of hearing advising a claimant that his or her appearance has been scheduled to be by VTC, the claimant will then have an absolute right to decline to appear by VTC, irrespective of any preference he or she may have previously stated in this regard, and to choose to appear in person, under the practices on rescheduling and use of in-person appearance sites that we have described above. A timely statement by the claimant of any objection to appearing by VTC or of a desire to appear in person will constitute good cause for rescheduling the claimant's appearance to be in person (*see* §§ 404.936(e) and 416.1436(e) as revised in these final rules).

Our policy of giving claimants their option to decline to appear by VTC after issuance of the notice of hearing is designed to promote the effective use of VTC procedures while also maintaining a meaningful option for claimants who want to appear in person. We believe that claimants will carefully consider whether they should exercise this option since doing so could delay the occurrence of their hearings, even under the rescheduling and site-usage practices we have described above for expediting the rescheduling of hearings to allow in-person appearances. We believe this policy will help to ensure that VTC procedures will be frequently used where available and, thus, that these procedures will be effective in improving the overall efficiency of the hearings process, even though some hearings will have to be rescheduled because claimants decide against appearing by VTC. We believe the policy is warranted with respect to the individuals affected because the option of appearing by VTC will allow them to have their hearings before an ALJ in the shortest possible time.

Comment: An ALJ commented that claimants should not be given the option of demanding an in-person hearing instead of a VTC hearing. The commenter's reasoning was that VTC either is or is not in accord with due process and, if it is (as this commenter believes), the claimant has no legal basis for insisting on in-person proceedings. The commenter further contended that giving this option would be based, not on a legal right, but on an attempt to accommodate the claimant's preferences, and that mere preferences should be outweighed by the costs to the Agency and the public of accommodating those preferences for a hearing in a more costly forum. The commenter reported that it was his impression—based on pre-ALJ experience with use of VTC in criminal proceedings—that the participants in proceedings conducted by VTC paid little attention to the medium once the proceedings began. In this commenter's view, there is no legitimate reason to object to VTC procedures and many less than legitimate reasons for preferences against those procedures, including judge shopping and claimant discomfort at being ''on TV.''

Response: We believe that the hearing proceedings we conduct by VTC will be fundamentally fair and that they will fully protect the claimant's right to procedural due process. However, as explained below, there are sound reasons for assuring that all claimants retain an opportunity to appear in person at their hearings. Preserving that opportunity for claimants is also consistent with our general policy, as explained in SSR 96–10p, of using technology to provide claimants an optional way of communicating with us.

That certain procedures will provide due process does not mean that there are no legal issues to consider regarding those procedures. Use of VTC technology in administrative hearings is relatively new. In these final rules, we are interpreting the word ''hearing'' as used in sections 205(b)(1) and 1631(c)(1)(A) of the Social Security Act (the Act) to include hearings at which the claimant will appear by VTC, a technology that was not available when these statutes were created, as well as hearings at which the claimant appears in person before the ALJ. Our earliest regulations interpreting the hearing provisions of the Act specified that the claimant had a right to request a hearing ''before'' the decisionmaker (20 CFR 403.707, 1940), and our current regulations specify that claimants may appear ''in person'' at the hearing (20 CFR 404.929 and 416.1429), and that they have a ''right to appear before the administrative law judge, either personally or by means of a designated representative * * *'' (20 CFR 404.950(a) and 416.1450(a)). Therefore, we believe it is legally prudent to ensure that all claimants retain the opportunity to appear in person.

Claimant credibility is an important issue in many of our hearings, and some claimants may have strong opinions about whether they can best project their own credibility by appearing in person as opposed to appearing by VTC. Preserving an option for claimants to appear in person should increase their

comfort level in appearing by VTC and help to ensure that they perceive the hearing process as fair. The satisfaction of claimants with their hearing experiences is, of course, an important consideration in the administration of the Social Security hearings process.

It is also important that we try to ensure that preferences against appearing by VTC do not undermine the effectiveness with which we are able to use VTC, as could happen if such preferences frequently caused claimants to decline to appear by VTC. However, we believe we should pursue that end by promoting and continually improving the claimant-service advantages of VTC while also preserving the opportunity of claimants to appear in person.

Comment: An organization stated that we should guarantee the right of claimants to an in-person hearing to the extent of allowing the claimant to withdraw consent to participate in VTC proceedings even up to the point of arriving at the VTC site (because they may not realize that they do not want to proceed with a VTC appearance until they arrive at the site), and by ensuring that claimants do not lose their place in queue if they decline (or withdraw consent for) a VTC hearing.

Response: Under the provisions of §§ 404.936 and 416.1436, as they currently exist and as revised when these final rules become effective, claimants who object to the time or place of the hearing are required to ''notify the [ALJ] at the earliest possible opportunity before the time set for the hearing.'' Under our existing provisions on dismissing requests for hearing based on failure to appear at a scheduled hearing, a request for hearing may be dismissed if a claimant does not appear at the scheduled hearing and has not given the ALJ, before the time set for the hearing, a good reason why he or she cannot appear at the scheduled hearing. (*See* §§ 404.957(b) and 416.1457(b), which we are not revising.) Under the above provisions, a claimant who has been scheduled to appear by VTC may establish good cause for changing the time or place of the hearing by notifying the ALJ at the earliest possible opportunity before the time set for the hearing that he or she has an objection to appearing by VTC. The notice of hearing will advise the claimant of that requirement. A timely statement by the claimant of any objection to appearing by VTC will cause the ALJ to find that there is good cause to change the time and place of the scheduled hearing and to reschedule the hearing for a time and place at which the claimant may appear in person (*see* §§ 404.936(e) and 416.1436(e)). No hard and fast rule for the latest time for a claimant to object to appearing by VTC may be set because many different factors (including the delayed appointment of a representative who opposes participation in VTC) could affect whether the claimant has notified the ALJ of his or her objection at the earliest possible time. In addition, as we discussed above, claimants who decide to decline to appear by VTC will not lose their place in the queue of individuals awaiting hearings.

Comment: An organization commented that while VTC hearings have the potential to be an improvement over some in-person hearings (such as those conducted in hotel rooms), there are concerns and we should not schedule a VTC hearing and require the claimant to respond affirmatively to choose an in-person hearing. This commenter noted that many claimants with mental impairments, cognitive limits, low education, and communication limitations will have difficulty understanding and responding to the notice.

Response: As discussed above, we believe that the policy of generally requiring claimants to take action to opt out of a scheduled appearance by VTC will be administratively beneficial and otherwise warranted. For the reasons set forth below, we also believe that the policy of generally requiring claimants affirmatively to decline to appear by VTC will not involve any significant risks for claimants, including those individuals who do not have an appointed representative and who may have mental, educational, and linguistic limitations—

- Hearing office staff will have provided claimants with information concerning their options for how they may appear at the hearing during the pre-hearing case preparation that occurs before the notice of hearing is issued;
- The ALJ will have discretion to prevent issuance of a notice scheduling a claimant to appear by VTC in instances in which the ALJ concludes that there are circumstances that make it necessary not to have the claimant appear by VTC;
- The notices of hearing used to schedule claimants to appear by VTC will explain VTC procedures and the option to appear in person in clear, easily understood language; and
- The claimant will be able to opt out of appearing by VTC merely by stating a desire not to appear in that way or a desire to appear in person.

Comment: An organization of individuals who represent claimants in proceedings before us reported that it generally supported the proposed rules and the use of VTC hearings, so long as the right to a full and fair hearing is adequately protected and the quality of VTC hearings is ensured. This organization reported that its members had had mixed experiences with the VTC tests and noted that while a member who had experience with one VTC hearing was dissatisfied with the quality of the VTC transmission (which was not sufficient to allow the ALJ to perceive shortness of breath and sweating experienced by the claimant), another member who had represented several hundred claimants in the Iowa test now preferred VTC to in-person hearings because of the calming effect that VTC procedures had on his clients, the reduction in claimant travel, and the quality of VTC facilities. This organization offered the general comment that its members could be expected not to encourage their clients to participate in VTC hearings if there is no travel advantage and the quality of the hearing experience is inadequate.

Response: We believe that providing high quality VTC facilities and travel advantages for claimants who use VTC services will be of critical importance in ensuring the active cooperation of claimant representatives in encouraging their clients to use those services. We will not achieve our goals in implementing VTC procedures unless claimant representatives support their use. For that reason, and because providing claimants high quality hearing experiences with as little inconvenience to them as reasonably possible is inherently part of our overall mission, we intend to ensure that our VTC facilities are of high quality and that the travel claimants are required to undertake to attend their hearings is reduced by participation in our VTC services. The Associate Commissioner for Hearings and Appeals will consider those factors in determining whether a service area should be designated as ready for VTC use.

Comment: An organization commented that we should establish procedures to ensure that files can be reviewed and that additional evidence is associated with the file. The organization noted that problems have occurred in these respects at in-person, remote-site hearings, especially where the hearing is conducted by a visiting ALJ, and these problems would also exist in VTC hearings.

Response: As we stated in the NPRM, we will make certain that claimants participating in VTC procedures will have the ''same access'' to the hearing record as individuals not participating in those procedures. It is our intent in this regard to ensure that claimants who

make in-person appearances and those who participate in VTC procedures will have equal and sufficient access to the record. The sufficiency of record access in an area will be one of the factors the Associate Commissioner for Hearings and Appeals considers in deciding whether to declare an area ready for use of VTC procedures.

Comment: While only one of the ALJs who commented on the NPRM opposed the proposal to give claimants the right to choose not to have their hearings conducted by VTC, all but one of the commenting ALJs strongly opposed the proposal to allow claimants to veto the use of VTC to conduct the appearances of vocational experts (VEs) and medical experts (MEs). (The comments of the remaining ALJ dealt with matters that were not within the scope of the NPRM.) The ALJs who opposed this provision included five ALJs who conducted hearings in the Iowa test and the Association of Administrative Law Judges.

The reasons offered for opposing this proposal included that it would defeat the purpose of using VTC as a way to obtain expert testimony when it is impractical for the expert to appear in person, and that it could force ALJs to forgo needed testimony or to take testimony through the time consuming and unwieldy method of written interrogatories. Concern was expressed that the right to veto the appearance of an expert by VTC could be used to prevent the taking of expert testimony that might be adverse to the claimant and to facilitate ''expert shopping.'' It was pointed out that claimants can already object to witnesses based on bias or qualifications. The view was also expressed that due process is fully accorded to the claimant if the claimant can see and cross-examine the expert and confront the expert with documentary evidence.

The ALJs who commented based on their experience in the Iowa test strongly emphasized the practical problems that allowing claimants to veto having an expert testify by VTC would cause. These ALJs stated that using VTC to take the testimony of VEs is necessary to utilize these experts effectively because the cost of a VE's appearance can be reduced if, as is possible using VTC procedures, a docket of multiple appearances can be arranged for the expert. They also emphasized the value of VTC in reducing the problems involved in scheduling hearings, citing the example of how much easier it is to make arrangements for one VE to appear by VTC in four hearings occurring on a given day at four different sites than it is to arrange for four VEs to make in-person appearances, at odd times in their workdays, at four sites.

The ALJs involved in the Iowa test further emphasized that the practical problems in not using VTC to take VE testimony are greatly compounded when it comes to securing the testimony of MEs. They reported that it is only through VTC that they are able to provide ME testimony for hearings being held in remote sites, and that MEs will not travel to remote sites when it is technically possible to testify in hearings being held at such sites via VTC. These ALJs also reported that it was their experience that it is almost impossible to get MEs to testify in the larger urban areas where the hearing offices are located, and that it is sometimes necessary to rely on MEs testifying from the medical centers in Ames and Iowa City even in cases being heard in the West Des Moines area.

Response: In considering this comment, we have concluded that claimants should not be empowered to veto use of VTC to take the testimony of expert witnesses. Therefore, we have deleted from §§ 404.938 and 416.1438 the proposed provisions that would have given claimants that power. Because this represents a significant change from the proposed rule, we have decided to offer an additional opportunity for public comment on this provision.

Under these final rules, decisions as to whether hearings will be conducted with a witness or witnesses appearing by VTC will be made by the ALJ. The claimant may state objections to a witness appearing by VTC, just as they may state objections to any aspect of the hearing, and they may object to a witness on the basis of perceived bias or lack of expertise. However, a claimant's objection to a witness appearing by VTC will not prevent use of VTC for the appearance, unless the ALJ determines that the claimant's objection is based on a circumstance that warrants having the witness appear in person.

The analysis of the commenting ALJs concerning the impracticalities of giving claimants veto power over the medium whereby expert witnesses make their appearance has caused us to reevaluate our proposal in that regard. We believe these commenters are correct in indicating that giving claimants that power would undermine one of the primary practical benefits of using VTC procedures and adversely impact our ability to use those procedures effectively to improve the hearings process. The commenters also effectively emphasize the significance of the positive practical benefits that can flow from relying on VTC procedures in scheduling and conducting the appearances of expert witnesses.

An important point made in this comment is that implementation of VTC procedures reduces the readiness of experts to travel to remote sites. This is a result that might be expected logically, we believe, and the experience of the ALJs in the Iowa test bears out its occurrence.

Unless we ensure ALJ authority to use VTC to take expert testimony by not empowering claimants to veto its use for that purpose, the reduced readiness of expert witnesses to travel when VTC appearances are technologically possible will adversely affect our ability to preserve a reasonable opportunity for claimants to appear in person if they choose to opt out of scheduled appearances by VTC. If the authority of ALJs to secure expert testimony by VTC is not ensured, the reduced willingness of experts to travel when VTC technology is available could also reduce the efficiency with which we are able to schedule the appearances of experts at the hearings of individuals who live near hearing offices in urban areas and appear in person in those offices for their hearings.

MEs and VEs testify as impartial witnesses. They testify based on the evidence entered into the record and not based on any examination or personal evaluation of the claimant. Where they testify by VTC and their testimony is adverse to a party's claim, the party and his or her representative, if any, will have a complete opportunity to confront and examine the witness regarding the matters that are important with respect to expert testimony—*i.e.*, the expertise of the witness and the accuracy of his or her testimony.

Affording claimants the power to veto the appearance of expert witnesses by VTC would be inconsistent with our existing practices and instructions regarding use of interrogatories to secure the testimony of expert witnesses. While emphasizing the preferability of securing live testimony where feasible, and requiring the ALJ to consider and rule on any claimant objection to the use of interrogatories, our instructions do not mandate non-use of interrogatories merely because a claimant objects to their use. *See* Hearings, Appeals and Litigation Law Manual (HALLEX), sections I–2–530, I–2–542, and I–2–557. Thus, allowing claimants to veto the live testimony that experts can give by VTC would invest claimants with an authority that they do not currently have with respect to interrogatories.

Under these final rules, ALJs will have discretion to determine that the

appearance of any individual must be conducted in person. Thus, to the extent that circumstances could arise in which it would be advisable to schedule an in-person appearance by an expert witness even though a VTC appearance would be possible technologically, the ALJ may schedule such an appearance. That action could be appropriate, for example, where the claimant alleges personal bias or dishonesty on the part of the expert and the ALJ determines that the claimant should have the opportunity to cross-examine the witness in person because of the greater immediacy of an in-person confrontation.

Comment: An organization commented that the ALJ has exclusive control over the way hearings are conducted, so long as they are fundamentally fair and comport with requirements of due process, and such authority necessarily implies authority to settle disputes concerning the appropriate form of a hearing in a particular case. This commenter was concerned that the proposed rules did not expressly reflect the authority of ALJs to determine if a hearing will be conducted wholly or in part by VTC, and that the lack of clarity of these rules in this regard could lead to confusion and litigation.

Response: We agree that the proposed rules were unclear in this respect. In §§ 404.936 and 416.1436, the final rules clearly reflect the authority of the ALJ to determine how hearings are conducted with respect to the use of VTC to conduct appearances, while also setting forth specific policies that direct how that authority is to be exercised.

In paragraph (c) of §§ 404.936 and 416.1436, the final rules provide that in setting the time and place of the hearing, the ALJ will determine if the appearance of the claimant or that of any other individual who is to appear at the hearing will be made in person or by VTC. Determining the medium by which appearances will be made is part of the ALJ's function of setting the time and place of the hearing because determining the hearing's ''place'' requires consideration of whether VTC technology will be used to conduct an appearance or appearances. See below under *Additional Changes* regarding the definition of ''place'' included in the final rules.

The final rules include provisions in paragraph (c) of §§ 404.936 and 416.1436 that require the ALJ to direct that the appearance of an individual be conducted by VTC if VTC technology is available to conduct the appearance, use of VTC to conduct the appearance would be more efficient than conducting the appearance in person, and the ALJ does not determine that there is a circumstance preventing use of VTC to conduct the appearance. In setting these guidelines, it is our intent that ALJs routinely schedule appearances by VTC in areas that we have designated as ready for VTC use. An appearance in person should be scheduled in these areas only if the ALJ determines that there is a circumstance in the particular case that would make it inappropriate to use VTC in that case.

The final rules also include provisions requiring the ALJ to find good cause to change a scheduled VTC appearance of a party to an in-person appearance if the party objects to appearing by VTC. These provisions are located in paragraph (e) of §§ 404.936 and 416.1436.

Comment: An organization commented that VTC hearings have not been shown to equal the quality and accuracy of in-person hearings and that national rollout should await the study referenced in the NPRM to ensure that claimants have access to full and fair hearings.

Response: We anticipate that we will gradually rollout use of VTC procedures nationally as we are able to make high-quality VTC technology available in different areas. Under that approach, claimants and the hearing process will be able to benefit from VTC technology as soon as it is available, and we will be able to improve our VTC procedures as we move toward full national implementation.

Based on our experience in using VTC, we believe that VTC does not change adjudicative quality or change decisional outcomes. We will continue to assess the results of VTC procedures as we go forward. We will consider the accuracy and efficiency of VTC procedures and the reactions of claimants and their representatives to those procedures.

Additional Changes

Our decision not to use terminology referring to a hearing as a ''video teleconference hearing'' or an ''in-person hearing,'' and to use instead language that distinguishes between appearances made in-person and by VTC, has resulted in editorial changes throughout the rules as proposed in the NPRM. These changes include eliminating the phrase ''and type of hearing'' from the proposed heading for §§ 404.936 and 416.1436. In the final rules, that heading reads, as it does in the current rules: ''Time and place for a hearing before an administrative law judge.''

To facilitate this change in terminology, and to address a question that the proposed rules did not address, we have included in §§ 404.936 and 416.1436 language defining the term ''place.'' Under these final rules, generally, the ''place'' of the hearing is the hearing office or other site at which claimant is located when he or she makes his or her appearance before the administrative law judge, whether in person or by video teleconferencing. If there are multiple parties, the ''place'' of the hearing is the site or sites at which the parties are located when they make their appearances, whether in person or by VTC. That will be the ''place'' of the hearing even though the ALJ and a witness or witnesses may be located at one or more other sites. Thus, in notifying claimants of the ''place'' of their hearings, we will notify them, under these final rules as under our current rules, of the places at which they should arrive in order to make their appearances.

The rules as proposed were unclear regarding the function of the ALJ in setting the time and place of the hearing. We have clarified the rules in this regard by changing the final rules to use the language of the current regulations, which specifies that the ''[ALJ] sets the time and place for the hearing.'' Use of the existing language is possible based on the definition of ''place'' noted above.

These final rules provide needed headings for the multiple paragraphs of §§ 404.936 and 416.1436. In doing that, the final rules distinguish the ''General'' material in current paragraph (a) from the matter included therein on where we hold hearings, and move the matter dealing with location into a separate, new paragraph (b) that has the heading, ''Where we hold hearings.'' The rules include the definition of ''place'' in that paragraph.

The final rules also create a new paragraph (c) under the heading, ''Determining how appearance will be made.'' This paragraph sets forth the rules, as discussed above, under which, in setting the time and place for the hearing, the ALJ determines if an appearance or appearances are to be made by VTC or in person. We have also included in this paragraph a reference to §§ 404.950 and 416.1450, which describe procedures under which parties to the hearing and witnesses appear and present evidence at hearings.

Paragraph (b) of the current regulations is redesignated paragraph (d) and given the heading, ''Objecting to the time or place of the hearing.'' The language of this paragraph follows the

language of current paragraph (b). For reasons previously discussed, paragraph (d) of the final rules does not include, as the comparable language of the proposed rules did, language distinguishing between the ''site and/or time'' of a ''video teleconference hearing'' and the ''time and/or place'' of an ''in person hearing.''

The claimant's right to veto his or her appearance by VTC by objecting to it is established in paragraph (e) of §§ 404.936 and 416.1436 of the final rules. The heading for this paragraph is, ''Good Cause for changing the time or place.'' Paragraph (e) of the final rules follows the language of paragraph (c) of the current rules except for the additions at the beginning of the paragraph that describe both the right of a claimant to object if he or she is scheduled to appear by VTC at the place of the hearing, and the required reaction of the ALJ to such an objection. Those additions make it clear that there is no evidentiary requirement that the claimant must satisfy in establishing this ''good cause'' condition (such as exists regarding the other ''good cause'' conditions described in the paragraph). Nor is there any requirement that the claimant state a reason for objecting to appearing by VTC beyond his or her wish not to do so.

The power of the claimant to veto a VTC appearance pertains in these final rules (with request for comment) only to his or her own appearance, not to the appearances of any other party or witness. The decision made in these final rules not to distinguish between hearings as ''in-person hearings'' or ''VTC hearings'' makes it possible to preserve the right of claimants to control the manner of their own appearances without expanding that right to include control over the manner in which other individuals make their appearances at the hearing.

The heading assigned to the last paragraph of §§ 404.936 and 416.1436 in the final rules, paragraph (f), is, ''Good cause in other circumstances.'' The language of this paragraph follows the language of paragraph (d) of the current §§ 404.936 and 416.1436.

The final rules make a number of changes in the sections of the regulations that deal with the notice of hearing before an administrative law judge, §§ 404.938 and 416.1438. In the current regulations, these sections consist of a single paragraph that includes material that deals with the issuance of notices, information included in notices, and acknowledgment of the notice of hearing. In the proposed rules, this material was placed in a paragraph (a) with the heading, ''General notice information.'' The proposed rules also added a new paragraph (b) with the heading, ''Hearing via video teleconferencing [,]'' which included material about the scheduling of a ''[VTC] hearing'' and information included in notices of such hearings. The proposed rules also added a new paragraph (c) with the heading, ''For a hearing before an [ALJ,]'' which discussed the scheduling of an ''in-person hearing.'' In these final rules, paragraph (a) deals with the issuance of notices and has the heading, ''Issuing the notice.'' Paragraph (b) deals with information contained in notices, including notices that schedule an appearance or appearances by VTC, and has the heading, ''Notice information.'' Paragraph (c) deals with acknowledgment of the notice of hearing and has the heading, ''Acknowledging the notice of hearing.''

The language of the final rules follows the language of the current rules, except as regards the notice information pertaining to use of VTC procedures and acknowledgment of receipt of the notice of hearing. Paragraph (b) states that the claimant will be told if his or her appearance or that of any other party or witness is scheduled to be made by VTC rather than in person. If we have scheduled the claimant to appear at the hearing by VTC, the notice of hearing will also tell the claimant that the scheduled place for the hearing is a teleconferencing site and explain what it means to appear at the hearing by VTC. The notice will also tell the claimant how to object to appearing by VTC and how to request a hearing at a place for appearing in person. In paragraph (c), the information provided by the current rules regarding acknowledgement of receipt of the notice of hearing is expanded to include a statement explaining that the notice will ask the claimant to return a form acknowledging receipt of the notice. It has long been our practice to include an acknowledgement form with the notice of hearing. We plan to modify the current form to include a check block that claimants may use to object to appearing by VTC.

The final rules also make conforming changes in §§ 404.950 and 416.1450. In paragraph (a) of these sections, we specify that claimants may appear before the ALJ either in person or by VTC, and that if the claimant's appearance is made by a designated representative, the representative may appear in person or by VTC. In paragraph (e) of these sections, we specify that witnesses may appear at a hearing in person or by VTC.

Additional Comments

We invite your comments on the issue of whether claimants should or should not be empowered to veto use of VTC to take the testimony of expert witnesses. Comments may be submitted by the date and to the addresses shown above.

Electronic Version

The electronic file of this document is available on the Internet at *http://www.access.gpo.gov/su docs/aces/aces140.html*. It is also available on the Internet site for SSA (*i.e.*, SSA Online) at *http://www.ssa.gov/regulations*.

Regulatory Procedures

Executive Order 12866, As Amended by Executive Order 13258

The Office of Management and Budget (OMB) has reviewed these rules in accordance with Executive Order 12866, as amended by Executive Order 13258.

Regulatory Flexibility Act

We certify that these rules will not have a significant economic impact on a substantial number of small entities as they affect individuals only. Therefore, a regulatory flexibility analysis as provided in the Regulatory Flexibility Act, as amended, is not required.

Paperwork Reduction Act

These final rules contain reporting requirements as shown in the table below. Where the public reporting burden is accounted for in Information Collection Requests for the various forms that the public uses to submit the information to SSA, a 1-hour placeholder burden is being assigned to the specific reporting requirement(s) contained in these rules; we are seeking clearance of the burdens referenced in these rules because the rules were not considered during the clearance of the forms.

Section	Annual number of resonses	Frequency of response	Average burden per response (minutes)	Estimated annual burden (hours)
404.929	1	1	1	1
404.936(d), (e) & (f)	92,000	Once	10	15,333
404.938(c)	300,000	Once	1	5,000
404.950(a)	210,000	Once	30	105,000
416.1429	1	1	1	1
416.1436(d), (e) & (f)	75,000	Once	10	12,500
416.1438(c)	250,000	Once	1	4,166
416.1450(a)	172,000	Once	30	86,000
Total	1,099,002			228,001

An Information Collection Request has been submitted to OMB for clearance. While these rules will be effective 30 days from publication, these burdens will not be effective until cleared by OMB. We are soliciting comments on the burden estimate; the need for the information; its practical utility; ways to enhance its quality, utility and clarity; and on ways to minimize the burden on respondents, including the use of automated collection techniques or other forms of information technology. We will publish a notice in the **Federal Register** upon OMB's approval of the information collection requirement(s). Comments should be submitted to the OMB desk officer for SSA within 30 days of publication of this final rule at the following address: Office of Management and Budget, Attn: Desk Officer for SSA, New Executive Office Building, Room 10230, 725 17th St., NW., Washington, DC 20530.

(Catalog of Federal Domestic Assistance Program Nos. 96.001, Social Security—Disability Insurance; 96.002, Social Security—Retirement Insurance; 96.003, Social Security—Special Benefits for Persons Aged 72 and Over; 96.004, Social Security—Survivors Insurance; 96.006, Supplemental Security Income.)

List of Subjects

20 CFR 404

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

20 CFR 416

Administrative practice and procedure, Aged, Blind, Disability benefits, Public assistance programs, Reporting and recordkeeping requirements, Supplemental Security Income (SSI).

Dated: October 25, 2002.

Jo Anne B. Barnhart,

Commissioner of Social Security.

For the reasons set out in the preamble, subpart J of part 404 and subpart N of part 416 of chapter III of title 20 of the Code of Federal Regulations are amended as set forth below:

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

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

Authority: Secs. 201(j), 204(f), 205(a), (b), (d)–(h), and (j), 221, 225, and 702(a)(5) of the Social Security Act (42 U.S.C. 401(j), 404(f), 405(a), (b), (d)–(h), and (j), 421, 425, and 902(a)(5)); 31 U.S.C. 3720A; sec. 5, Pub. L. 97–455, 96 Stat. 2500 (42 U.S.C. 405 note); secs. 5, 6(c)–(e), and 15, Pub. L. 98–460, 98 Stat. 1802 (42 U.S.C. 421 note).

2. Section 404.929 is revised to read as follows:

§ 404.929 Hearing before an administrative law judge—general.

If you are dissatisfied with one of the determinations or decisions listed in § 404.930 you may request a hearing. The Associate Commissioner for Hearings and Appeals, or his or her delegate, shall appoint an administrative law judge to conduct the hearing. If circumstances warrant, the Associate Commissioner, or his or her delegate, may assign your case to another administrative law judge. At the hearing you may appear in person or by video teleconferencing, submit new evidence, examine the evidence used in making the determination or decision under review, and present and question witnesses. The administrative law judge who conducts the hearing may ask you questions. He or she shall issue a decision based on the hearing record. If you waive your right to appear at the hearing, either in person or by video teleconferencing, the administrative law judge will make a decision based on the evidence that is in the file and any new evidence that may have been submitted for consideration.

3. Section 404.936 is revised to read as follows:

§ 404.936 Time and place for a hearing before an administrative law judge.

(a) *General.* The administrative law judge sets the time and place for the hearing. He or she may change the time and place, if it is necessary. After sending you reasonable notice of the proposed action, the administrative law judge may adjourn or postpone the hearing or reopen it to receive additional evidence any time before he or she notifies you of a hearing decision.

(b) *Where we hold hearings.* We hold hearings in the 50 States, the District of Columbia, American Samoa, Guam, the Northern Mariana Islands, the Commonwealth of Puerto Rico and the Virgin Islands. The ''place'' of the hearing is the hearing office or other site(s) at which you and any other parties to the hearing are located when you make your appearance(s) before the administrative law judge, whether in person or by video teleconferencing.

(c) *Determining how appearances will be made.* In setting the time and place of the hearing, the administrative law judge determines whether your appearance or that of any other individual who is to appear at the hearing will be made in person or by video teleconferencing. The administrative law judge will direct that the appearance of an individual be conducted by video teleconferencing if video teleconferencing technology is available to conduct the appearance, use of video teleconferencing to conduct the appearance would be more efficient than conducting the appearance in person, and the administrative law judge does not determine that there is a circumstance in the particular case preventing use of video teleconferencing to conduct the appearance. Section 404.950 sets forth procedures under which parties to the hearing and witnesses appear and present evidence at hearings.

(d) *Objecting to the time or place of the hearing.* If you object to the time or place of your hearing, you must notify the administrative law judge at the earliest possible opportunity before the time set for the hearing. You must state the reason for your objection and state the time and place you want the hearing to be held. If at all possible, the request should be in writing. The administrative law judge will change the time or place of the hearing if you have good cause, as determined under paragraph (e) and (f) of this section. Section 404.938 provides procedures we will follow when you do not respond to a notice of hearing.

(e) *Good cause for changing the time or place.* If you have been scheduled to appear by video teleconferencing at the place of your hearing and you notify the ALJ as provided in paragraph (d) of this section that you object to appearing in that way, the administrative law judge will find your wish not to appear by video teleconferencing to be a good reason for changing the time or place of your scheduled hearing and will reschedule your hearing for a time and place at which you may make your appearance before the administrative law judge in person. The administrative law judge will also find good cause for changing the time or place of your scheduled hearing, and will reschedule your hearing, if your reason is one of the following circumstances and is supported by the evidence:

(1) You or your representative are unable to attend or to travel to the scheduled hearing because of a serious physical or mental condition, incapacitating injury, or death in the family; or

(2) Severe weather conditions make it impossible to travel to the hearing.

(f) *Good cause in other circumstances.* In determining whether good cause exists in circumstances other than those set out in paragraph (e) of this section, the administrative law judge will consider your reason for requesting the change, the facts supporting it, and the impact of the proposed change on the efficient administration of the hearing process. Factors affecting the impact of the change include, but are not limited to, the effect on the processing of other scheduled hearings, delays which might occur in rescheduling your hearing, and whether any prior changes were granted to you. Examples of such other circumstances, which you might give for requesting a change in the time or place of the hearing, include, but are not limited to, the following:

(1) You have attempted to obtain a representative but need additional time;

(2) Your representative was appointed within 30 days of the scheduled hearing and needs additional time to prepare for the hearing;

(3) Your representative has a prior commitment to be in court or at another administrative hearing on the date scheduled for the hearing;

(4) A witness who will testify to facts material to your case would be unavailable to attend the scheduled hearing and the evidence cannot be otherwise obtained;

(5) Transportation is not readily available for you to travel to the hearing;

(6) You live closer to another hearing site; or

(7) You are unrepresented, and you are unable to respond to the notice of hearing because of any physical, mental, educational, or linguistic limitations (including any lack of facility with the English language) which you may have.

4. Section 404.938 is revised to read as follows:

§ 404.938 Notice of a hearing before an administrative law judge.

(a) *Issuing the notice.* After the administrative law judge sets the time and place of the hearing, we will mail notice of the hearing to you at your last known address, or give the notice to you by personal service, unless you have indicated in writing that you do not wish to receive this notice. The notice will be mailed or served at least 20 days before the hearing.

(b) *Notice information.* The notice of hearing will contain a statement of the specific issues to be decided and tell you that you may designate a person to represent you during the proceedings. The notice will also contain an explanation of the procedures for requesting a change in the time or place of your hearing, a reminder that if you fail to appear at your scheduled hearing without good cause the ALJ may dismiss your hearing request, and other information about the scheduling and conduct of your hearing. You will also be told if your appearance or that of any other party or witness is scheduled to be made by video teleconferencing rather than in person. If we have scheduled you to appear at the hearing by video teleconferencing, the notice of hearing will tell you that the scheduled place for the hearing is a teleconferencing site and explain what it means to appear at your hearing by video teleconferencing. The notice will also tell you how you may let us know if you do not want to appear in this way and want, instead, to have your hearing at a time and place where you may appear in person before the ALJ.

(c) *Acknowledging the notice of hearing.* The notice of hearing will ask you to return a form to let us know that you received the notice. If you or your representative do not acknowledge receipt of the notice of hearing, we will attempt to contact you for an explanation. If you tell us that you did not receive the notice of hearing, an amended notice will be sent to you by certified mail. *See* § 404.936 for the procedures we will follow in deciding whether the time or place of your scheduled hearing will be changed if you do not respond to the notice of hearing.

5. In § 404.950, paragraphs (a) and (e) are revised to read as follows:

§ 404.950 Presenting evidence at a hearing before an administrative law judge.

(a) *The right to appear and present evidence.* Any party to a hearing has a right to appear before the administrative law judge, either in person or, when the conditions in § 404.936(c) exist, by video teleconferencing, to present evidence and to state his or her position. A party may also make his or her appearance by means of a designated representative, who may make the appearance in person or by video teleconferencing.

* * * * *

(e) *Witnesses at a hearing.* Witnesses may appear at a hearing in person or, when the conditions in § 404.936(c) exist, by video teleconferencing. They shall testify under oath or affirmation, unless the administrative law judge finds an important reason to excuse them from taking an oath or affirmation. The administrative law judge may ask the witnesses any questions material to the issues and shall allow the parties or their designated representatives to do so.

* * * * *

PART 416—SUPPLEMENTAL SECURITY INCOME FOR THE AGED, BLIND, AND DISABLED

6. The authority citation for subpart N of part 416 continues to read as follows:

Authority: Secs. 702(a)(5), 1631, and 1633 of the Social Security Act (42 U.S.C. 902(a)(5), 1383, and 1383b); 31 U.S.C. 3720A.

7. Section 416.1429 is revised to read as follows:

§ 416.1429 Hearing before an administrative law judge—general.

If you are dissatisfied with one of the determinations or decisions listed in § 416.1430 you may request a hearing. The Associate Commissioner for Hearings and Appeals, or his or her delegate, shall appoint an

administrative law judge to conduct the hearing. If circumstances warrant, the Associate Commissioner, or his or her delegate, may assign your case to another administrative law judge. At the hearing you may appear in person or by video teleconferencing, submit new evidence, examine the evidence used in making the determination or decision under review, and present and question witnesses. The administrative law judge who conducts the hearing may ask you questions. He or she shall issue a decision based on the hearing record. If you waive your right to appear at the hearing, either in person or by video teleconferencing, the administrative law judge will make a decision based on the evidence that is in the file and any new evidence that may have been submitted for consideration.

8. Section 416.1436 is revised to read as follows:

§ 416.1436 Time and place for a hearing before an administrative law judge.

(a) *General.* The administrative law judge sets the time and place for the hearing. He or she may change the time and place, if it is necessary. After sending you reasonable notice of the proposed action, the administrative law judge may adjourn or postpone the hearing or reopen it to receive additional evidence any time before he or she notifies you of a hearing decision.

(b) *Where we hold hearings.* We hold hearings in the 50 States, the District of Columbia, and the Northern Mariana Islands. The ''place'' of the hearing is the hearing office or other site(s) at which you and any other parties to the hearing are located when you make your appearance(s) before the administrative law judge, whether in person or by video teleconferencing.

(c) *Determining how appearances will be made.* In setting the time and place of the hearing, the administrative law judge determines whether your appearance or that of any other individual who is to appear at the hearing will be made in person or by video teleconferencing. The administrative law judge will direct that the appearance of an individual be conducted by video teleconferencing if video teleconferencing technology is available to conduct the appearance, use of video teleconferencing to conduct the appearance would be more efficient than conducting the appearance in person, and the administrative law judge does not determine that there is a circumstance in the particular case preventing use of video teleconferencing to conduct the appearance. Section 416.1450 sets forth procedures under which parties to the hearing and witnesses appear and present evidence at hearings.

(d) *Objecting to the time or place of the hearing.* If you object to the time or place of your hearing, you must notify the administrative law judge at the earliest possible opportunity before the time set for the hearing. You must state the reason for your objection and state the time and place you want the hearing to be held. If at all possible, the request should be in writing. The administrative law judge will change the time or place of the hearing if you have good cause, as determined under paragraph (e) and (f) of this section. Section 416.1438 provides procedures we will follow when you do not respond to a notice of hearing.

(e) *Good cause for changing the time or place.* If you have been scheduled to appear by video teleconferencing at the place of your hearing and you notify the ALJ as provided in paragraph (d) of this section that you object to appearing in that way, the administrative law judge will find your wish not to appear by video teleconferencing to be a good reason for changing the time or place of your scheduled hearing and will reschedule your hearing for a time and place at which you may make your appearance before the administrative law judge in person. The administrative law judge will also find good cause for changing the time or place of your scheduled hearing, and will reschedule your hearing, if your reason is one of the following circumstances and is supported by the evidence:

(1) You or your representative are unable to attend or to travel to the scheduled hearing because of a serious physical or mental condition, incapacitating injury, or death in the family; or

(2) Severe weather conditions make it impossible to travel to the hearing.

(f) *Good cause in other circumstances.* In determining whether good cause exists in circumstances other than those set out in paragraph (e) of this section, the administrative law judge will consider your reason for requesting the change, the facts supporting it, and the impact of the proposed change on the efficient administration of the hearing process. Factors affecting the impact of the change include, but are not limited to, the effect on the processing of other scheduled hearings, delays which might occur in rescheduling your hearing, and whether any prior changes were granted to you. Examples of such other circumstances, which you might give for requesting a change in the time or place of the hearing, include, but are not limited to, the following:

(1) You have attempted to obtain a representative but need additional time;

(2) Your representative was appointed within 30 days of the scheduled hearing and needs additional time to prepare for the hearing;

(3) Your representative has a prior commitment to be in court or at another administrative hearing on the date scheduled for the hearing;

(4) A witness who will testify to facts material to your case would be unavailable to attend the scheduled hearing and the evidence cannot be otherwise obtained;

(5) Transportation is not readily available for you to travel to the hearing;

(6) You live closer to another hearing site; or

(7) You are unrepresented, and you are unable to respond to the notice of hearing because of any physical, mental, educational, or linguistic limitations (including any lack of facility with the English language) which you may have.

9. Section 416.1438 is revised to read:

§ 416.1438 Notice of a hearing before an administrative law judge.

(a) *Issuing the notice.* After the administrative law judge sets the time and place of the hearing, we will mail notice of the hearing to you at your last known address, or give the notice to you by personal service, unless you have indicated in writing that you do not wish to receive this notice. The notice will be mailed or served at least 20 days before the hearing.

(b) *Notice information.* The notice of hearing will contain a statement of the specific issues to be decided and tell you that you may designate a person to represent you during the proceedings. The notice will also contain an explanation of the procedures for requesting a change in the time or place of your hearing, a reminder that if you fail to appear at your scheduled hearing without good cause the ALJ may dismiss your hearing request, and other information about the scheduling and conduct of your hearing. You will also be told if your appearance or that of any other party or witness is scheduled to be made by video teleconferencing rather than in person. If we have scheduled you to appear at the hearing by video teleconferencing, the notice of hearing will tell you that the scheduled place for the hearing is a teleconferencing site and explain what it means to appear at your hearing by video teleconferencing. The notice will also tell you how you may let us know if you do not want to appear in this way and want, instead, to have your hearing at a time and place where you may appear in person before the ALJ.

(c) *Acknowledging the notice of hearing.* The notice of hearing will ask you to return a form to let us know that you received the notice. If you or your representative do not acknowledge receipt of the notice of hearing, we will attempt to contact you for an explanation. If you tell us that you did not receive the notice of hearing, an amended notice will be sent to you by certified mail. *See* § 416.1436 for the procedures we will follow in deciding whether the time or place of your scheduled hearing will be changed if you do not respond to the notice of hearing.

10. In § 416.1450, paragraphs (a) and (e) are revised to read as follows:

§ 416.1450 Presenting evidence at a hearing before an administrative law judge.

(a) *The right to appear and present evidence.* Any party to a hearing has a right to appear before the administrative law judge, either in person or, when the conditions in § 416.1436(c) exist, by video teleconferencing, to present evidence and to state his or her position. A party may also make his or her appearance by means of a designated representative, who may make the appearance in person or by video teleconferencing.

* * * * *

(e) *Witnesses at a hearing.* Witnesses may appear at a hearing in person or, when the conditions in § 416.1436(c) exist, video teleconferencing. They shall testify under oath or affirmation, unless the administrative law judge finds an important reason to excuse them from taking an oath or affirmation. The administrative law judge may ask the witnesses any questions material to the issues and shall allow the parties or their designated representatives to do so.

* * * * *

[FR Doc. 03–2402 Filed 1–31–03; 8:45 am]

BILLING CODE 4191–02–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[AL–200311; FRL–7444–7]

Approval and Promulgation of Air Quality Implementation Plans; Alabama Update to Materials Incorporated by Reference

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule; notice of administrative change.

SUMMARY: EPA is updating the materials submitted by Alabama that are incorporated by reference (IBR) into the State implementation plan (SIP). The regulations affected by this update have been previously submitted by the State agency and approved by EPA. This update affects the SIP materials that are available for public inspection at the Office of the Federal Register (OFR), Office of Air and Radiation Docket and Information Center, and the Regional Office.

EFFECTIVE DATE: This action is effective February 3, 2003.

ADDRESSES: SIP materials which are incorporated by reference into 40 CFR part 52 are available for inspection at the following locations: Environmental Protection Agency, Region 4, 61 Forsyth Street, SW., Atlanta, GA 30303; Office of Air and Radiation Docket and Information Center, Room B–108, 1301 Constitution Avenue, (Mail Code 6102T) NW., Washington, DC 20460, and Office of the Federal Register, 800 North Capitol Street, NW., Suite 700, Washington, DC.

FOR FURTHER INFORMATION CONTACT: Mr. Sean Lakeman at the above Region 4 address or at (404) 562–9043.

SUPPLEMENTARY INFORMATION: The SIP is a living document which the State can revise as necessary to address the unique air pollution problems in the state. Therefore, EPA from time to time must take action on SIP revisions containing new and/or revised regulations as being part of the SIP. On May 22, 1997 (62 FR 27968), EPA revised the procedures for incorporating by reference Federally-approved SIPs, as a result of consultations between EPA and OFR. The description of the revised SIP document, IBR procedures and ''Identification of plan'' format are discussed in further detail in the May 22, 1997, **Federal Register** document. On December 22, 1998, EPA published a document in the **Federal Register** (63 FR 70669) beginning the new IBR procedure for Alabama. In this document EPA is doing the update to the material being IBRed.

EPA has determined that today's rule falls under the ''good cause'' exemption in section 553(b)(3)(B) of the Administrative Procedures Act (APA) which, upon finding ''good cause,'' authorizes agencies to dispense with public participation and section 553(d)(3) which allows an agency to make a rule effective immediately (thereby avoiding the 30-day delayed effective date otherwise provided for in the APA). Today's rule simply codifies provisions which are already in effect as a matter of law in Federal and approved State programs. Under section 553 of the APA, an agency may find good cause where procedures are ''impractical, unnecessary, or contrary to the public interest.'' Public comment is ''unnecessary'' and ''contrary to the public interest'' since the codification only reflects existing law. Immediate notice in the CFR benefits the public by updating citations.

Statutory and Executive Order Reviews

Under Executive Order 12866 (58 FR 51735, October 4, 1993), this action is not a ''significant regulatory action'' and therefore is not subject to review by the Office of Management and Budget. For this reason, this action is also not subject to Executive Order 13211, ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001). This action merely approves state law as meeting Federal requirements and imposes no additional requirements beyond those imposed by state law. Accordingly, the Administrator certifies that this rule will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). Because this rule approves pre-existing requirements under state law and does not impose any additional enforceable duty beyond that required by state law, it does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4).

This rule also does not have tribal implications because it will not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal government and Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes, as specified by Executive Order 13175 (65 FR 67249, November 9, 2000). This action also does not have federalism implications because it does not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132 (64 FR 43255, August 10, 1999). This action merely approves a state rule implementing a Federal standard, and does not alter the relationship or the distribution of power and responsibilities established in the Clean Air Act. This rule also is not subject to Executive Order 13045 ''Protection of Children from Environmental Health Risks and Safety

Risks'' (62 FR 19885, April 23, 1997), because it is not economically significant.

In reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the Clean Air Act. In this context, in the absence of a prior existing requirement for the State to use voluntary consensus standards (VCS), EPA has no authority to disapprove a SIP submission for failure to use VCS. It would thus be inconsistent with applicable law for EPA, when it reviews a SIP submission, to use VCS in place of a SIP submission that otherwise satisfies the provisions of the Clean Air Act. Thus, the requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) do not apply. This rule does not impose an information collection burden under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

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

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by April 4, 2003. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (*See* section 307(b)(2).)

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Carbon monoxide, Incorporation by reference, Intergovernmental relations, Lead, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements, Sulfur oxides, Volatile organic compounds.

Dated: January 16, 2003.

A. Stanley Meiburg,

Acting Regional Administrator, Region 4.

Chapter I, title 40, Code of Federal Regulations, is amended as follows:

PART 52—[AMENDED]

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

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

Subpart B—Alabama

2. Section 52.50 paragraph (b), (c), (d) and (e) are revised to read as follows:

§ 52.50 Identification of plan.

* * * * *

(b) Incorporation by reference.

(1) Material listed in paragraph (c) and (d) of this section with an EPA approval date prior to January 1, 2003, was approved for incorporation by reference by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Material is incorporated as it exists on the date of the approval, and notice of any change in the material will be published in the **Federal Register**. Entries in paragraphs (c) and (d) of this section with EPA approval dates after January 1, 2003, will be incorporated by reference in the next update to the SIP compilation.

(2) EPA Region 4 certifies that the rules/regulations provided by EPA in the SIP compilation at the addresses in paragraph (b)(3) of this section are an exact duplicate of the officially promulgated State rules/regulations which have been approved as part of the State implementation plan as of January 1, 2003.

(3) Copies of the materials incorporated by reference may be inspected at the Region 4 EPA Office at 61 Forsyth Street, SW., Atlanta, GA 30303; the Office of the Federal Register, 800 North Capitol Street, NW., Suite 700, Washington, DC; or at the EPA, Office of Air and Radiation Docket and Information Center, Room B–108, 1301 Constitution Avenue, (Mail Code 6102T) NW., Washington, DC 20460.

(c) EPA approved Alabama regulations.

EPA APPROVED ALABAMA REGULATIONS

State citation	Title/subject	State effective date	EPA approval date	Explanation
Chapter No. 335–3–1 General Provision				
Section 335–3–1–.01	Purpose	06/22/89	03/19/90 55 FR 10062	
Section 335–3–1–.02	Definitions	08/10/00	12/08/00 65 FR 76940	
Section 335–3–1–.03	Ambient Air Quality Standards	10/13/98	03/01/99 64 FR 9918	
Section 335–3–1–.04	Monitoring, Records, and Reporting	10/15/96	06/06/97 62 FR 30991	
Section 335–3–1–.05	Sampling and Test Methods	06/22/89	03/19/90 55 FR 10062	
Section 335–3–1–.06	Compliance Schedule	10/15/96	06/06/97 62 FR 30991	
Section 335–3–1–.07	Maintenance and Malfunctioning of Equipment; Reporting	10/15/89	03/19/90 55 FR 10062	
Section 335–3–1–.08	Prohibition of Air Pollution	08/10/00	12/08/00 65 FR 76940	
Section 335–3–1–.09	Variances	10/15/96	06/06/97 62 FR 30991	

EPA APPROVED ALABAMA REGULATIONS—Continued

State citation	Title/subject	State effective date	EPA approval date	Explanation
Section 335–3–1–.10	Circumvention	06/22/89	03/19/90 55 FR 10062	
Section 335–3–1–.11	Severability	10/15/96	06/06/97 62 FR 30991	
Section 335–3–1–.12	Bubble Provision	06/22/89	03/19/90 55 FR 10062	
Section 335–3–1–.13	Credible Evidence	04/13/99	11/03/99 64 FR 59633	
Section 335–3–1–.14	Emissions Reporting Requirements Relating to Budgets for NO_x Emissions.	04/06/01	07/16/01 66 FR 36921	
Chapter No. 335–3–2 Air Pollution Emergency				
Section 335–3–2–.01	Air Pollution Emergency	06/22/89	03/19/90 55 FR 10062	
Section 335–3–2–.02	Episode Criteria	08/10/00	12/08/00 65 FR 76940	
Section 335–3–2–.03	Special Episode Criteria	06/22/89	03/19/90 55 FR 10062	
Section 335–3–2–.04	Emission Reduction Plans	06/22/89	03/19/90 55 FR 10062	
Section 335–3–2–.05	Two Contaminant Episode	06/22/89	03/19/90 55 FR 10062	
Section 335–3–2–.06	General Episodes	06/22/89	03/19/90 55 FR 10062	
Section 335–3–2–.07	Local Episodes	06/22/89	03/19/90 55 FR 10062	
Section 335–3–2–.08	Other Sources	10/15/96	06/06/97 62 FR 30991	
Section 335–3–2–.09	Other Authority Not Affected	06/22/89	03/19/90 55 FR 10062	
Chapter No. 335–3–3 Control of Open Burning and Incineration				
Section 335–3–3–.01	Open Burning	08/10/00	12/08/00 65 FR 76940	
Section 335–3–3–.02	Incinerators	06/22/89	03/19/90 55 FR 10062	
Section 335–3–3–.03	Incineration of Wood, Peanut, and Cotton Ginning Waste	08/10/00	12/08/00 65 FR 76940	
Chapter No. 335–3–4 Control of Particulate Emissions				
Section 335–3–4–.01	Visible Emissions	10/15/96	06/06/97 62 FR 30991	
Section 335–3–4–.02	Fugitive Dust and Fugitive Emissions	10/15/96	06/06/97 62 FR 30991	
Section 335–3–4–.03	Fuel Burning Equipment	10/15/96	06/06/97 62 FR 30991	
Section 335–3–4–.04	Process Industries—General	10/15/96	06/06/97 62 FR 30991	
Section 335–3–4–.05	Small Foundry Cupola	06/22/89	03/19/90 55 FR 10062	
Section 335–3–4–.06	Cotton Gins	06/22/89	03/19/90 55 FR 10062	
Section 335–3–4–.07	Kraft Pulp Mills	10/15/96	06/06/97 62 FR 30991	
Section 335–3–4–.08	Wood Waste Boilers	08/10/00	12/08/00 65 FR 76940	
Section 335–3–4–.09	Coke Ovens	08/10/00	12/08/00 65 FR 76940	
Section 335–3–4–.10	Primary Aluminum Plants	06/22/89	03/19/90 55 FR 10062	
Section 335–3–4–.11	Cement Plants	10/15/96	06/06/97 62 FR 30991	
Section 335–3–4–.12	Xylene Oxidation Process	06/22/89	03/19/90 55 FR 10062	
Section 335–3–4–.13	Sintering Plants	06/22/89	03/19/90 55 FR 10062	

EPA APPROVED ALABAMA REGULATIONS—Continued

State citation	Title/subject	State effective date	EPA approval date	Explanation
Section 335–3–4–.14	Grain Elevators	10/15/96	06/06/97 62 FR 30991	
Section 335–3–4–.15	Secondary Lead Smelters	10/15/96	06/06/97 62 FR 30991	
Section 335–3–4–.17	Steel Mills Located in Etowah County	10/15/96	06/06/97 62 FR 30991	
Chapter No. 335–3–5 Control of Sulfur Compound Emissions				
Section 335–3–5–.01	Fuel Combustions	10/15/96	06/06/97 62 FR 30991	
Section 335–3–5–.02	Sulfuric Acid Plants	10/15/96	06/06/97 62 FR 30991	
Section 335–3–5–.03	Petroleum Production	08/10/00	12/08/00 65 FR 76940	
Section 335–3–5–.04	Kraft Pulp Mills	08/10/00	12/08/00 65 FR 76940	
Section 335–3–5–.05	Process Industries—General	06/22/89	03/19/90 55 FR 10062	
Chapter No. 335–3–6 Control of Organic Emissions				
Section 335–3–6–.01	Applicability	10/15/96	06/06/97 62 FR 30991	
Section 335–3–6–.02	VOC Water Separation	06/22/89	03/19/90 55 FR 10062	
Section 335–3–6–.03	Loading and Storage of VOC	06/22/89	03/19/90 55 FR 10062	
Section 335–3–6–.04	Fixed-Roof Petroleum Liquid Storage Vessels	10/15/96	06/06/97 62 FR 30991	
Section 335–3–6–.05	Bulk Gasoline Plants	10/15/96	06/06/97 62 FR 30991	
Section 335–3–6–.06	Bulk Gasoline Terminals	08/10/00	12/08/00 65 FR 76940	
Section 335–3–6–.07	Gasoline Dispensing Facilities—Stage I	10/15/96	06/06/97 62 FR 30991	
Section 335–3–6–.08	Petroleum Refinery Sources	06/22/89	03/19/90 55 FR 10062	
Section 335–3–6–.09	Pumps and Compressors	06/22/89	03/19/90 55 FR 10062	
Section 335–3–6–.10	Ethylene Producing Plants	06/22/89	03/19/90 55 FR 10062	
Section 335–3–6–.11	Surface Coating	10/15/96	06/06/97 62 FR 30991	
Section 335–3–6–.12	Solvent Metal Cleaning	10/15/96	06/06/97 62 FR 30991	
Section 335–3–6–.13	Cutback Asphalt	10/15/96	06/06/97 62 FR 30991	
Section 335–3–6–.14	Petition for Alternative Controls	06/22/89	03/19/90 55 FR 10062	
Section 335–3–6–.15	Compliance Schedules	10/15/96	06/06/97 62 FR 30991	
Section 335–3–6–.16	Test Methods and Procedures	08/10/00	12/08/00 65 FR 76940	
Section 335–3–6–.17	Manufacture of Pneumatic Tires	10/15/95	06/06/97 62 FR 30991	
Section 335–3–6–.18	Manufacture of Synthesized Pharmaceutical Products	10/15/96	06/06/97 62 FR 30991	
Section 335–3–6–.19	Reserved	.....		
Section 335–3–6–.20	Leaks from Gasoline Tank Trucks and Vapor Collection Systems.	10/15/96	06/06/97 62 FR 30991	
Section 335–3–6–.21	Leaks from Petroleum Refinery Equipment	10/15/96	06/06/97 62 FR 30991	
Section 335–3–6–.22	Graphic Arts	10/15/96	06/06/97 62 FR 30991	
Section 335–3–6–.23	Petroleum Liquid Storage in External Floating Roof Tanks	10/15/96	06/06/97 62 FR 30991	
Section 335–3–6–.24	Applicability	10/15/96	06/06/97 62 FR 30991	

EPA APPROVED ALABAMA REGULATIONS—Continued

State citation	Title/subject	State effective date	EPA approval date	Explanation
Section 335–3–6–.25	VOC Water Separation	06/22/89	03/19/90 55 FR 10062	
Section 335–3–6–.26	Loading and Storage of VOC	06/22/89	03/19/90 55 FR 10062	
Section 335–3–6–.27	Fixed-Roof Petroleum Liquid Storage Vessels	10/15/96	06/06/97 62 FR 30991	
Section 335–3–6–.28	Bulk Gasoline Plants	10/15/96	06/06/97 62 FR 30991	
Section 335–3–6–.29	Gasoline Terminals	10/15/96	06/06/97 62 FR 30991	
Section 335–3–6–.30	Gasoline Dispensing Facilities Stage I	10/15/96	06/06/97 62 FR 30991	
Section 335–3–6–.31	Petroleum Refinery Sources	06/22/89	03/19/90 55 FR 10062	
Section 335–3–6–.32	Surface Coating	10/15/96	06/06/97 62 FR 30991	
Section 335–3–6–.33	Solvent Metal Cleaning	06/22/89	03/19/90 55 FR 10062	
Section 335–3–6–.34	Cutback Asphalt	10/15/96	06/06/97 62 FR 30991	
Section 335–3–6–.35	Petition for Alternative Controls	06/22/89	03/19/90 55 FR 10062	
Section 335–3–6–.36	Compliance Schedules	10/15/96	06/06/97 62 FR 30991	
Section 335–3–6–.37	Test Methods and Procedures	10/15/96	06/06/97 62 FR 30991	
Section 335–3–6–.38	Manufacture of Pneumatic Tires	06/22/89	03/19/90 55 FR 10062	
Section 335–3–6–.39	Manufacture of Synthesized Pharmaceutical Products	10/15/96	06/06/97 62 FR 30991	
Section 335–3–6–.40	Reserved	.....		
Section 335–3–6–.41	Leaks from Gasoline Tank Trucks and Vapor Collection Systems.	10/15/96	06/06/97 62 FR 30991	
Section 335–3–6–.42	Leaks from Petroleum Refinery Equipment	10/15/96	06/06/97 62 FR 30991	
Section 335–3–6–.43	Graphic Arts	06/22/89	03/19/90 55 FR 10062	
Section 335–3–6–.44	Petroleum Liquid Storage in External Floating Roof Tanks	10/15/96	06/06/97 62 FR 30991	
Section 335–3–6–.45	Large Petroleum Dry Cleaners	10/15/96	06/06/97 62 FR 30991	
Section 335–3–6–.46	Aerospace Assembly and Component and Component Coatings Operation.	06/22/89	03/19/09 55 FR 10062	
Section 335–3–6–.47	Leaks from Coke by-Product Recovery Plant Equipment	10/15/96	06/06/97 62 FR 30991	
Section 335–3–6–.48	Emissions from Coke by-Product Recovery Plant Coke Oven Gas Bleeder.	10/15/96	06/06/97 62 FR 30991	
Section 335–3–6–.49	Manufacture of Laminated Countertops	06/22/89	03/19/90 55 FR 10062	
Section 335–3–6–.50	Paint Manufacture	10/15/96	06/06/97 62 FR 30991	
Section 335–3–6–.53	List of EPA Approved and Equivalent Test Methods and Procedures for the Purpose of Determining VOC Emissions.	06/26/91	09/27/91 58 FR 50262	
Chapter No. 335–3–7 Carbon Monoxide Emissions				
Section 335–3–7–.01	Metals Productions	06/22/89	03/19/90 55 FR 10062	
Section 335–3–7–.02	Petroleum Processes	06/22/89	03/19/90 55 FR 10062	
Chapter No. 335–3–8 Nitrogen Oxides Emissions				
Section 335–3–8–.01	Standards for Portland Cement Kilns	04/06/01	07/17/01 66 FR 36921	
Section 335–3–8–.02	Nitric Acid Manufacturing	10/15/96	06/06/97 62 FR 30991	
Section 335–3–8–.03	NO_X Emissions from Electric Utility Generating Units	10/24/00	11/07/01 66 FR 56223	

EPA APPROVED ALABAMA REGULATIONS—Continued

State citation	Title/subject	State effective date	EPA approval date	Explanation
Section 335–3–8–.04	Standards for Stationary Reciprocating Internal Combustion Engines (Reserved).	04/06/01	07/17/01 66 FR 36921	
Section 335–3–8–.05	NO_X Budget Trading Program	04/06/01	07/17/01 66 FR 36921	
Section 335–3–8–.06	Authorized Account Representative for NO_X Budget Sources	04/06/01	07/17/01 66 FR 36921	
Section 335–3–8–.07	Permits	04/06/01	07/17/01 66 FR 36921	
Section 335–3–8–.08	Compliance Certification	04/06/01	07/17/01 66 FR 36921	
Section 335–3–8–.09	NO_X Allowance Allocations	04/06/01	07/17/01 66 FR 36921	
Section 335–3–8–.10	NO_X Allowance Tracking System	04/06/01	07/17/01 66 FR 36921	
Section 335–3–8–.11	NO_X Allowance Transfers	04/06/01	07/17/01 66 FR 36921	
Section 335–3–8–.12	Monitoring and Reporting	04/06/01	07/17/01 66 FR 36921	
Section 335–3–8–.13	Individual Unit Opt-ins	05/07/02	07/17/01 66 FR 36921	
Section 335–3–8–.14	New Combustion Sources	04/06/01	07/17/01 66 FR 36921	
Chapter No. 335–3–9 Control Emissions From Motor Vehicles				
Section 335–3–9–.01	Visible Emission Restriction for Motor Vehicles	10/15/96	06/06/97 62 FR 30991	
Section 335–3–9–.02	Ignition System and Engine Speed	08/10/00	12/08/00 65 FR 76940	
Section 335–3–9–.03	Crankcase Ventilation Systems	08/10/00	12/08/00 65 FR 76940	
Section 335–3–9–.04	Exhaust Emission Control Systems	06/22/89	03/19/90 55 FR 10062	
Section 335–3–9–.05	Evaporative Loss Control Systems	06/22/89	03/19/90 55 FR 10062	
Section 335–3–9–.06	Other Prohibited Acts	08/10/00	12/08/00 65 FR 76940	
Section 335–3–9–.07	Effective Date	10/15/96	06/06/97 62 FR 30991	
Chapter No. 335–3–12 Continuous Monitoring Requirements for Existing Sources				
Section 335–3–12–.01	General	06/22/89	03/19/90 55 FR 10062	
Section 335–3–12–.02	Emission Monitoring and Reporting Requirements	02/17/98	09/14/98 63 FR 49005	
Section 335–3–12–.03	Monitoring System Malfunction	06/22/89	03/19/90 55 FR 10062	
Section 335–3–12–.04	Alternate Monitoring and Reporting Requirements	06/22/89	03/19/90 55 FR 10062	
Section 335–3–12–.05	Exemptions and Extensions	06/22/89	03/19/90 55 FR 10062	
Chapter No. 335–3–13 Control of Fluoride Emissions				
Section 335–3–13–.01	General	10/15/96	06/06/97 62 FR 30991	
Section 335–3–13–.02	Superphosphoric Acid Plants	10/15/96	06/06/97 62 FR 30991	
Section 335–3–13–.03	Diammonium Phosphate Plants	10/15/96	06/06/97 62 FR 30991	
Section 335–3–13–.04	Triple Superphosphoric Plants	10/15/96	06/06/97 62 FR 30991	
Section 335–3–13–.05	Granular Triple Superphosphoric Storage Facilities	10/15/96	06/06/97 62 FR 30991	
Section 335–3–13–.06	Wet Process Phosphoric Acid Plants	10/15/96	06/06/97 62 FR 30991	

EPA APPROVED ALABAMA REGULATIONS—Continued

State citation	Title/subject	State effective date	EPA approval date	Explanation
Chapter No. 335–3–14 Air Permits				
Section 335–3–14–.01	General Provisions	02/17/98	09/14/98 63 FR 49008	
Section 335–3–14–.02	Permit Procedures	10/15/96	06/06/97 62 FR 30991	
Section 335–3–14–.03	Standards for Granting Permits	08/10/96	12/02/00 65 FR 76940	
Section 335–3–14–.04	Air Permits Authorizing Construction in Clean Air Areas (prevention of Significant Deterioration (PSD)).	02/05/02	04/20/02 67 FR 17288	
Section 335–3–14–.05	Air Permits Authorizing Construction in or Near Nonattainment Areas.	08/10/00	12/02/00 65 FR 76940	
Chapter No. 335–3–15 Synthetic Minor Operating Permits				
Section 335–3–15–.01	Definitions	10/15/96	06/06/97 62 FR 30991	
Section 335–3–15–.02	General Provisions	08/10/00	12/02/00 65 FR 76940	
Section 335–3–15–.03	Applicability	11/23/93	10/20/94 59 FR 52916	
Section 335–3–15–.04	Synthetic Minor Operating Permit Requirements	10/15/96	06/06/97 62 FR 30991	
Section 335–3–15–.05	Public Participation	10/15/96	06/06/97 62 FR 30991	
Chapter No. 335–3–17 Conformity of Federal Actions to State Implementation Plans				
Section 335–3–17–.01	Transportation Conformity	03/27/98	05/11/00 65 FR 30361	
Section 335–3–17–.02	General Conformity	03/27/98	05/11/00 65 FR 30361	
Chapter No. 335–3–20 Control of Fuels				
Section 335–3–20–.01	Definitions	10/24/00	11/07/01 66 FR 56219	
Section 335–3–20–.02	Control of Fuels	10/24/00	11/07/01 66 FR 56219	
Section 335–3–20–.03	Recordkeeping, Reporting, and Testing	10/24/00	11/07/01 66 FR 56219	

(d) EPA approved Alabama source specific requirements.

EPA APPROVED ALABAMA SOURCE-SPECIFIC REQUIREMENTS

Name of source	Permit No.	State effective date	EPA approval date	Explanation
None.				

(e) EPA approved Alabama non-regulatory provisions.

EPA APPROVED ALABAMA NON-REGULATORY PROVISIONS

Name of nonregulatory SIP provision	Applicable geographic or nonattainment area	State submittal date/effective date	EPA approval date	Explanation
Birmingham 1990 Baseline Emissions Inventory	Birmingham Ozone Nonattainment Area.	11/13/92	06/04/99 64 FR 29961	
Alabama Interagency Transportation Conformity Memorandum of Agreement.		01/20/00	05/11/00 65 FR 30362	
Alabama Fuel Waiver Request-Appendix II of Attainment Demonstration of the 1-hour NAAQS for Ozone for the Birmingham Nonattainment Area.	Birmingham Ozone Nonattainment Area.	12/01/00	11/07/01 66 FR 56220	

EPA APPROVED ALABAMA NON-REGULATORY PROVISIONS—Continued

Name of nonregulatory SIP provision	Applicable geographic or nonattainment area	State submittal date/effective date	EPA approval date	Explanation
Attainment Demonstration of the 1-hour NAAQS for Ozone for the Birmingham Nonattainment Area.	Birmingham Ozone Non-attainment Area 1.	2/01/00	11/07/01 66 FR 56224	

[FR Doc. 03–2172 Filed 1–31–03; 8:45 am]
BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[MD129/130–3089a; FRL–7437–7]

Approval and Promulgation of Air Quality Implementation Plans; Maryland; Amendments to Volatile Organic Compound Requirements From Specific Processes

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: EPA is taking direct final action to approve revisions to the Maryland State Implementation Plan (SIP). The revisions consist of two (2) amendments to Maryland's air pollution control regulations governing specific processes on volatile organic compound (VOC) requirements. The revisions pertain to alternative method of compliance and good operating practices. EPA is fully approving these revisions in accordance with the requirements of the Clean Air Act.

DATES: This rule is effective on April 4, 2003 without further notice, unless EPA receives adverse written comments by March 5, 2003. If EPA receives such comments, it will publish a timely withdrawal of the direct final rule in the **Federal Register** and inform the public that the rule will not take effect.

ADDRESSES: Written comments should be mailed to Walter K. Wilkie, Acting Chief, Air Quality Planning and Information Services Branch, Mailcode 3AP21, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103. Copies of the documents relevant to this action are available for public inspection during normal business hours at the Air Protection Division, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103; the Air and Radiation Docket and Information Center, U.S. Environmental Protection Agency, 1301 Constitution Avenue, NW., Washington, DC 20460; and Maryland Department of the Environment, 1800 Washington Blvd., Suite 730, Baltimore, Maryland 21230.

FOR FURTHER INFORMATION CONTACT: Betty Harris at (215) 814–2168, or by e-mail at *harris.betty@epa.gov.* Please note that while questions may be posed via telephone and e-mail, formal comments must be submitted in writing, as indicated in the **ADDRESSES** section of this document.

SUPPLEMENTARY INFORMATION:

I. Background

On November 20, 2001 and December 6, 2001, the State of Maryland submitted a formal revision to its State Implementation Plan (SIP). The SIP revision submitted by the Maryland Department of the Environment (MDE) consists of amended volatile organic compound (VOC) requirements to specific processes in the Code of Maryland Administrative Regulations (COMAR 26.11.19).

II. Summary of SIP Revision

A. On November 20, 2001, MDE submitted an amendment to COMAR 26.11.19.02B(2)(d). This amendment provides an alternative method for a source to achieve compliance with VOC requirements. The amendment allows sources that are subject to VOC limits in coatings or inks or other similar products, to reduce emissions by using water-based coatings, resins, inks, or similar products that contain less than twenty-five percent VOC by volume of the volatile portion of the product. This amendment was published in the MDE Register on January 30, 1998, and a public hearing was held on March 4, 1998. The amendment was adopted on April 9, 1998, and became effective on May 4, 1998.

B. On December 6, 2001, MDE submitted COMAR 26.11.19.02I. MDE expanded this rule to include good operating practices, equipment cleanup procedures and VOC storage tank vapor control requirements to reduce VOC emissions from any source presently subject to any VOC emission standard, limitation or requirement. The expanded rule was published in MDE Register on September 21, 2001, and a public hearing was held on October 23, 2001. The rule was adopted on November 6, 2001 and became effective on December 10, 2001.

III. Final Action

EPA is approving SIP revisions submitted by MDE on November 20, 2001 and December 6, 2001, respectively, the amendments to the VOC requirements [COMAR 26.11.19.02B(2)(d), COMAR 26.11.19.02I] concerning an alternative method of compliance for specific VOC processes; good operating practices, equipment cleanup, and VOC storage. EPA is publishing this rule without prior proposal because the Agency views this as a noncontroversial amendment and anticipates no adverse comment. However, in the ''Proposed Rules'' section of today's **Federal Register**, EPA is publishing a separate document that will serve as the proposal to approve the SIP revision if adverse comments are filed. This rule will be effective on April 4, 2003 without further notice unless EPA receives adverse comment by March 5, 2003. If EPA receives adverse comment, EPA will publish a timely withdrawal in the **Federal Register** informing the public that the rule will not take effect. EPA will address all public comments in a subsequent final rule based on the proposed rule. EPA will not institute a second comment period on this action. Any parties interested in commenting must do so at this time. Please note that if EPA receives adverse comment on an amendment, paragraph, or section of this rule and if that provision may be severed from the remainder of the rule, EPA may adopt as final those provisions of the rule that are not the subject of an adverse comment.

IV. Regulatory Assessment

A. General Requirements

Under Executive Order 12866 (58 FR 51735, October 4, 1993), this action is not a ''significant regulatory action'' and therefore is not subject to review by the Office of Management and Budget. For this reason, this action is also not subject to Executive Order 13211, ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001). This action merely approves state law as meeting Federal

requirements and imposes no additional requirements beyond those imposed by state law. Accordingly, the Administrator certifies that this rule will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). Because this rule approves pre-existing requirements under state law and does not impose any additional enforceable duty beyond that required by state law, it does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). This rule also does not have tribal implications because it will not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified by Executive Order 13175 (65 FR 67249, November 9, 2000). This action also does not have Federalism implications because it does not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132 (64 FR 43255, August 10, 1999). This action merely approves a state rule implementing a Federal standard, and does not alter the relationship or the distribution of power and responsibilities established in the Clean Air Act. This rule also is not subject to Executive Order 13045 ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997), because it is not economically significant.

In reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the Clean Air Act. In this context, in the absence of a prior existing requirement for the State to use voluntary consensus standards (VCS), EPA has no authority to disapprove a SIP submission for failure to use VCS. It would thus be inconsistent with applicable law for EPA, when it reviews a SIP submission, to use VCS in place of a SIP submission that otherwise satisfies the provisions of the Clean Air Act. Thus, the requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) do not apply. This rule does not impose an information collection burden under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

B. Submission to Congress and the Comptroller General

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

C. Petitions for Judicial Review

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by April 4, 2003. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action.

This action pertains to Maryland's amendments to volatile organic compound requirements from specific processes and may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 52

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

Dated: December 31, 2002.

Thomas C. Voltaggio,

Acting Regional Administrator, Region III.

40 CFR part 52 is amended as follows:

PART 52—[AMENDED]

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

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

Subpart V—Maryland

2. Section 52.1070 is amended by adding paragraphs (c)(174) and (c)(175) to read as follows:

§ 52.1070 Identification of plan.

* * * * *

(c) * * *

(174) Revisions to the Maryland State Implementation Plan submitted on November 20, 2001, by the Maryland Department of the Environment:

(i) Incorporation by reference.

(A) Letter dated November 20, 2001 from the Maryland Department of the Environment transmitting a revision to Maryland State Implementation Plan concerning an alternative method for a source to achieve compliance with volatile organic compound (VOC) requirements for specific processes.

(B) Revisions to Code of Maryland Administrative Regulation (COMAR) 26.11.19.02B (Applicability, Determining Compliance, Reporting and General Requirements—Method of Compliance), effective May 4, 1998, which revises paragraph .02B(2)(c), adds a new paragraph .02B(2)(d), and renumbers former paragraph .02B(2)(d) as .02B(2)(e).

(ii) Additional Material.—Remainder of the State submittal pertaining to the revision listed in paragraph (c)(174)(i) of this section.

(175) Revisions to the Maryland State Implementation Plan submitted on December 6, 2001, by the Maryland Department of the Environment:

(i) Incorporation by reference.

(A) Letter dated December 6, 2001 from the Maryland Department of the Environment transmitting additions to Maryland's State Implementation Plan, concerning good operating practices, equipment cleanup procedures, and volatile organic compound (VOC) storage tank vapor control requirements for specific processes.

(B) Addition of Code of Maryland Administrative Regulation (COMAR) 26.11.19.02I—(Applicability, Determining Compliance, Reporting and General Requirements—Good Operating Practices, Cleanup, and VOC Storage), effective December 10, 2001.

(ii) Additional Material.—Remainder of the State submittal pertaining to the revision listed in paragraph (c)(175)(i) of this section.

[FR Doc. 03–2434 Filed 1–31–03; 8:45 am]

BILLING CODE 6560–50–P

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

48 CFR Parts 1804, 1827, 1835, and 1852

RIN 2700–AC33

Scientific and Technical Reports

AGENCY: National Aeronautics and Space Administration (NASA).

ACTION: Final rule.

SUMMARY: This final rule adopts with changes the proposed rule published in the **Federal Register** on November 14, 2001. This final rule amends the NFS to clarify the review requirements for data produced under research and development (R&D) contracts, including data contained in final reports, and the review requirements for final reports prior to inclusion in NASA's Center for AeroSpace Information (CASI) scientific and technical information (STI) database.

EFFECTIVE DATE: February 3, 2003.

FOR FURTHER INFORMATION CONTACT: Celeste Dalton, NASA Headquarters, Office of Procurement, Contract Management Division (Code HK), (202) 358–1645, e-mail: *cdalton@hq.nasa.gov.*

SUPPLEMENTARY INFORMATION:

A. Background

NFS clause 1852.235–70, Center for Aerospace Information—Final Scientific and Technical Reports, is required in all R&D contracts. Paragraph (e) of the current NFS clause 1852.235–70 requires that contractors not release the final report required under the contract, outside of NASA, until a document availability authorization (DAA) review has been completed by NASA and availability of the report has been determined. The DAA review completed by NASA is intended to ensure that NASA disseminates NASA scientific and technical information (STI) in a manner consistent with U.S. laws and regulations, Federal information policy, intellectual property rights, technology transfer protection requirements, and budgetary and technological limitations. The DAA review process applies only to the publication and dissemination of NASA STI by NASA or under the direction of NASA.

This final report review requirement has been incorrectly interpreted by some university contractors as restricting their right to publish any of the data produced under the contract that may be included in the Final Report until NASA has completed its DAA review. The intent of paragraph (e) is to restrict only the release of the ''The Final Report'' as delivered under the contract until NASA completes its DAA review and availability of the report has been determined. This clause normally does not restrict the contractor's ability to publish, or otherwise disseminate, data produced during the performance of the contract, including data contained in the Final Report, as provided under FAR clause 52.227–14, Rights in Data—General. However, in certain limited situations, contract requirements may include research activity that will result in data subject to export control, national security restrictions, or other restrictions designated by NASA, or may require that the contractor receives or is given access to data that includes restrictive markings, *e.g.*, proprietary information of others. In these circumstances, NASA requires a review of data produced under the contract, before the contractor may publish, release, or otherwise disseminate the data.

This final rule clarifies the above by—

(a) Revising the existing clause, 1852.235–70, to delete reference to the submission of the final report. This revised clause is titled ''Center for Aerospace Information,'' and advises contractors of the services provided by CASI;

(b) Establishing a new clause 1852.235–73, Final Scientific and Technical Reports, that requires submission of a final report; states that the contractor may publish, or otherwise disseminate, data produced during the performance of the contract, including data contained in the final report, without prior review by NASA; and retains restriction on release of the final report as delivered under the contract until NASA has completed its DAA review;

(c) Establishing an Alternate I to the new 1852.235–73 clause, for use in contracts for fundamental research in which the contractor may publish, or otherwise disseminate, data produced during performance of the contract, including the final report, without prior review by NASA;

(d) Establishing an Alternate II to the new 1852.235–73 clause, for use in contracts in which data resulting from the research activity may be subject to export control, national security restrictions or other restrictions designated by NASA, or, to the extent the contractor receives or is given access to data that includes restrictive markings, may include proprietary information of others, and thus will require NASA review before the contractor may publish, release, or otherwise disseminate data produced during the performance of the contract;

(e) Establishing a new clause 1852.235–74, Additional Reports of Work—Research and Development, for use in contracts in which monthly, quarterly and other reports in addition to the Final Report may be considered necessary for monitoring contract performance; and

(f) Moving the coverage for Reports of Work from Part 1827, Patents, Data, and Copyrights, to 1835, Research and Development Contracting, by deleting section 1827.406–70, Reports of Work, and adding §§ 1835.010, Scientific and technical reports, and 1835.011, Data.

NASA published a proposed rule in the **Federal Register** on November 14, 2001 (66 FR 57028). Public comments were received from one association. The comments suggested a change to the prescription for use of Alternate I to 1852.235–73 and objected to the inclusion of ''information disclosing an invention in which the government may have rights'' as an example of when it would be appropriate to use the proposed clause 1852.235–75, Review of Final Scientific and Technical Reports and Other Data. The comments were considered in formulation of this final rule. NASA is adopting the proposed rule as final with changes. The changes: (a) Modify, for consistency, the clause proscription for use of Alternate I to 1852.235–73; (b) delete the previously proposed clause 1852.235–75; (c) revise Alternate II of the new clause 1852.235–73 to include language from the deleted clause, and modifies that language to delete reference to ''information disclosing an invention in which the government may have rights'' since the FAR Patent Rights clause (52.227–11) requires the contractor to disclose inventions to the government, but does not restrict the publication of information disclosing an invention; (d) encourage electronic submission of reports; and (e) align the submission of documents with existing internal review procedures. Finally, this final rule amends an address in section 1804.202.

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 final rule is not a major rule under 5 U.S.C. 804.

B. Regulatory Flexibility Act

NASA certifies that this final rule will not have a significant economic impact on a substantial number of small business entities within the meaning of the Regulatory Flexibility Act (5 U.S.C. 601, *et seq.*), because these changes only clarify existing rights and responsibilities relating to release of

data produced in performance of a contract.

C. Paperwork Reduction Act

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

List of Subjects in 48 CFR Parts 1804, 1827, 1835, and 1852

Government procurement.

Tom Luedtke,

Assistant Administrator for Procurement.

Accordingly, 48 CFR Parts 1804, 1827, 1835, and 1852 are amended as follows:

1. The authority citation for 48 CFR Parts 1804, 1827, 1835, and 1852 continues to read as follows:

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

PART 1804—ADMINISTRATIVE MATTERS

2. Revise section 1804.202 to read as follows:

1804.202 Agency distribution requirements.

In addition to the requirements in FAR 4.201, the contracting officer shall distribute one copy of each R&D contract, including the Statement of Work, to the NASA Center for AeroSpace Information (CASI), Attention: Acquisitions Collections Development Specialist, 7121 Standard Drive, Hanover, MD 21076–1320.

PART 1827—PATENTS, DATA, AND COPYRIGHTS

1827.406–70 [Removed]

3. Remove section 1827.406–70.

PART 1835—RESEARCH AND DEVELOPMENT CONTRACTING

4. Add sections 1835.010 and 1835.011 to read as follows:

1835.010 Scientific and technical reports.

(a)(i) *Final reports.* Final reports must be furnished by contractors for all R&D contracts. The final report should summarize the results of the entire contract, including recommendations and conclusions based on the experience and results obtained. The final report should include tables, graphs, diagrams, curves, sketches, photographs, and drawings in sufficient detail to explain comprehensively the results achieved under the contract. The final report should comply with formatting and stylistic guidelines contained in NPG 2200.2A, Guidelines for Documentation, Approval, and Dissemination of NASA Scientific and Technical Information. Electronic formats for submission of reports should be used to the maximum extent practical. When reports are submitted electronically, the contracting officer should also request the submission of a paper copy of the report that could be used to validate items such as math and symbols that can be transposed due to font substitution or other electronic transmission problems. Information regarding appropriate electronic formats for final reports is available from center STI/Publications Managers or the NASA Center for AeroSpace Information (CASI) at *http://www.sti.nasa.gov* under ''Publish STI—Electronic File Formats.''

(ii) In addition to the final report submitted to the contracting officer, the contractor shall concurrently provide CASI and the center STI/Publications Manager with a copy of the letter transmitting the final report to the contracting officer.

(iii) It is NASA policy to provide the widest practicable and appropriate dissemination of scientific and technical information (STI) derived from NASA activities, including that generated under NASA research and development contracts. One mechanism for disseminating NASA STI is through CASI. Before approving a final report delivered under a contract for inclusion in the CASI repository, NASA must complete a document availability authorization (DAA) review. The DAA review is intended to ensure that NASA disseminates NASA STI in a manner consistent with U.S. laws and regulations, federal information policy and publication standards, intellectual property rights, technology transfer protection requirements, and budgetary and technological limitations. NASA Form 1676, NASA Scientific and Technical Document Availability Authorization (DAA), or a center-specific version of this form, is used to complete this review. The DAA review process applies to the publication and dissemination of NASA STI by NASA or under the direction of NASA. The final report, as delivered under the contract, must not be released outside of NASA until NASA's DAA review has been completed and the availability of the document has been determined by NASA.

(iv) *Additional reports of work.* In addition to the final report required by paragraph (a)(i) of this section, the contracting officer, in consultation with the program or project manager, should consider the desirability of requiring periodic reports and reports on the completion of significant units or phases of work for monitoring contract performance. Any additional reports must be included in the clause at 1852.235–74 as a contract deliverable. (*See* FAR 27.403.)

(v) Upon receipt of the final report, or any additional reports required by 1852.235–74 if included in the contract, the contracting officer shall forward the reports to the contracting officer's technical representative (COTR) for review and acceptance. The COTR shall ensure that the DAA review is initiated upon acceptance of the final report or any additional reports that NASA elects to publish or release outside of NASA or present at internal meetings at which foreign nationals may be present. Upon completion of the DAA review, the COTR shall ensure that the DAA-approved STI and the original approved DAA form are sent to the center STI/Publication Manager. The contractor should be advised of the final availability determination. These responsibilities should be included in the COTR Delegation, NASA Form 1634.

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

1835.011 Data.

(a) In addition to any reports required by 1835.010, the contracting officer shall specify what additional data, (type, quantity, and quality) is required under the contract, for example, presentations, journal articles, and seminar notes. (*See* FAR 27.403.)

5. Revise Section 1835.070 to read as follows:

1835.070 NASA contract clauses and solicitation provision.

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

(b) The contracting officer shall insert the clause at 1852.235–71, Key Personnel and Facilities, in contracts when source selection has been substantially predicated upon the possession by a given offeror of special capabilities, as represented by key personnel or facilities.

(c) The contracting officer shall ensure that the provision at 1852.235–72, Instructions for Responding to NASA Research Announcements, is inserted in all NRAs. The instructions

may be supplemented, but only to the minimum extent necessary.

(d) The contracting officer shall insert the clause at 1852.235–73, Final Scientific and Technical Reports, in all research and development contracts, and in interagency agreements and cost-reimbursement supply contracts involving research and development work.

(1) The contracting officer, after consultation with and concurrence of the program or project manager and the center Export Control Administrator, shall insert the clause with its Alternate I when the contract includes ''fundamental research'' as defined at 22 CFR 120.11(8) and no prior review of data, including the final report, produced during the performance of the contract is required for export control or national security purposes before the contractor may publish, release, or otherwise disseminate the data.

(2) The contracting officer, after consultation with and concurrence by the program or project manager and where necessary the center Export Control Administrator, shall insert the clause with its Alternate II, when prior review of all data produced during the performance of the contract is required before the contractor may publish, release, or otherwise disseminate the data. For example, when data produced during performance of the contract may be subject to export control, national security restrictions, or other restrictions designated by NASA; or, to the extent the contractor receives or is given access to data that includes restrictive markings, may include proprietary information of others.

(e) The contracting officer shall insert a clause substantially the same as the clause at 1852.235–74, Additional Reports of Work—Research and Development, in all research and development contracts, and in interagency agreements and cost-reimbursement supply contracts involving research and development work, when periodic reports, such as monthly or quarterly reports, or reports on the completion of significant units or phases of work are required for monitoring contract performance. The clause should be modified to reflect the reporting requirements of the contract and to indicate the timeframe for submission of the final report.

PART 1852—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

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

1852.235–70 Center for AeroSpace Information.

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

Center for Aerospace Information (Feb, 2003.)

(a) The Contractor should register with and avail itself of the services provided by the NASA Center for AeroSpace Information (CASI) (*http://www.sti.nasa.gov*) for the conduct of research or research and development required under this contract. CASI provides a variety of services and products as a NASA repository and database of research information, which may enhance contract performance.

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

(c) Information regarding CASI and the services available can be obtained at the Internet address contained in paragraph (a) of this clause or at the following address: Center for AeroSpace Information (CASI), 7121 Standard Drive, Hanover, Maryland 21076–1320, E-mail: *help@sti.nasa.gov*, Phone: 301–621–0390, Fax: 301–621–0134.

(End of clause)

7. Add sections 1852.235–73 and 1852.235–74 to read as follows:

1852.235–73 Final Scientific and Technical Reports.

As prescribed in 1835.070(d) insert the following clause:

Final Scientific and Technical Reports (Feb, 2003.)

(a) The Contractor shall submit to the Contracting Officer a final report that summarizes the results of the entire contract, including recommendations and conclusions based on the experience and results obtained. The final report should include tables, graphs, diagrams, curves, sketches, photographs, and drawings in sufficient detail to explain comprehensively the results achieved under the contract.

(b) The final report shall be of a quality suitable for publication and shall follow the formatting and stylistic guidelines contained in NPG 2200.2A, Guidelines for Documentation, Approval, and Dissemination of NASA Scientific and Technical Information. Electronic formats for submission of reports should be used to the maximum extent practical. Before electronically submitting reports containing scientific and technical information (STI) that is export-controlled or limited or restricted, contact the Contracting Officer to determine the requirements to electronically transmit these forms of STI. If appropriate electronic safeguards are not available at the time of submission, a paper copy or a CD–ROM of the report shall be required. Information regarding appropriate electronic formats for final reports is available at *http://www.sti.nasa.gov* under ''Publish STI—Electronic File Formats.''

(c) The last page of the final report shall be a completed Standard Form (SF) 298, Report Documentation Page.

(d) In addition to the final report submitted to the Contracting Officer, the Contractor shall concurrently provide to the Center STI/Publication Manager and the NASA Center for AeroSpace Information (CASI) a copy of the letter transmitting the final report to the Contracting Officer. The copy of the letter shall be submitted to CASI at the following address: Center for AeroSpace Information (CASI), Attn: Acquisitions Collections Development Specialist, 7121 Standard Drive, Hanover, Maryland 21076–1320.

(e) In accordance with paragraph (d) of the Rights in Data—General clause (52.227–14) of this contract, the Contractor may publish, or otherwise disseminate, data produced during the reports required by 1852.235–74 when included in the contract, without prior review by NASA. The Contractor is responsible for reviewing publication or dissemination of the data for conformance with laws and regulations governing its distribution, including intellectual property rights, export control, national security and other requirements, and to the extent the contractor receives or is given access to data necessary for the performance of the contract which contain restrictive markings, for complying with such restrictive markings. Should the Contractor seek to publish or otherwise disseminate the final report, or any additional reports required by 1852.235–74 if applicable, as delivered to NASA under this contract, the Contractor may do so once NASA has completed its document availability authorization review, and availability of the report has been determined.

Alternate I (FEB 2003)

As prescribed by 1835.070(d)(1), insert the following as paragraph (e) of the basic clause:

(e) The data resulting from this research activity is ''fundamental research'' which will be broadly shared within the scientific community. No foreign national access or dissemination restrictions apply to this research activity. The Contractor may publish, release, or otherwise disseminate data produced during the performance of this contract, including the final report, without prior review by NASA for export control or national security purposes. However, NASA retains the right to review the final report to ensure that proprietary information, which may have been provided to the Contractor, is not released without authorization and for consistency with NASA publication standards. Additionally, the Contractor is responsible for reviewing any publication, release, or dissemination of the data for conformance with other restrictions expressly set forth in this contract, and to the extent it receives or is given access to data necessary for the performance of the contract which contain restrictive markings, for compliance with such restrictive markings.

Alternate II (FEB 2003)

As prescribed by 1835.070(d)(2), insert the following as paragraph (e) of the basic clause:

(e) Data resulting from this research activity may be subject to export control, national security restrictions or other restrictions designated by NASA; or, to the extent the Contractor receives or is given access to data necessary for the performance of the contract which contain restrictive markings, may include proprietary information of others. Therefore, the Contractor shall not publish, release, or otherwise disseminate, except to NASA, data produced during the performance of this contract, including data contained in the final report and any additional reports required by 1852.235–74 when included in the contract, without prior review by NASA. Should the Contractor seek to publish, release, or otherwise disseminate data produced during the performance of this contract, the Contractor may do so once NASA has completed its document availability authorization review and the availability of the data has been determined.

(End of clause)

1852.235–74 Additional Reports of Work—Research and Development.

As prescribed in 1835.070(e), insert a clause substantially the same as the following:

Additional Reports of Work—Research and Development (FEB 2003)

In addition to the final report required under this contract, the Contractor shall submit the following report(s) to the Contracting Officer:

(a) *Monthly progress reports.* The Contractor shall submit separate monthly reports of all work accomplished during each month of contract performance. Reports shall be in narrative form, brief, and informal. They shall include a quantitative description of progress, an indication of any current problems that may impede performance, proposed corrective action, and a discussion of the work to be performed during the next monthly reporting period.

(b) *Quarterly progress reports.* The Contractor shall submit separate quarterly reports of all work accomplished during each three-month period of contract performance. In addition to factual data, these reports should include a separate analysis section interpreting the results obtained, recommending further action, and relating occurrences to the ultimate objectives of the contract. Sufficient diagrams, sketches, curves, photographs, and drawings should be included to convey the intended meaning.

(c) *Submission dates.* Monthly and quarterly reports shall be submitted by the 15th day of the month following the month or quarter being reported. If the contract is awarded beyond the middle of a month, the first monthly report shall cover the period from award until the end of the following month. No monthly report need be submitted for the third month of contract effort for which a quarterly report is required. No quarterly report need be submitted for the final three months of contract effort since that period will be covered in the final report. The final report shall be submitted within ____ days after the completion of the effort under the contract.

(End of clause)

[FR Doc. 03–2435 Filed 1–31–03; 8:45 am]

BILLING CODE 7510–01–P

Proposed Rules

Federal Register
Vol. 68, No. 22
Monday, February 3, 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.

SMALL BUSINESS ADMINISTRATION

13 CFR Part 120

Business Loan Program

AGENCY: U.S. Small Business Administration.

ACTION: Advance notice of proposed rulemaking (ANPRM); notice of extension of the comment period.

SUMMARY: By means of an advance notice of proposed rulemaking (ANPRM), the U.S. Small Business Administration (SBA) is requesting comments addressing the Certified Development Company (CDC) Loan Program (the ''CDC Program'' or the ''504 Program''). After a review of the comments, SBA will consider proposing amendments to existing program regulations that will improve overall program management.

SBA is revisiting the 504 Program policies as a prudent management exercise in light of major changes in the economy, the financial services industry, technology, and in CDCs' operations since the program's inception in 1980. The review has also been prompted by SBA's on-going discussions with the 504 industry and by specific requests made to SBA to expand CDCs' product base to include 7(a) loans or Small Business Investment Companies. In particular, SBA is seeking comments on the following: Whether the 504 Program is meeting its statutory purpose as defined in section 501(a) of the Small Business Investment Act; the appropriate long-term goals and annual performance measures for the program given its statutory requirement; the appropriate data elements required to assure solid program oversight while minimizing public data collection burdens; operational or regulatory impediments to providing long-term financing in rural or urban areas; and programmatic changes that could increase CDC competition and increase small businesses' access to loans.

The ANPRM is intended to stimulate dialogue on these and other issues pertaining to the CDC Program. The ANPRM was published on December 6, 2002, 67 FR 72622. The comment period closes on February 4, 2003. Because of the broad range of topics and issues addressed in the ANPRM, and due to requests from the public and members of Congress, SBA is extending the time period for comments by an additional 30 days to March 6, 2003. We do this because of our desire to have a meaningful dialogue on the important issues that seek to enhance SBA's efforts to serve small businesses through the CDC Program.

DATES: The comment period for the ANPRM published December 6, 2002 (67 FR 72622) is extended through March 6, 2003.

ADDRESSES: Address all comments to: James E. Rivera, Associate Administrator for Financial Assistance, U.S. Small Business Administration, 409 Third Street, SW., 8th Floor, Washington, DC 20416. Comments may be sent by e-mail to *ANPR@sba.gov.*

FOR FURTHER INFORMATION CONTACT: Gail H. Hepler, Chief, 504 Loan Policy Branch, U.S. Small Business Administration, 409 Third Street, SW., 8th Floor, Washington, DC 20416. Questions may be sent by e-mail to *gail.helpler@sba.gov* or by telephone at (202) 205–7530. This is not a toll-free number.

Dated: January 27, 2003.

James E. Rivera,

Associate Administrator for Financial Assistance.

[FR Doc. 03–2399 Filed 1–31–03; 8:45 am]

BILLING CODE 8025–01–P

SMALL BUSINESS ADMINISTRATION

13 CFR Part 121

RIN 3245–AF03

Small Business Size Standards; Facilities Support Services (Including Base Maintenance)

AGENCY: Small Business Administration (SBA).

ACTION: Proposed rule.

SUMMARY: The U.S. Small Business Administration (SBA) proposes to increase the size standard for the Facilities Support Services industry (North American Industry Classification System (NAICS) code 561210) from $6 million in average annual receipts to $30 million and the size standard for the sub-category of Base Maintenance from $23 million to $30 million. This proposed revision is being made to better define the size of businesses in this industry that the SBA believes should be eligible for Federal small business assistance programs.

DATES: Comments must be received on or before April 4, 2003.

ADDRESSES: Send written comments to Gary M. Jackson, Assistant Administrator for Size Standards, 409 Third Street, SW, Mail Code 6530, Washington DC 20416; by email to *SIZESTANDARDS@sba.gov;* or by facsimile at (202) 205–6390. Upon request, SBA will make all public comments available to any person or entity.

FOR FURTHER INFORMATION CONTACT: Diane Heal, Office of Size Standards, Office of Government Contracting and Business Development, (202) 205–6618.

SUPPLEMENTARY INFORMATION: SBA has received requests from firms in the Facilities Support Services industry to review its $6 million size standard for this industry and the $23 million size standard for Base Maintenance, a sub-category of the industry. These size standards are based on annual receipts of the business, as described in 13 CFR 121.104. These firms argue that a size standard increase is warranted to reflect the size of Federal contracts issued in this area. These contracts include a broad spectrum of services involving administrative support, custodial services, facilities repair and maintenance, and technical services, which often are $10 million per year or more in value. A small business can lose its small businesses status with only one or two contracts. Costs on these types of contracts have increased greater than the general inflation rate, especially due to changes in the mandated labor rates under the Service Contract Act and increased health insurance costs. The requestors believe that to help develop small businesses to be competitive with large businesses in this industry, the size standard should be increased to the $25 million to $30 million range.

Based on a review of these issues and data on the Facilities Support Services industry, SBA concludes that a higher size standard for activities in this industry is supportable. This rule

proposes a $30 million size standard for all activities in the Facilities Support Services industry. As explained below, SBA believes that the activities comprising this industry and the characteristics of firms in the industry no longer support the need for separate size standards for Base Maintenance and for all other facilities support activities. SBA solicits comments on all aspects of this proposed rule, including its methodology and analysis. Below is a discussion of the SBA's size standards methodology and the analysis leading to the proposed $30 million size standard.

Size Standards Methodology: Congress granted SBA discretion to establish detailed size standards (15 U.S.C. 632(a)(2)). SBA's Standard Operating Procedure (SOP) 90 01 3, ''Size Determination Program'' (available on SBA's Web site at *http://www.sba.gov/library/soproom.html)* sets out four categories for establishing and evaluating size standards: (1) The structure of the industry and its various economic characteristics, (2) SBA program objectives and the impact of different size standards on these programs, (3) whether a size standard successfully excludes those businesses which are dominant in the industry, and (4) other factors if applicable. Other factors, including the impact on other agencies' programs, may come to the attention of SBA during the public comment period or from SBA's own research on the industry. No formula or weighting has been adopted so that the factors may be evaluated in the context of a specific industry. Below is a discussion of SBA's analysis of the economic characteristics of an industry, the impact of a size standard on SBA programs, and the evaluation of whether a firm at or below a size standard could be considered dominant in the industry under review.

Industry Analysis: Section 3(a)(2) of the Small Business Act (15 U.S.C. 632 (a)(3)), requires that size standards vary by industry to the extent necessary to reflect differing industry characteristics. SBA has two ''base'' or ''anchor'' size standards that apply to most industries—500 employees for manufacturing industries and $6 million in average annual receipts for nonmanufacturing industries. SBA established 500 employees as the anchor size standard for the manufacturing industries at SBA's inception in 1953 and shortly thereafter established a $1 million average annual receipts size standard for the nonmanufacturing industries. The receipts-based anchor size standard for the nonmanufacturing industries was adjusted periodically for inflation so that, currently, the anchor size standard is $6 million. Anchor size standards are presumed to be appropriate for an industry unless its characteristics indicate that larger firms have a much greater significance within that industry than the ''typical industry.''

When evaluating a size standard, the characteristics of the specific industry under review are compared to the characteristics of a group of industries, referred to as a comparison group. A comparison group is a large number of industries grouped together to represent the typical industry. It can be comprised of all industries, all manufacturing industries, all industries with receipt-based size standards, or some other logical grouping.

If the characteristics of a specific industry are similar to the average characteristics of the comparison group, then the anchor size standard is considered appropriate for the industry. If the specific industry's characteristics are significantly different from the characteristics of the comparison group, a size standard higher or, in rare cases, lower than the anchor size standard may be considered appropriate. The larger the differences between the specific industry's characteristics and the comparison group's characteristics, the larger the difference between the appropriate industry size standard and the anchor size standard. SBA will consider adopting a size standard below the anchor size standard only when (1) all or most of the industry characteristics are significantly smaller than the average characteristics of the comparison group, or (2) other industry considerations strongly suggest that the anchor size standard would be an unreasonably high size standard for the industry under review.

The primary evaluation factors that SBA considers in analyzing the structural characteristics of an industry are listed in 13 CFR 121.102 (a) and (b). Those factors include average firm size, distribution of firms by size, start-up costs, and industry competition. The analysis also examines the possible impact of a size standard revision on SBA's programs as an evaluation factor. SBA generally considers these five factors to be the most important evaluation factors in establishing or revising a size standard for an industry. However, it will also consider and evaluate other information that it believes relevant to the decision on a size standard for a particular industry. Public comments submitted on proposed size standards are also an important source of additional information that SBA closely reviews before making a final decision on a size standard. Below is a brief description of each of the five evaluation factors.

1. ''Average firm size'' is simply total industry receipts (or number of employees) divided by the number of firms in the industry. If the average firm size of an industry is significantly higher than the average firm size of a comparison industry group, this fact would be viewed as supporting a size standard higher than the anchor size standard. Conversely, if the industry's average firm size is similar to or significantly lower than that of the comparison industry group, it would be a basis to adopt the anchor size standard or, in rare cases a lower size standard.

2. ''Distribution of firms by size'' is the proportion of industry receipts, employment, or other economic activity accounted for by firms of different sizes in an industry. If the preponderance of an industry's economic activity is by smaller firms, this tends to support adopting the anchor size standard. A size standard higher than the anchor size standard is supported for an industry in which the distribution of firms indicates that economic activity is concentrated among the largest firms in an industry. In this rule, SBA is comparing the size of firms within an industry to the size of firms in the comparison group at which predetermined percentages of receipts are generated by firms smaller than a particular size firm. For example, assume for the industry under review that 50 percent of total industry receipts are generated by firms of $28.5 million in receipts and less. This contrasts with the comparison group (composed of industries with the nonmanufacturing anchor size standard of $6 million) in which firms of $5.8 million and less in receipts generated 50 percent of total industry receipts. Viewed in isolation, the higher figure for the industry under review suggests that a size standard higher than the nonmanufacturing anchor size standard may be warranted. Other size distribution comparisons in the industry analysis include 40 percent, 60 percent, and 70 percent, as well as the 50 percent comparison discussed above.

3. ''Start-up costs'' affect a firm's initial size because entrants into an industry must have sufficient capital to start and maintain a viable business. To the extent that firms entering into one industry have greater financial requirements than firms do in other industries, SBA is justified in considering a higher size standard. In lieu of direct data on start-up costs, SBA uses a proxy measure to assess the financial burden for entry-level firms. For this analysis, SBA has calculated

nonpayroll costs per establishment for each industry. This is derived by first calculating the percent of receipts in an industry that are either retained or expended on costs other than payroll costs. (The figure comprising the numerator of this percentage is mostly composed of capitalization costs, overhead costs, materials costs, and the costs of goods sold or inventoried.) This percentage is then applied to average establishment receipts to arrive at nonpayroll costs per establishment (an establishment is a business entity operating at a single location). An industry with a significantly higher level of nonpayroll costs per establishment than that of the comparison group is likely to have higher start-up costs, which would tend to support a size standard higher than the anchor size standard. Conversely, if the industry showed a significantly lower nonpayroll costs per establishment when compared to the comparison group, the anchor size standard would be considered the appropriate size standard.

4. ''Industry competition'' is assessed by measuring the proportion or share of industry receipts obtained by firms that are among the largest firms in an industry. In this proposed rule, SBA compares the proportion of industry receipts generated by the four largest firms in the industry—generally referred to as the ''four-firm concentration ratio—with the average four-firm concentration ratio for industries in the comparison groups. If a significant proportion of economic activity within the industry is concentrated among a few relatively large producers, SBA tends to set a size standard relatively higher than the anchor size standard in order to assist firms in a broader size range to compete with firms that are larger and more dominant in the industry. In general, however, SBA does not consider this to be an important factor in assessing a size standard if the four-firm concentration ratio falls below 40 percent for an industry under review.

5. ''Impact of size standard revisions on SBA programs'' refers to the possible impact a size standard change may have on the level of small businesses assistance. This assessment most often focuses on the proportion or share of Federal contract dollars awarded to small businesses in the industry in question. In general, the lower the share of Federal contract dollars awarded to small businesses in an industry which receives significant Federal procurement revenues, the greater is the justification for a size standard higher than the existing one.

Another factor to evaluate the impact of a proposed size standard on SBA programs is the volume of guaranteed loans within an industry and the size of firms obtaining those loans. This factor is sometimes examined to assess whether the current size standard may be restricting the level of financial assistance to firms in that industry. If small businesses receive significant amounts of assistance through these programs, or if the financial assistance is provided mainly to small businesses much lower than the size standard, a change to the size standard (especially if it is already above the anchor size standard) may not be necessary.

Elimination of Base Maintenance size standard: Currently, there are two size standards for activities in the Facilities Support Services industry—$23 million for Base Maintenance and $6 million for all other facilities support activities. In 1966, when SBA established a size standard for Base Maintenance, no facilities support related industry existed. Base Maintenance and other Facilities Support Services were classified under a general industry titled ''Business Services, Not Elsewhere Classified,'' along with airplane rental, drafting services, lecture bureaus, and many other miscellaneous business services. The revisions to the 1972 Standard Industrial Classification (SIC) System moved facilities support activities to a new industry titled ''Personnel Supply Services, Not Elsewhere Classified,'' which also consisted of temporary help services. The 1987 revisions to the SIC System eliminated this industry and established two new industries—''Facilities Support Management Services'' and ''Help Supply Services.'' In the absence of data on the new Facilities Support Management industry, SBA retained its $13.5 million size standard for Base Maintenance and applied its $3.5 million ''nonmanufacturing anchor size standard'' in effect at that time to all other industry activities.

The current NAICS industry description of Facilities Support Services is very similar to SBA's description of Base Maintenance (see footnotes 12 and 13 of 13 CFR 121.201). Facilities Support Services comprises establishments providing staff to perform a range of support services within a client's facilities. They do not provide staff to perform the core responsibilities of the client. SBA defines Base Maintenance in a similar manner, but limits the sub-industry to services and special trade activities related to supporting a specific base operation. SBA believes that firms performing Base Maintenance services also perform, or have the capability to perform, most other facilities support activities. Given the close similarity of the descriptions of Facilities Support Services and Base Maintenance, SBA believes a single size standard is appropriate for all activities within the Facilities Support Services industry.

Evaluation of Industry Size Standard: The two tables below show the characteristics for the Facilities Support Services industry and for the two comparison groups. The first comparison group is comprised of all industries with a $6 million receipts-based size standard, referred to as the nonmanufacturing anchor group. Since SBA assumes that the $6 million anchor size standard is appropriate for a nonmanufacturing industry, this is the most logical set of industries to group together for the industry analysis to assess whether a size standard at the anchor size standard or higher is appropriate. The second comparison group consists of nonmanufacturing industries which have the highest levels of receipt-based size standards established by SBA, referred to as the nonmanufacturing higher-level size standard group. Size standards for these industries range from $21 million to $29 million. If an industry's characteristics are significantly larger than those of the nonmanufacturing anchor group, SBA will compare them to the characteristics of the higher-level size standards group. By doing so, SBA can assess if a size standard among its highest receipts-based size standards is appropriate or whether an intermediate size standard between the anchor size standard and the higher size standards should be selected.

SBA examined economic data on the Facilities Support Services industry and the comparison group industries taken from a special tabulation of the 1997 Economic Census prepared under contract by the U.S. Bureau of the Census (Census), Federal contract award data for fiscal years 1999–2001 from the U.S. General Services Administration's Federal Procurement Data Center, and loan data from SBA's internal data base for SBA guaranteed loans.

Industry Structure Consideration: Table 1 below examines the size distribution of firms. For this factor, SBA is evaluating the size of firm that accounts for predetermined percentages of total industry receipts (40 percent, 50 percent, 60 percent, and 70 percent). The table shows firms up to a specific size that, along with smaller firms, account for a specific percentage of total industry receipts.

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Table 1: Size Distribution of Firms in the Facilities Support Services Industry, Nonmanufacturing Anchor Group, and Higher-level Size Standard Group (Data in Millions of Dollars)

Category	Size of Firm at 40%	Size of Firm at 50%	Size of Firm at 60%	Size of Firm at 70%
Facilities Support Services	$55.0	$134.8	$475.3	$1,333.6
Nonmanufacturing Anchor Group	$3.2	$5.8	$11.8	$28.0
Higher-level Size Standards	$24.2	$50.4	$135.6	$423.6

The Facilities Support Services industry is comprised of firms significantly larger than firms in the nonmanufacturing anchor group. Facilities Support Services firms of $55 million and less in receipts account for 40 percent of total industry receipts while firms of $3.2 million and less in receipts in the nonmanufacuturing anchor group received 40 percent of total industry receipts. For the remaining percentages of industry receipts, firms in the Facilities Support Services industry range between 11 to 47 times larger than the size of firms in the nonmanufacturing anchor group. In relation to the higher-level size standards group, Facilities Support Services firms are two to three times larger at every percentage level. These data indicate that a size standard at least comparable to SBA's highest receipts-based size standard of $29 million is appropriate for the Facilities Support Services industry.

Table 2 lists the other three evaluation factors for the Facilities Support Services industry and the comparison groups. These include comparisons of average firm size, the measurement of start-up costs as measured by nonpayroll receipts per establishment, and the four-firm concentration ratio.

Table 2: Industry Characteristics of the Facilities Support Services Industry, Nonmanufacturing Anchor Group, and Higher-level Size Standards Group

Category	Average Firm Size		Non payroll receipts per establishment (million $)	Four Firm Concentration Ratio
	Receipts (millions)	Employees		
Facilities Support Services	$6.2	93.0	$1.73	21.4%
Nonmanufacturing Anchor Group	$0.95	10.6	$0.56	14.4%
Higher-level Size Standards Group	$4.6	21.4	$1.80	26.7%

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The Facilities Support Services industry's average firm size in receipts is over six times larger than the average firm size in the nonmanufacturing anchor group and one-third higher than the higher-level size standard group. Moreover, its average firm size in employees is four to nine times the average sizes of these two comparison groups. The average size of firms in the Facilities Support Services industry is substantially higher than the comparison groups and also supports a size standard at least comparable to SBA's highest receipts-based size standard of $29 million.

As a measure of industry start-up costs, the nonpayroll receipts per establishment indicator for Facilities Support Services is twice that of the anchor comparison group, and at about the same as the higher-level size standard group. This factor suggests a Facilities Support Services size standard within the $21 million to $29 million range of size standards of the higher-level size standards group.

The Facilities Support Services four-firm concentration ratio is appreciably higher than the average of industries in the nonmanufacturer anchor group, but moderately below the level of the higher-level size standard. This factor shows the Facilities Support Services industry to be a relatively competitive industry where a size standard is between the $6 million nonmanufacturer anchor size standard and $21 million (the lowest size standard of the higher level size standard).

SBA Program Considerations: SBA also reviews its size standards in relationship to its programs. Since the

SBA is reviewing the Facilities Support Services industry's size standard because of concerns regarding the application of the size standard to Federal procurement, this proposed rule gives more consideration to the pattern of Federal contract awards than to the level of financial assistance to small businesses to assess whether its size standard should be revised. SBA provides a relatively small amount of financial assistance to Facilities Support Services firms. In fiscal years 2000 and 2001, an average of 19 loans for $4.5 million were guaranteed to firms in the Facilities Support Services industry. Most of these loans were to firms with less than $2 million in receipts. It's unlikely that an increase to the size standard will have a significant impact on the amount of new loans in SBA's financial programs or will crowd-out other small businesses from obtaining SBA guaranteed loans. Consequently, this factor is not part of the assessment of the size standard.

In the case of Federal procurements to Facilities Support Service firms, the share of Federal contracts awarded to small businesses supports an increase to the current size standard. Small Facilities Support Service firms account for 30.5 percent of total industry receipts but have received only 12 percent of the dollar value of Federal contracts awarded during fiscal years 1999 to 2001. Moreover, two-thirds of small business awards are made though programs reserved for small businesses or 8(a) firms. This disproportional share of Federal contract dollars relative to industry receipts generated by small Facilities Support Service firms indicates that contract requirements make it difficult for smaller firms to perform on Federal Facilities Support Services contracts. An increase to the size standard would be beneficial to small businesses in this industry by allowing them to grow in size to better perform the contract requirements.

Overview: Based on the analysis of each evaluation factor, SBA is proposing a $30 million size standard for Facilities Support Services. Two evaluation factors support a size standard of $29 million or higher, one factor supports a size standard within the range of SBA's higher-level size standards ($21 to $29 million), and one factor supports an intermediate range size standard between $6 million and $21 million. The assessment of small business participation in Federal procurements supports a size standard higher than the current Base Maintenance size standard of $23 million. The low amount of participation of small businesses in Federal government procurement is of special concern and suggests that contract requirements may indeed influence the size of Facilities Support Services firms that can perform the requirements of Federal contracts. The SBA believes that a size standard of $30 million, significantly higher than the current size standard of $23 million, is well supported by the analysis of industry data and will help small businesses in this industry compete for Federal contracts without including businesses that are so large that they could harm the ability of much smaller-sized small businesses to compete successfully for Federal contracts.

Dominant in Field of Operation: Section 3(a) of the Small Business Act defines a small concern as one that is (1) independently owned and operated, (2) not dominant in its field of operation and (3) within detailed definitions or size standards established by the SBA Administrator. The SBA considers as part of its evaluation of a size standard whether a business concern at or below a proposed size standard would be considered dominant in its field of operation. This assessment generally considers the market share of firms at the proposed or final size standard or other factors that may show whether a firm can exercise a major controlling influence on a national basis in which significant numbers of business concerns are engaged.

The SBA has determined that no firm at or below the proposed size standard for the Facilities Support Services industry would be of a sufficient size to dominate its field of operation. The largest firm at the proposed size standard level generates less than 0.4 percent of total industry receipts. This level of market share effectively precludes any ability for a firm at or below the proposed size standard to exert a controlling effect on this industry.

Alternative Size Standards: SBA considered an alternative size standard $35 million. As the industry evaluation showed, some of the factors might support a size standard at this level, but other factors supported a size standard within the range of its highest size standards ($21 million to $29 million). The industry data also show that firms earning $35 million in receipts tend to have more establishments than firms between $10 million to $30 million in size. This finding suggests that firms with $35 million in receipts have developed competitive capabilities that enable them to successfully expand operations.

SBA welcomes public comments on its proposed $30 million size standard for the Facilities Support Services industry. Comments on alternatives to the proposal, including the option of retaining the current size standards at $6 million and $23 million discussed above, should present the reasons that would make them preferable to the proposed size standard.

Compliance With Executive Orders 12866, 12988, and 13132, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Paperwork Reduction Act (44 U.S.C. Ch. 35)

The Office of Management and Budget (OMB) has determined that this rule is a ''significant'' regulatory action for purposes of Executive Order 12866 because size standards determine which businesses are eligible for Federal small business programs. This is not a major rule under the Congressional Review Act, 5 U.S.C. 800. For the purpose of the Paperwork Reduction Act, 44 U.S.C. Ch. 35, SBA has determined that this rule would not impose new reporting or record keeping requirements. For purposes of Executive Order 13132, SBA has determined that this rule does not have any federalism implications warranting the preparation of a Federalism Assessment. For purposes of Executive Order 12988, SBA has determined that this rule is drafted, to the extent practicable, in accordance with the standards set forth in that order. Our Regulatory Impact Analysis follows.

Regulatory Impact Analysis

1. Need for This Regulatory Action

SBA is chartered to aid and assist small businesses through a variety of financial, procurement, business development, and advocacy programs. To effectively assist the intended beneficiaries of these programs, SBA must establish distinct definitions of which businesses are deemed small businesses. The Small Business Act (15 U.S.C. 632(a)) delegates to the SBA Administrator the responsibility for establishing small business definitions. The Act also requires that small business definitions vary to reflect industry differences. The supplementary information to this proposed rule explains the approach SBA follows when analyzing a size standard for a particular industry. Based on that analysis, SBA believes that a change in the Facilities Support Services size standard is needed to better reflect small businesses in this industry.

2. What Are the Potential Benefits and Costs of This Regulatory Action?

The most significant benefit to businesses obtaining small business status as a result of this rule will be eligibility for Federal small business assistance programs. Under this rule, 177 additional firms may obtain small business status and become eligible for these programs. Of these 177, 19 are between the current $23 million Base Maintenance size standards and the $30 million proposed size standard. Federal small business assistance programs include SBA's financial assistance programs and Federal procurement preference programs for small businesses, 8(a) firms, small disadvantaged businesses (SDB), small businesses located in Historically Underutilized Business Zones (HUBZone), as well as those awarded through full and open competition after application of the HUBZone or SDB price evaluation adjustment. Other Federal agencies use SBA size standards for a variety of regulatory and program purposes. SBA does not have information on each of these uses to evaluate the impact of size standards changes. In cases where SBA size standards are not appropriate, an agency may establish its own size standards with the approval of the SBA Administrator (see 13 CFR 121.902). Through the assistance of these programs, small businesses may benefit by becoming more knowledgeable, stable, and competitive businesses.

The benefits of a size standard increase to a more appropriate level would affect three groups: (1) Businesses that benefit by gaining small business status from the proposed size standard and use small business assistance programs; (2) growing small businesses that may exceed the current size standard in the near future and who will retain small business status under the proposed size standard; and (3) Federal agencies that award contracts under procurement programs that require small business status.

Newly defined small businesses would benefit from the SBA's 7(a) Guaranteed Loan Program. SBA estimates that approximately $2.5 million to $5.5 million in new Federal loan guarantees could be made to these newly defined small businesses. Because of the $2 million maximum size of SBA 7(a) loan guarantees, most loans are made to small businesses well below the size standard. Thus increasing the size standard will likely result in a smaller increase in guaranteed loans to small businesses than the estimated range. These additional loan guarantees, because of their limited magnitude, will have virtually no impact on the overall availability of loans for SBA's loan programs, which have averaged about 40,000 loans totaling about $10 billion per year in recent years.

The newly defined small businesses would also benefit from SBA's economic injury disaster loan program. Since this program is contingent upon the occurrence and severity of a disaster, no meaningful estimate of benefits can be projected.

SBA estimates that firms gaining small business status could potentially obtain Federal contracts worth $65 million to $95 million under the small business set-aside program, the 8(a), Small Disadvantaged Business, and HUBZone programs, or unrestricted contracts. This estimate is based on an analysis of small business participation in Federal contracting and the industry market share of businesses between the current and proposed size standards. During fiscal years 1999–2001, small businesses obtained 11.8 percent of Facilities Support Services contract dollars out of approximately $12 billion in total Federal Facilities Support Services contracts. About two-thirds of small business awards were made as small business set-aside or 8(a) contracts. Most facilities support contracts are for Base Maintenance services, which has a $23 million size standard. Businesses between $23 million and $30 million account for 3.6 percent of industry sales.

Federal agencies may benefit from the higher size standards if the newly defined and expanding small businesses compete for more set-aside procurements. The larger base of small businesses would likely increase competition and would lower the prices on set-aside procurements. A large base of small businesses may create an incentive for Federal agencies to set aside more procurements creating greater opportunities for all small businesses. Small business opportunities will be enhanced in open procurements as they gain experience in Federal contracting through the set-aside and other small business procurement preference programs. Large businesses with small business subcontracting goals may also benefit from a larger pool of small businesses by enabling them to better achieve their subcontracting goals and at lower prices. No estimate of cost savings from these contracting decisions can be made since data are not available to directly measure price or competitive trends on Federal contracts.

To the extent that 177 additional firms become active in Government programs, this may entail some additional administrative costs to the Federal government associated with additional bidders for Federal small business procurement programs, additional firms seeking SBA guaranteed lending programs, and additional firms eligible for enrollment in SBA's PRO-Net data base program. Among businesses in this group seeking SBA assistance, there will be some additional costs associated with compliance and verification associated with certification of small business status and protests of small business status. These costs are likely to generate minimal incremental costs since mechanisms are currently in place to handle these administrative requirements.

The costs to the Federal Government may be higher on some Federal contracts. With greater number of businesses defined as small, Federal agencies may choose to set-aside more contracts for competition among small businesses rather than using full and open competition. The movement from unrestricted to set-aside contracting is likely to result in competition among fewer bidders. Also, higher costs may result if additional full and open contracts are awarded to HUBZone and SDB businesses as a result of a price evaluation preference. The additional costs associated with fewer bidders, however, are likely to be minor since, as a matter of policy, procurements may be set aside for small businesses or reserved for the 8(a), HUBZone Programs only if awards are expected to be made at fair and reasonable prices.

The proposed size standard may have distributional effects among large and small businesses. Although the actual outcome of the gains and losses among small and large businesses cannot be estimated with certainty, several trends are likely to emerge. First, there will likely be a transfer of some Federal contracts to small businesses from large businesses. Large businesses may have fewer Federal contract opportunities as Federal agencies decide to set aside more Federal procurements for small businesses. Also, some Federal contracts may be awarded to HUZone or SDB concerns instead of large businesses since those two categories of small businesses may be eligible for a price evaluation adjustment for contracts competed on a full and open basis. Similarly, currently defined small businesses may obtain fewer Federal contacts due to the increased competition from more businesses defined as small. This transfer may be offset by a greater number of Federal procurements set aside for all small

businesses. The number of newly defined and expanding small businesses that are willing and able to sell to the Federal Government will limit the potential transfer of contracts away from large and currently defined small businesses. The potential distributional impacts of these transfers may not be estimated with any degree of precision because the data on the size of business receiving a Federal contract are limited to identifying small or other-than-small businesses.

The revision to current size standards for Facilities Support Services is consistent with SBA's statutory mandate to assist small businesses. This regulatory action promotes the Administration's objectives. One of SBA's goals in support of the Administration's objectives is to help individual small businesses succeed through fair and equitable access to capital and credit, government contracts, and management and technical assistance. Reviewing and modifying size standards when appropriate ensures that intended beneficiaries have access to small business programs designed to assist them. Size standards do not interfere with state, local, and tribal governments in the exercise of their government functions. In a few cases, state and local governments have voluntarily adopted SBA's size standards for their programs to eliminate the need to establish an administrative mechanism for developing their own size standards.

Initial Regulatory Flexibility Analysis

Under the Regulatory Flexibility Act (RFA), this rule may have a significant impact on a substantial number of small entities. As described above in the Regulatory Impact Analysis, this rule may impact small entities in two ways. First, small businesses in the Facilities Support Services industry competing for Federal Government procurements reserved for small business, and SDB and HUBZone businesses eligible for price adjustment, may face greater competition from newly eligible small businesses. Second, additional Federal procurements for Facilities Support Services may be set aside for small businesses as the pool of eligible small businesses expands.

The proposed size standard may affect small businesses participating in programs of other agencies that use SBA size standards. As a practical matter, SBA cannot fully estimate the impact of a size standard change on each and every Federal program that uses its size standards. In cases where an SBA's size standard is not appropriate, the Small Business Act and SBA's regulations allow Federal agencies to develop different size standards with the approval of the SBA Administrator (13 CFR 121.902). For purposes of a regulatory flexibility analysis, agencies must consult with SBA's Office of Advocacy when developing different size standards for their programs.

Immediately below, SBA sets forth an initial regulatory flexibility analysis (IRFA) of this proposed rule addressing the following questions: (1) What is the need for and objective of the rule, (2) what is SBA's description and estimate of the number of small entities to which the rule will apply, (3) what is the projected reporting, recordkeeping, and other compliance requirements of the rule, (4) what are the relevant Federal rules which may duplicate, overlap or conflict with the proposed rule, and (5) what alternatives will allow the Agency to accomplish its regulatory objectives while minimizing the impact on small entities?

1. What Is the Need for and Objective of the Rule?

The revision to the size standards for Facilities Support Services more appropriately defines the size of businesses in these industries that SBA believes should be eligible for Federal small business assistance programs. A review of the latest available industry data supports a change to the size standard.

2. What Is SBA's Description and Estimate of the Number of Small Entities to Which the Rule Will Apply?

Within the Facilities Support Services industry, 896 out of 1,219 businesses are small. SBA estimates that 177 additional businesses out of 1,219 firms in the Facilities Support Services industry would be considered small as a result of this rule, if adopted. Of these 177, 19 are between the current $23 million Base Maintenance size standards and the $30 million proposed size standard. These businesses would be eligible to seek available SBA assistance provided that they meet other program requirements. Businesses becoming eligible for SBA assistance as a result of this rule, if finalized, cumulatively generate approximately $25.8 billion out of a total of $75.8 billion in receipts, or 34.1 percent of industry receipts. The small business coverage in the Facilities Support Services industry would increase by 3.6 percent of total receipts. SBA estimates that $2.5 million to $5.5 million additional loans may be guaranteed by SBA and $65 million to $95 million in additional Federal contracts may be awarded to the newly eligible small businesses.

3. What Are the Projected Reporting, Record Keeping, and Other Compliance Requirements of the Rule and an Estimate of the Classes of Small Entities That Will Be Subject to the Requirements?

A new size standard does not impose any additional reporting, record keeping or compliance requirements on small entities. Increasing size standards expands access to SBA programs that assist small businesses, but does not impose a regulatory burden as they neither regulate nor control business behavior.

4. What Are the Relevant Federal Rules Which May Duplicate, Overlap or Conflict With the Proposed Rule?

This proposed rule overlaps other Federal rules that use SBA's size standards to define a small business. Under Section 632(a)(2)(C) of the Small Business Act, unless specifically authorized by statute, Federal agencies must use SBA's size standards to define a small business. In 1995, SBA published in the **Federal Register** a list of statutory and regulatory size standards that identified the application of SBA's size standards as well as other size standards used by Federal agencies (60 FR 57988–57991, dated November 24, 1995). SBA is not aware of any Federal rule that would duplicate or conflict with establishing size standards.

SBA cannot completely estimate the impact of a size standard change on each and every Federal program that uses its size standards. In cases where an SBA's size standard is not appropriate, the Small Business Act and SBA's regulations allow Federal agencies to develop different size standards with the approval of the SBA Administrator (13 CFR 121.902). For purposes of a regulatory flexibility analysis, agencies must consult with SBA's Office of Advocacy when developing different size standards for their programs.

5. What Alternatives Will Allow the Agency To Accomplish Its Regulatory Objectives While Minimizing the Impact on Small Entities?

SBA considered two alternative size standards. First, it considered adopting the current $23 million Base Maintenance size standard to all activities in the Facilities Support Services industry. SBA believes this size standard level is inadequate given that most Federal contracts obtained by small businesses have been awarded through reserved contracting methods. This indicates that small businesses at

the current size standard have not developed to a size to be competitive for most Facilities Support Services contracts. Thus, a size standard higher than $23 million will help small businesses to grow to a more competitive level.

Second, SBA considered proposing a $35 million standard for the Facilities Support Services industry. As discussed in the supplementary analysis, some industry factors support a size standard at this level. Businesses at that size and larger tend to have more establishments than those between $10 million to $35 million. This indicates that businesses of $35 million have developed more competitively than currently defined small businesses.

List of Subjects in 13 CFR Part 121

Administrative practice and procedure, Government procurement, Government property, Grant programs—business, Loan programs—business, Small businesses.

For the reasons stated in the preamble, SBA proposes to amend part 121 of title 13 Code of Federal Regulations as follows:

PART 121—SMALL BUSINESS SIZE REGULATIONS

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

Authority: 15 U.S.C. 632(a), 634(b)(6), 637(a), 644(c) and 662(5) and Sec. 304, Pub. L. 103–403, 108 Stat. 4175, 4188.

2. Amend § 121.201 as follows:

a. In the table ''Small Business Size Standards by NAICS Industry,'' under the heading NAICS Subsector 561, ''Administrative and Support Services,'' revise the entry for 561210 to read as follows; and,

b. Revise footnotes 12 and 13 to read as follows:

§ 121.201 What size standards has SBA identified by North American Industry Classification System codes?

* * * * *

SMALL BUSINESS SIZE STANDARDS BY NAICS INDUSTRY

NAICS codes	NAICS U.S. industry title	Size standards in millions of dollars	Size standards in number of employees
*	* * * * *	*	*
	Subsector 561—Administrative and Support Services		
*	* * * * *	*	*
561210	Facilities Support Services [12]	.....	$30.0[12]
*	* * * * *	*	*

Footnotes

* * * * * *

[12] *NAICS code 562120—Facilities Support Services:*

(a) If one or more activities of Facilities Support Services as defined in paragraph (b) (below in this footnote) can be identified with a specific industry and that industry accounts for 50 percent or more of the value of an entire procurement, then the proper classification of the procurement is that of the specific industry, not Facilities Support Services.

(b) ''Facilities Support Services'' requires the performance of three or more separate activities in the areas of services or specialty trade construction industries. If services are performed, these service activities must each be in a separate NAICS industry. If the procurement requires the use of specialty trade contractors (plumbing, painting, plastering, carpentry, etc.), all such specialty trade construction activities are considered a single activity and classified as Base Housing Maintenance. Since Base Housing Maintenance is only one activity, two additional activities of separate NAICS industries are required for a procurement to be classified as ''Facilities Support Services.''

[13] *NAICS code 238990 '' Base Housing Maintenance:* If a procurement requires the use of multiple specialty trade contractors (*i.e.*, plumbing, painting, plastering, carpentry, etc.), and no specialty trade accounts for 50 percent or more of the value of the procurement, all such specialty trade construction activities are considered a single activity and classified as Base Housing Maintenance.

* * * * *

Dated: November 15, 2002.

Hector V. Barreto,

Administrator.

[FR Doc. 03–2455 Filed 1–31–03; 8:45 am]

BILLING CODE 8025–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 25

[Docket No. NM242; Notice No. 25–03–01–SC]

Special Conditions: Embraer Model 170–100 and 170–200 Airplanes; Sudden Engine Stoppage; Operation Without Normal Electrical Power; Interaction of Systems and Structures

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed special conditions.

SUMMARY: This notice proposes special conditions for the Embraer Model 170–100 and 170–200 airplanes. These airplanes will have novel or unusual design features when compared to the state of technology envisioned in the airworthiness standards for transport category airplanes. These design features are associated with (1) engine size and torque load which affect sudden engine stoppage, (2) electrical and electronic flight control systems which perform critical functions, and

(3) systems which affect the structural performance of the airplane. The applicable airworthiness regulations do not contain adequate or appropriate safety standards for these design features. These proposed special conditions contain the additional safety standards that the Administrator considers necessary to establish a level of safety equivalent to that established by the existing airworthiness standards. Additional special conditions will be issued for other novel or unusual design features of the Embraer Model 170–100 and 170–200 airplanes.

DATES: Comments must be received on or before March 20, 2003.

ADDRESSES: Comments on this proposal may be mailed in duplicate to: Federal Aviation Administration, Transport Airplane Directorate, Attention: Rules Docket (ANM–113), Docket No. NM242, 1601 Lind Avenue SW., Renton, Washington 98055–4056; or delivered in duplicate to the Transport Airplane Directorate at the above address. All comments must be marked: *Docket No. NM242.* Comments may be inspected in the Rules Docket weekdays, except Federal holidays, between 7:30 a.m. and 4 p.m.

FOR FURTHER INFORMATION CONTACT: Tom Groves, FAA, International Branch, ANM–116, Transport Airplane Directorate, Aircraft Certification Service, 1601 Lind Avenue SW., Renton, Washington 98055–4056; telephone (425) 227–1503; facsimile (425) 227–1149.

SUPPLEMENTARY INFORMATION:

Comments Invited

The FAA invites interested persons to participate in this rulemaking by submitting written comments, data, or views. The most helpful comments reference a specific portion of the special conditions, explain the reason for any recommended change, and include supporting data. We ask that you send us two copies of written comments.

We will file in the docket all comments we receive, as well as a report summarizing each substantive public contact with FAA personnel concerning these proposed special conditions. The docket is available for public inspection before and after the comment closing date. If you wish to review the docket in person, go to the address in the **ADDRESSES** section of this notice between 7:30 a.m. and 4 p.m., Monday through Friday, except Federal holidays.

We will consider all comments we receive on or before the closing date for comments. We will consider comments filed late if it is possible to do so without incurring expense or delay. We may change the proposed special conditions in light of the comments we receive.

If you want the FAA to acknowledge receipt of your comments on this proposal, include with your comments a pre-addressed, stamped postcard on which the docket number appears. We will stamp the date on the postcard and mail it back to you.

Background

On May 20, 1999, Embraer applied for a type certificate for its new Model 170 airplane. Two basic versions of the Model 170 are included in the application. The Model 170–100 airplane is a 69–78 passenger twin-engine regional jet with a maximum takeoff weight of 81,240 pounds. The Model 170–200 is a lengthened fuselage derivative of the 170–100. Passenger capacity for the Model 170–200 is increased to 86, and maximum takeoff weight is increased to 85,960 pounds.

Type Certification Basis

Under the provisions of 14 CFR 21.17, Embraer must show that the Model 170–100 and 170–200 airplanes meet the applicable provisions of 14 CFR part 25, as amended by Amendments 25–1 through 25–98.

If the Administrator finds that the applicable airworthiness regulations (*i.e.*, part 25, as amended) do not contain adequate or appropriate safety standards for the Embraer Model 170–100 and 170–200 airplanes because of novel or unusual design features, special conditions are prescribed under the provisions of § 21.16.

In addition to the applicable airworthiness regulations and special conditions, the Embraer Model 170–100 and 170–200 airplanes must comply with the fuel vent and exhaust emission requirements of 14 CFR part 34 and the noise certification requirements of 14 CFR part 36, and the FAA must issue a finding of regulatory adequacy pursuant to section 611 of Public Law 93–574, the ''Noise Control Act of 1972.''

Special conditions, as defined in 14 CFR 11.19, are issued in accordance with § 11.38 and become part of the type certification basis in accordance with § 21.17(a)(2), Amendment 21–69, effective September 16, 1991.

Special conditions are initially applicable to the model for which they are issued. Should the type certificate for that model be amended later to include any other model that incorporates the same novel or unusual design feature, or should any other model already included on the same type certificate be modified to incorporate the same novel or unusual design features, the special conditions would also apply to the other model under the provisions of § 21.101(a)(1), Amendment 21–69, effective September 16, 1991.

Novel or Unusual Design Features

The Embraer Model 170–100 and 170–200 airplanes will incorporate the following novel or unusual design features:

Engine Size and Torque Load

Since 1957 the limit engine torque load which is posed by sudden engine stoppage due to malfunction or structural failure—such as compressor jamming—has been a specific requirement for transport category airplanes. Design torque loads associated with typical failure scenarios were estimated by the engine manufacturer and provided to the airframe manufacturer as limit loads. These limit loads were considered simple, pure torque static loads. However, the size, configuration, and failure modes of jet engines have changed considerably from those envisioned when the engine seizure requirement of § 25.361(b) was first adopted. Current engines are much larger and are now designed with large bypass fans capable of producing much larger torque, if they become jammed.

Relative to the engine configurations that existed when the rule was developed in 1957, the present generation of engines are sufficiently different and novel to justify issuance of special conditions to establish appropriate design standards. The latest generation of jet engines are capable of producing, during failure, transient loads that are significantly higher and more complex than the generation of engines that were present when the existing standard was developed. Therefore, the FAA has determined that special conditions are needed for the Embraer Model 170–100 and 170–200 airplanes.

Electrical and Electronic Systems Which Perform Critical Functions

The Embraer Model 170–100 and 170–200 airplanes will have an electronic flight control system which performs critical functions. The current airworthiness standards of part 25 do not contain adequate or appropriate standards for the protection of this system from the adverse effects of operations without normal electrical power. Accordingly, this system is considered to be a novel or unusual design feature. Since the loss of normal

electrical power may be catastrophic to the airplane, special conditions are proposed to retain the level of safety envisioned by 14 CFR 25.1351(d).

Interactions of Systems and Structures

The Embraer Model 170–100 and 170–200 airplanes will have systems that affect the structural performance of the airplane, either directly or as a result of a failure or malfunction. These novel or unusual design features are systems that can alleviate loads in the airframe and, when in a failure state, can create loads in the airframe. The current regulations do not adequately account for the effects of these systems and their failures on structural performance.

Discussion

Engine Size and Torque Loads

In order to maintain the level of safety envisioned in 14 CFR 25.361(b), a more comprehensive criterion is needed for the new generation of high bypass engines. The proposed special conditions would distinguish between the more common seizure events and those rarer seizure events resulting from structural failures. For the rare but severe seizure events, the proposed criteria allow some deformation in the engine supporting structure (ultimate load design) in order to absorb the higher energy associated with the high bypass engines, while at the same time protecting the adjacent primary structure in the wing and fuselage by providing a higher safety factor. The criteria for the more severe events would no longer be a pure static torque load condition, but would account for the full spectrum of transient dynamic loads developed from the engine failure condition.

Electrical and Electronic Systems Which Perform Critical Functions

The Embraer Model 170–100 and 170–200 airplanes will require a continuous source of electrical power for the electronic flight control systems. Section § 25.1351(d), ''Operation without normal electrical power,'' requires safe operation in visual flight rule (VFR) conditions for a period of not less than five minutes with inoperative normal power. This rule was structured around a traditional design utilizing mechanical connections between the flight control surfaces and the pilot controls. Such traditional designs enable the flightcrew to maintain control of the airplane while taking the time to sort out the electrical failure, start engines if necessary, and re-establish some of the electrical power generation capability.

The Embraer Model 170–100 and 170–200 airplanes will utilize an electronic flight control system for the pitch and yaw control (elevator, stabilizer, and rudder). There is no mechanical linkage between the pilot controls and these flight control surfaces. Pilot control inputs are converted to electrical signals which are processed and then transmitted via wires to the control surface actuators. At the control surface actuators, the electrical signals are converted to an actuator command, which moves the control surface.

In order to maintain the same level of safety as an airplane with conventional flight controls, an airplane with electronic flight controls, such as the Embraer Model 170, must not be time limited in its operation, including being without the normal source of electrical power generated by the engine or the Auxiliary Power Unit (APU) generators.

Service experience has shown that the loss of all electrical power generated by the airplane's engine generators or APU is not extremely improbable. Thus, it must be demonstrated that the airplane can continue safe flight and landing (including steering and braking on ground) after total loss of the normal electrical power with only the use of its emergency electrical power systems. These emergency electrical power systems must be able to power loads that are essential for continued safe flight and landing. The emergency electrical power system must be designed to supply electrical power for the following:

- Immediate safety, without the need for crew action, following the loss of the normal engine generator electrical power system (which includes APU power), and
- Continued safe flight and landing, and
- Restarting the engines.

For compliance purposes, a test of the loss of normal engine generator power must be conducted to demonstrate that when the failure condition occurs during night Instrument Meteorological Conditions (IMC), at the most critical phase of the flight relative to the electrical power system design and distribution of equipment loads on the system, the following conditions are met:

1. After the unrestorable loss of normal engine and APU generator power, the airplane engine restart capability must be provided and operations continued in IMC.

2. The airplane is demonstrated to be capable of continued safe flight and landing. The length of time must be computed based on the maximum diversion time capability for which the airplane is being certified. Consideration for speed reductions resulting from the associated failure must be made.

3. The availability of APU operation should not be considered in establishing emergency power system adequacy.

Interaction of Systems and Structure

The Embraer Model 170 has systems that affect the structural performance of the airplane. These systems can serve to alleviate loads in the airframe and, when in a failure state, can create loads in the airframe. This degree of system and structures interaction was not envisioned in the structural design regulations of 14 CFR part 25. This proposed special condition provides comprehensive structural design safety margins as a function of systems reliability.

Applicability

As discussed above, these special conditions are applicable to the Embraer Model 170–100 and 170–200 airplanes. Should Embraer apply at a later date for a change to the type certificate to include another model incorporating the same novel or unusual design features, these special conditions would apply to that model as well under the provisions of § 21.101(a)(1), Amendment 21–69, effective September 16, 1991.

Conclusion

This action affects only certain novel or unusual design features on the Embraer Model 170–100 and 170–200 airplanes. It is not a rule of general applicability, and it affects only the applicant who applied to the FAA for approval of these features on the airplane.

List of Subjects in 14 CFR Part 25

Aircraft, Aviation safety, Reporting and recordkeeping requirements.

The authority citation for these special conditions is as follows:

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

The Proposed Special Conditions

Accordingly, the Federal Aviation Administration (FAA) proposes the following special conditions as part of the type certification basis for Embraer Model 170–100 and 170–200 airplanes.

Sudden Engine Stoppage. In lieu of compliance with 14 CFR 25.361(b), the following special conditions apply:

1. For turbine engine installations: The engine mounts, pylons and adjacent supporting airframe structure must be designed to withstand 1g level flight loads acting simultaneously with the

maximum limit torque loads imposed by each of the following:

a. Sudden engine deceleration due to a malfunction which could result in a temporary loss of power or thrust.

b. The maximum acceleration of the engine.

2. For auxiliary power unit installations: The power unit mounts and adjacent supporting airframe structure must be designed to withstand 1g level flight loads acting simultaneously with the maximum limit torque loads imposed by each of the following:

a. Sudden auxiliary power unit deceleration due to malfunction or structural failure.

b. The maximum acceleration of the auxiliary power unit.

3. For an engine supporting structure: An ultimate loading condition must be considered that combines 1g flight loads with the transient dynamic loads resulting from each of the following:

a. The loss of any fan, compressor, or turbine blade.

b. Where applicable to a specific engine design, and separately from the conditions specified in paragraph 3.a., any other engine structural failure that results in higher loads.

4. The ultimate loads developed from the conditions specified in paragraphs 3.a. and 3.b. above must be multiplied by a factor of 1.0 when applied to engine mounts and pylons and multiplied by a factor of 1.25 when applied to adjacent supporting airframe structure.

Operation Without Normal Electrical Power. In lieu of compliance with 14 CFR 25.1351(d), the following special conditions apply:

It must be demonstrated by test or by a combination of test and analysis, that the airplane can continue safe flight and landing with inoperative normal engine and APU generator electrical power (in other words, without electrical power from any source, except for the battery and any other standby electrical sources). The airplane operation should be considered at the critical phase of flight and include the ability to restart the engines and maintain flight for the maximum diversion time capability being certified.

Interaction of Systems and Structures: In lieu of compliance with 14 CFR 25.1351(d), the following special conditions apply:

1. *General:* For airplanes equipped with systems that affect structural performance, either directly or as a result of a failure or malfunction, the influence of these systems and their failure conditions must be taken into account when showing compliance with the requirements of 14 CFR part 25, subparts C and D. The following criteria must be used for showing compliance with these special conditions for airplanes equipped with flight control systems, autopilots, stability augmentation systems, load alleviation systems, flutter control systems, and fuel management systems. If these special conditions are used for other systems, it may be necessary to adapt the criteria to the specific system.

(a) The criteria defined herein address only the direct structural consequences of the system responses and performances and cannot be considered in isolation but should be included in the overall safety evaluation of the airplane. These criteria may in some instances duplicate standards already established for this evaluation. These criteria are only applicable to structures whose failure could prevent continued safe flight and landing. Specific criteria that define acceptable limits on handling characteristics or stability requirements when operating in the system degraded or inoperative modes are not provided in these special conditions.

(b) Depending upon the specific characteristics of the airplane, additional studies that go beyond the criteria provided in these special conditions may be required in order to demonstrate the capability of the airplane to meet other realistic conditions, such as alternative gust or maneuver descriptions, for an airplane equipped with a load alleviation system.

(c) The following definitions are applicable to these special conditions.

Structural performance: Capability of the airplane to meet the structural requirements of 14 CFR part 25.

Flight limitations: Limitations that can be applied to the airplane flight conditions following an in-flight occurrence and that are included in the flight manual (*e.g.*, speed limitations, avoidance of severe weather conditions, etc.).

Operational limitations: Limitations, including flight limitations that can be applied to the airplane operating conditions before dispatch (*e.g.*, fuel, payload, and Master Minimum Equipment List limitations).

Probabilistic terms: The probabilistic terms (probable, improbable, extremely improbable) used in these special conditions are the same as those used in § 25.1309.

Failure condition: The term failure condition is the same as that used in § 25.1309; however, these special conditions apply only to system failure conditions that affect the structural performance of the airplane (*e.g.*, system failure conditions that induce loads, lower flutter margins, or change the response of the airplane to inputs such as gusts or pilot actions).

2. *Effects of Systems on Structures.* The following criteria will be used in determining the influence of a system and its failure conditions on the airplane structure.

(a) System fully operative. With the system fully operative, the following apply:

(1) Limit loads must be derived in all normal operating configurations of the system from all the limit conditions specified in subpart C, taking into account any special behavior of such a system or associated functions, or any effect on the structural performance of the airplane that may occur up to the limit loads. In particular, any significant nonlinearity (rate of displacement of control surface, thresholds, or any other system nonlinearities) must be accounted for in a realistic or conservative way when deriving limit loads from limit conditions.

(2) The airplane must meet the strength requirements of part 25 (static strength, residual strength), using the specified factors to derive ultimate loads from the limit loads defined above. The effect of nonlinearities must be investigated beyond limit conditions to ensure the behavior of the system presents no anomaly compared to the behavior below limit conditions. However, conditions beyond limit conditions need not be considered when it can be shown that the airplane has design features that will not allow it to exceed those limit conditions.

(3) The airplane must meet the aeroelastic stability requirements of § 25.629.

(b) System in the failure condition. For any system failure condition not shown to be extremely improbable, the following apply:

(1) At the time of occurrence. Starting from 1-g level flight conditions, a realistic scenario, including pilot corrective actions, must be established to determine the loads occurring at the time of failure and immediately after failure.

(i) For static strength substantiation, these loads multiplied by an appropriate factor of safety that is related to the probability of occurrence of the failure are ultimate loads to be considered for design. The factor of safety (FS) is defined in Figure 1.

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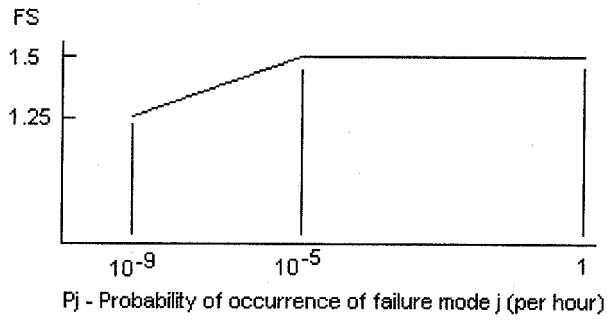
Figure 1
Factor of safety at the time of occurrence



(ii) For residual strength substantiation, the airplane must be able to withstand two-thirds of the ultimate loads defined in paragraph 2.(b)(1)(i) above.

(iii) Freedom from aeroelastic instability must be shown up to the speeds defined in § 25.629(b)(2). For failure conditions that result in speed increases beyond Vc/Mc, freedom from aeroelastic instability must be shown to increased speeds, so that the margins intended by § 25.629(b)(2) are maintained.

(iv) Failures of the system that result in forced structural vibrations (oscillatory failures) must not produce loads that could result in detrimental deformation of primary structure.

(2) For the continuation of the flight. For the airplane in the system failed state and considering any appropriate reconfiguration and flight limitations, the following apply:

(i) The loads derived from the following conditions at speeds up to Vc, or the speed limitation prescribed for the remainder of the flight, must be determined:

(A) The limit symmetrical maneuvering conditions specified in §§ 25.331 and 25.345.

(B) The limit gust and turbulence conditions specified in §§ 25.341 and 25.345.

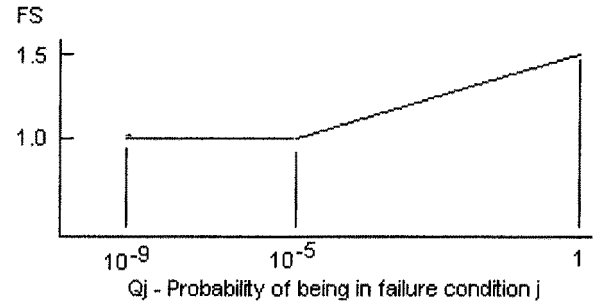
(C) The limit rolling conditions specified in § 25.349, and the limit unsymmetrical conditions specified in § 25.367 and § 25.427(b) and (c).

(D) The limit yaw maneuvering conditions specified in § 25.351.

(E) The limit ground loading conditions specified in §§ 25.473 and 25.491.

(ii) For static strength substantiation, each part of the structure must be able to withstand the loads defined in paragraph 2.(b)(2)(i) above, multiplied by a factor of safety depending on the probability of being in this failure state. The factor of safety is defined in Figure 2.

Figure 2
Factor of safety for continuation of flight



$Q_j = (T_j)(P_j)$ where:

T_j = Average time spent in failure condition j (in hours).

P_j = Probability of occurrence of failure mode j (per hour).

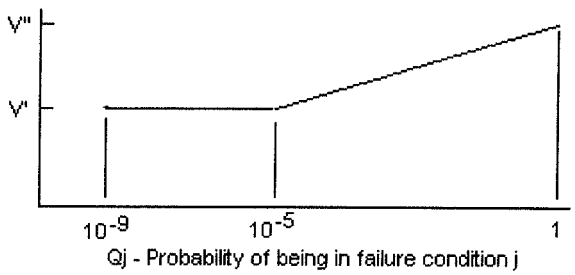
Note: If P_j is greater than 10^{-3} per flight hour, then a 1.5 factor of safety must be applied to all limit load conditions specified in subpart C.

(iii) For residual strength substantiation, the airplane must be able to withstand two thirds of the ultimate loads defined in paragraph 2.(b)(2)(ii) above.

(iv) If the loads induced by the failure condition have a significant effect on fatigue or damage tolerance, then their effects must be taken into account.

(v) Freedom from aeroelastic instability must be shown up to a speed determined from Figure 3. Flutter clearance speeds V^I and V^{II} may be based on the speed limitation specified for the remainder of the flight using the margins defined by § 25.629(b).

Figure 3
Clearance speed



V^I = Clearance speed as defined by § 25.629(b)(2).

V^{II} = Clearance speed as defined by § 25.629(b)(1).

$Q_j = (T_j)(P_j)$ where:

T_j = Average time spent in failure condition j (in hours).

P_j = Probability of occurrence of failure mode j (per hour).

Note: If P_j is greater than 10^{-3} per flight hour, then the flutter clearance speed must not be less than V^{II}.

(vi) Freedom from aeroelastic instability must also be shown up to V^I in Figure 3 above for any probable system failure condition combined with any damage required or selected for investigation by § 25.571(b).

(3) Consideration of certain failure conditions may be required by other sections of 14 CFR part 25, regardless of calculated system reliability. Where analysis shows the probability of these failure conditions to be less than 10^{-9}, criteria other than those specified in this paragraph may be used for structural substantiation to show continued safe flight and landing.

(c) Warning considerations. For system failure detection and warning, the following apply:

(1) The system must be checked for failure conditions, not extremely improbable, that degrade the structural capability below the level required by 14 CFR part 25, or significantly reduce the reliability of the remaining system. The flightcrew must be made aware of these failures before flight. Certain elements of the control system, such as mechanical and hydraulic components, may use special periodic inspections, and electronic components may use daily checks, in lieu of warning systems, to achieve the objective of this requirement. These certification maintenance requirements must be limited to components that are not readily detectable by normal warning systems and where service history shows that inspections will provide an adequate level of safety.

(2) The existence of any failure condition, not extremely improbable, during flight that could significantly affect the structural capability of the airplane, and for which the associated reduction in airworthiness can be minimized by suitable flight limitations, must be signaled to the flightcrew. For example, failure conditions that result in a factor of safety between the airplane strength and the loads of 14 CFR part 25, subpart C below 1.25, or flutter margins below V^{II}, must be signaled to the crew during flight.

(d) Dispatch with known failure conditions. If the airplane is to be dispatched in a known system failure condition that affects structural performance, or affects the reliability of the remaining system to maintain structural performance, then the provisions of these special conditions must be met for the dispatched condition and for subsequent failures. Flight limitations and expected operational limitations may be taken into account in establishing Qj as the combined probability of being in the dispatched failure condition and the subsequent failure condition for the safety margins in Figures 2 and 3. These limitations must be such that the probability of being in this combined failure state and then subsequently encountering limit load conditions is extremely improbable. No reduction in these safety margins is allowed if the subsequent system failure rate is greater than 10^{-3} per hour.

Issued in Renton, Washington, on January 9, 2003.

Ali Bahrami,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 03–2423 Filed 1–31–03; 8:45 am]

BILLING CODE 4910–13–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[DC052–7005, MD143–3096, VA152–5062; FRL–7445–8]

Approval and Promulgation of Air Quality Implementation Plans; District of Columbia, Maryland, Virginia; Post 1996 Rate-of-Progress Plans and One-Hour Ozone Attainment Demonstrations

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The EPA is proposing to conditionally approve the 1-hour ozone attainment demonstration and the 1996–1999 rate-of-progress (ROP) plans for the Metropolitan Washington DC ozone nonattainment area (the Washington area) submitted by the District of Columbia's Department of Health (DoH), by the Maryland Department of the Environment (MDE) and by the Virginia Department of Environmental Quality (VA DEQ), including enforceable commitments submitted by the District of Columbia, Virginia and Maryland as part of the 1-hour attainment demonstration plan to perform a mid-course review and to submit revised motor vehicle emissions budgets. We are also proposing to clarify what occurs if we issue a final conditional approval of any of these SIPs based on a State commitment to revise the SIP's 2005 motor vehicle emissions budgets in the future. If this occurs, the 2005 motor vehicle emissions budgets in the conditionally approved SIP will apply for transportation conformity purposes only until the budgets are revised consistent with the commitment and we have found the new budgets adequate. Once we have found the revised budgets adequate, then they would apply instead of the previous conditionally approved 2005 budgets. In the

alternative, the EPA is also proposing to disapprove the Washington area attainment demonstration with a protective finding for the 2005 motor vehicle emissions budgets and/or the 1996–1999 ROP plan with a protective finding for the 1999 motor vehicle emissions budgets.

DATES: Written comments must be received on or before March 5, 2003.

ADDRESSES: Comments may be mailed to Makeba Morris, Chief, Air Quality Planning and Information Services Branch, Mailcode 3AP21 U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103. Copies of the documents relevant to this action are available for public inspection during normal business hours at the Air Protection Division, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103; District of Columbia Department of Public Health, Air Quality Division, 51 N Street, NE., Washington, DC 20002; Maryland Department of the Environment, 1800 Washington Boulevard, Suite 705, Baltimore, Maryland 21230, Baltimore, Maryland 21224; and Virginia Department of Environmental Quality, 629 East Main Street, Richmond, Virginia 23219.

FOR FURTHER INFORMATION CONTACT: Christopher Cripps, (215) 814a–2179, or by e-mail at *cripps.christopher@epa.gov.*

SUPPLEMENTARY INFORMATION: The use of ''we,'' ''us,'' or ''our'' in this document refers to EPA.

This **SUPPLEMENTARY INFORMATION** section is organized to address the following questions:

I. What Action Is the EPA Proposing Today?
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  B. What Previous Action Has Been Taken on These SIP Revisions?
  C. What Is the Time Frame for Taking Action on These Washington Area SIP Revisions?
  D. What Is the Impact of the Reclassification of the Washington Area to Severe Ozone Nonattainment?
  E. What Is the Purpose of the Action EPA Is Taking Today?
III. Attainment Demonstrations
  A. What Is the Basis for the Attainment Demonstration SIP?
  B. What Is the Framework for Proposing Action on the Attainment Demonstration SIPs?
  C. The EPA's Review and Analysis of the District's, Maryland's and Virginia's Submittals Against the EPA's Framework for Proposing Action on the Attainment Demonstration SIPs
IV. Rate-of-Progress Plans
  A. What Agencies and Organizations Developed the 1996–1999 ROP Plan for the Area?
  B. What Are the Rate-of-progress Requirements Applicable to the Washington Area?
  C. How Is the 3 Percent per Year 1996–1999 Reduction Calculated?
  D. Nonattainment Area-Wide Plan—Apportionment of Reduction Needs
  E. What Control Strategies Are the District, Maryland and Virginia Including in the 1996–1999 ROP Plan?
  F. What Are the Total Reductions in the 1996—1999 ROP plan?
V. Applicability of Revised Motor Vehicle Emissions Budgets
  A. What Is the Background on Transportation Conformity?
  B. What Is the EPA Proposing Today Regarding Clarification of the Applicability of Revised Motor Vehicle Emissions Budgets?
  C. How Does the 18-Month Clock Apply With Respect to These Budgets Revisions?
  D. What Are the Budgets in the Plans?
  E. What Is the Status of the 1999 Motor Vehicle Emission Budgets Contained in the 1996–1999 ROP Plan for the Area?
VI. What Is the Basis for the Proposed Actions?
  A. Conditional Approval
  B. Disapproval in the Alternative
  C. Proposed Protective Findings
VII. Proposed Action
  A. The District of Columbia—Rate-of-Progress Plan
  B. The District of Columbia—Attainment Demonstration
  C. The State of Maryland—Rate-of-Progress Plan
  D. The State of Maryland—Attainment Demonstration
  E. The Commonwealth of Virginia—Rate-of-Progress Plan
  F. The Commonwealth of Virginia—Attainment Demonstration
  G. Applicability of Revised Motor Vehicle Emissions Budgets
VIII. Statutory and Executive Order Reviews

I. What Action Is the EPA Proposing Today?

The EPA is proposing conditional approval of the 1996–1999 ROP plans and the one-hour attainment demonstrations submitted by the DoH, MDE and VADEQ for the Washington area. The following tables identify submittal dates and amendment dates for the 1996–1999 ROP plans and the attainment demonstrations:

TABLE 1.—1996–1999 ROP PLANS

	DC	MD	VA
Initial submittal dates	November 10, 1997	December 24, 1997	December 19, 1997.
Amendment dates	May 25, 1999	May 20, 1999	May 25, 1999.

TABLE 2.—ATTAINMENT DEMONSTRATIONS

	DC	MD	VA
Initial submittal dates	April 24, 1998	April 29, 1998	April 29, 1998.
Amendment dates	October 27, 1998	August 17, 1998	August 18, 1998.
Supplemental dates	February 16, 2000	February 14, 2000 (MD SIP No. 00–01).	February 9, 2000.
Supplemental dates	March 22, 2000	March 31, 2000 (MD SIP No. 00–02).	March 31, 2000.

Hereafter, the SIP revisions in the preceding Table submitted in April 1998 will be called the ''1998 Plans;'' those submitted in February 2000 will be called the ''February 2000 plans;'' and those submitted in March 2000 will be called the ''March 2000 plans.''

As noted elsewhere in this document, the EPA is also proposing in the alternative to disapprove these SIPs if we do not finalize the conditional approval of these SIPs.

II. Background

A. What Is the Washington Nonattainment Area?

The Washington area is comprised of the entire District of Columbia (the District), a portion of Maryland (namely, Calvert, Charles, Frederick, Montgomery, and Prince George's Counties), and a portion of Virginia (namely, Alexandria, Arlington County, Fairfax, Fairfax County, Falls Church, Manassas, Manassas Park, Prince William County, and Stafford County).

B. What Previous Action Has Been Taken on These SIP Revisions?

On January 3, 2001 (66 FR 586), the EPA approved the 1996–1999 ROP plans, an attainment date extension and the attainment demonstrations for the Washington, DC area. A petition for review of that final rule was filed. On July 2, 2002, the United States Courts of Appeals for the District of Columbia Circuit (the Circuit Court) ruled on the petition and vacated our January 3, 2001, approval of the attainment demonstration, 1996–1999 ROP plan and extension of the attainment date. See *Sierra Club* v. *Whitman,* 294 F.3d 155, 163 (D.C. Cir. 2002). With respect to the attainment date extension, the Court found that the plain language of Clean Air Act ''sets a deadline without an exception for setbacks owing to ozone transport.'' *Id.* at 161. The Circuit Court said that the EPA was without authority to extend the Washington, DC area's attainment deadline unless it also ordered the area to be reclassified as a ''severe'' area. The Circuit Court also found that the attainment demonstration and ROP plan were deficient because neither SIP revision contained approved contingency measures as required by sections 172(c)(9) and 182(c)(9) of the Clean Air Act (CAA). *Id.* at 164. Furthermore, the Circuit Court determined that in addition to a nine percent reduction in baseline emissions from 1996 to 1999, an area with an attainment date in 2005 must submit a ROP plan that demonstrates additional ROP to 2005. *Id.* at 163. The Washington area's 1996–1999 ROP plan demonstrated ROP only through 1999. Lastly, although the Circuit Court upheld the EPA's definition of RACM ''[b]ecause the statutory provision is ambiguous and the EPA's construction of the term 'RACM' is reasonable'', the Court remanded this matter to the EPA to determine which measures, if any, are RACM to be implemented by the States in this case because the final rule did not present any determination on whether certain measures tendered as possible RACM in the notice of proposed rulemaking (64 FR 70460) met EPA's RACM definition. *Id.* at 162–63.

In response to the Circuit Court's ruling, on January 24, 2003 the EPA published a final action (68 FR 3410) determining that the Washington area failed to attain the serious ozone nonattainment deadline of November 15, 1999, and reclassifying the Washington area to severe ozone nonattainment.

C. What Is the Time Frame for Taking Action on These Washington Area SIP Revisions?

Under the CAA, the EPA is required to approve or disapprove a State's submission no later than 12 months after the submission is determined or deemed complete. On November 13, 2002, the Sierra Club filed a complaint in the United States District Court for the District of Columbia (District Court) against the EPA (*Sierra Club* v. *Whitman,* No. 1:02CV02235(JR)) claiming, among other things, that the EPA had not issued a final action on several SIP revisions (those listed in Tables 1 and 2 of this document) submitted by the District, Maryland and Virginia for the Washington area. On December 18, 2002, the District Court issued an order directing the EPA to publish, by February 3, 2003, a notice of proposed rulemaking on these SIP revisions and to publish by April 17, 2003, a final rule on these SIP revisions. This notice of proposed rulemaking complies with the Court's Order to publish a proposed notice by February 3, 2003.

D. What Is the Impact of the Reclassification of the Washington Area to Severe Ozone Nonattainment?

The reclassification to severe nonattainment imposes additional requirements on the Washington area including, among other things, CAA-mandated control measures, a fee program for major sources and ROP plans (an additional 9 percent reduction in base line emissions between 1999 and 2005). These new requirements, as well as all of the requirements for a severe ozone nonattainment SIP, must be submitted to the EPA by the date established in the reclassification final rule. (68 FR 3410).

Section 172(c)(9) of the CAA requires that specific measures must be undertaken if an area fails to make reasonable further progress, or to attain the NAAQS by the attainment date. Furthermore, such measures must be included in the SIP as contingency measures to take effect without further action by the State or the Administrator. As noted previously, the Circuit Court ruled that sections 172(c)(9) and 182(c)(9) of the CAA require that contingency measures must be included as an integral element in the attainment demonstration and ROP SIPs for the Washington area. The Court further determined that EPA lacked the authority to approve attainment demonstration and ROP SIPs without contingency measures. Therefore, the jurisdictions in the Washington area have committed to submit to the EPA those measures that qualify as contingency measures due to the failure of the Washington area to attain the ozone standard for serious areas by November 15, 1999. They have also committed to submit contingency measures for failure to meet the 1999 ROP milestone if we find that the area has not achieved the required reductions. The contingency measures for the 1999 ROP milestone and the contingency measures for failure to attain by 1999 could be the same measures. These measures need to provide for at least a 3 percent reduction in base line emissions and be fully adopted rules or measures that can be implemented without further action by the States or EPA after November 15, 1999. Such contingency measures must also meet all of the EPA's guidance and policy relating to contingency measures.

E. What Is the Purpose of the Action EPA Is Taking Today?

This proposed conditional approval is directed at issuing a final action on the previously submitted attainment demonstration and 1996–1999 ROP plan SIPs and associated RACM and contingency measures that now apply to the Washington area as elements required by classification as a severe ozone nonattainment area. In this case, the EPA could not approve a SIP that is not consistent with the principle in the CAA that attainment must be achieved as expeditiously as practicable but no later than November 15, 2005, the new attainment date provided under the statute. Furthermore, the EPA cannot fully approve the previously submitted serious area attainment demonstration because it lacks contingency measures, RACM and motor vehicle emission budgets that are consistent with a severe attainment deadline. Similarly, the EPA cannot fully approve the previously submitted 1996–1999 ROP plan because it lacks contingency measures.

Under section 110(k)(4) of the CAA, the EPA ''may approve a plan revision based on a commitment of the State to adopt specific enforceable measures by a date certain, but not later than 1 year after the date of approval of the plan revision. Any such conditional approval

shall be treated as a disapproval if the State fails to comply with such commitment.'' The EPA is proposing to conditionally approve these SIP submissions as a severe area attainment demonstration and the 1996–99 portion of the Washington area's ROP obligation on the basis of the commitments from the affected jurisdictions. EPA believes that this action is appropriate because the attainment date for the Washington area, which will be reclassified as severe effective March 25, 2003 (68 FR 3410), will be November 15, 2005, and because the States have committed in accordance with section 110(k)(4) to submit revisions to remedy the inadequacies with the RACM and contingency measure aspects of the attainment demonstration and the 1996–99 ROP plans. Since the Court viewed the contingency measures as an element of an attainment demonstration and ROP plan, and rejected EPA's argument that contingency measures were a separate SIP submission, EPA believes it is appropriate to proceed on the basis of a commitment to deal with that aspect of the attainment plan and ROP plan. Similarly, the RACM demonstration is merely another element of the attainment demonstration and EPA believes that it is appropriate to proceed with a conditional approval on the basis of a commitment regarding the RACM demonstration. As a consequence of the reclassification to severe, the Washington area will need to submit additional SIP revisions concerning other matters, such as the 1999–2005 ROP obligation and new NSR requirements, but EPA believes that it can proceed on the SIPs before it as a severe area attainment demonstration plan and a 1996–1999 ROP plan without those additional SIP submissions.

III. Attainment Demonstrations

A. What Is the Basis for the Attainment Demonstration SIP?

1. CAA Requirements

The Clean Air Act (CAA) requires the EPA to establish national ambient air quality standards (NAAQS or standards) for certain widespread pollutants that cause or contribute to air pollution that is reasonably anticipated to endanger public health or welfare. *See* sections 108 and 109 of the CAA. In 1979, the EPA promulgated the 1-hour 0.12 parts per million (ppm) ground-level ozone standard. 44 FR 8202 (February 8, 1979). Ground-level ozone is not emitted directly by sources. Rather, emissions of nitrogen oxides (NO_X) and volatile organic compounds (VOCs) react in the presence of sunlight to form ground-level ozone. Emissions of NO_X and VOC are referred to as precursors of ozone.

An area exceeds the 1-hour ozone standard each time an ambient air quality monitor records a 1-hour average ozone concentration above 0.124 ppm. An area is violating the standard if, over a consecutive three-year period, more than three exceedances are expected to occur at any one monitor. The CAA, as amended in 1990, required the EPA to designate as nonattainment any area that was violating the 1-hour ozone standard, generally based on air quality monitoring data from the three-year period from 1987–1989. CAA section 107(d)(4); 56 FR 56694 (Nov. 6, 1991). The CAA further classified these areas, based on the area's design value, as marginal, moderate, serious, severe or extreme. CAA section181(a). Marginal areas were suffering the least significant air pollution problems while the areas classified as severe and extreme had the most significant air pollution problems. The control requirements and dates by which attainment needs to be achieved vary with the area's classification. Marginal areas are subject to the fewest mandated control requirements and have the earliest attainment date. Severe and extreme areas are subject to more stringent planning requirements but are provided more time to attain the standard. Serious areas are required to attain the 1-hour standard by November 15, 1999, and severe areas are required to attain by November 15, 2005, or November 15, 2007. The Washington area was classified as a serious nonattainment area with an attainment date of November 15, 1999. On January 24, 2003, the EPA published a final rule (68 FR 3410) reclassifying the area to severe ozone nonattainment, with an attainment date of November 15, 2005.

Under section 182(c)(2) and (d) of the CAA, serious and severe areas were required to submit by November 15, 1994, demonstrations of how they would attain the 1-hour standard and how they would achieve reductions in VOC emissions of 9 percent for each three-year period until the attainment year (rate-of-progress or ROP). (In some cases, NO_X emission reductions can be substituted for the required VOC emission reductions.) Today, in this proposed rule, the EPA is proposing action on the attainment demonstration SIP submitted by DoH, the MDE and the VADEQ for the Washington area.

In general, an attainment demonstration SIP includes a modeling analysis component showing how the area will achieve the standard by its attainment date and the control measures necessary to achieve those reductions. Another component of the attainment demonstration SIP is motor vehicle emissions budgets for transportation conformity purposes. Transportation conformity is a process for ensuring that States consider the effects of emissions associated with new or improved federally-funded roadways on attainment of the standard. As described in section 176(c)(2)(A) of the CAA, attainment demonstrations must include the estimates of motor vehicle emissions that are consistent with attainment, which then act as budgets for the purposes of determining whether transportation plans and projects conform to the attainment SIP.[1]

2. What Are the Components of a Modeled Attainment Demonstration?

The EPA allows that States may rely upon a modeled attainment demonstration supplemented with additional evidence to demonstrate attainment.[2] In order to have a complete modeling demonstration submission, States should have submitted the required modeling analysis and identified any additional evidence that the EPA should consider in evaluating whether the area will attain the standard.

The EPA addressed the sufficiency of the modeling demonstration to attain by November 15, 2005, in its previous notices regarding the Washington area attainment demonstration. See 64 FR 70460, December 16, 1999, and 66 FR 586, January 3, 2001. Since the Circuit Court did not address issues regarding the adequacy of the modeling demonstration, EPA believes that it may approve that modeling demonstration at this time. EPA incorporates by reference herein its prior proposal, the comments submitted thereon, and its response to those comments. EPA is not reprinting that discussion here but will address any further comments submitted in response to this re-proposal of its approval of the modeling demonstration showing attainment of the Washington area by November 2005.

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[1] Under the CAA, the District of Columbia has the same attainment planning authorities and responsibilities as any of the 50 States.

[2] EPA issued guidance on the air quality modeling that is used to demonstrate attainment with the 1-hour ozone NAAQS. *See* U.S. EPA, (1991), Guideline for Regulatory Application of the Urban Airshed Model, EPA–450/4–91–013, (July 1991). (A copy may be found on EPA's web site at *http://www.epa.gov/ttn/scram/* (file name: ''UAMIVGUIDE'')). *See also* U.S. EPA, (1996), Guidance on Use of Modeled Results to Demonstrate Attainment of the Ozone NAAQS, EPA–454/B–95–007, (June 1996). A copy may be found on EPA's web site at *http://www.epa.gov/ttn/scram/* (file name: ''O3TEST'').

B. What Is the Framework for Proposing Action on the Attainment Demonstration SIPs?

In addition to the modeling analysis, the EPA has identified the following key elements which must be present in order for the EPA to approve or conditionally approve the 1-hour attainment demonstration SIPs. These elements are first listed in this section and then described in detail.

CAA Measures and Measures Relied on in the Modeled Attainment Demonstration—This includes adopted and submitted rules for all previously required CAA mandated measures for the specific area classification, including contingency measures should the are fail to attain by the required date, and RACM. This also includes measures that may not be required for the area classification but that the State relied on in the SIP submission for attainment and ROP plans on which the EPA is proposing to take action on today.

NO_X reductions consistent with the modeling demonstration: *Motor vehicle emissions budgets*—Motor vehicle emissions budgets that EPA can determine to be consistent with the underlying purpose of the applicable CAA requirements.

Tier 2/Sulfur program benefits where needed to demonstrate attainment—Inclusion of reductions expected from the EPA's Tier 2 tailpipe and low sulfur-in-fuel standards in the attainment demonstration and the motor vehicle emissions budgets.

Mid-course review—An enforceable commitment to conduct a mid-course review and evaluation based on air quality and emission trends. The mid-course review would show whether the adopted control measures are sufficient to reach attainment by the area's attainment date, or that additional control measures are necessary.

1. CAA Measures and Measures Relied on in the Modeled Attainment Demonstration

The Washington area needs to achieve substantial reductions from its 1990 emissions levels in order to attain. The EPA believes the Washington area needs all of the measures required under the CAA for its former serious nonattainment classification to attain the 1-hour ozone NAAQS. The District, Maryland and Virginia have adopted the control measures required under the CAA for the former serious area classification as well as additional control measures within the local modeling domain that were relied on for purposes of the modeled attainment demonstration.

The Washington area attainment demonstration does not contain a RACM analysis which the Circuit Court held was required under section 172(c)(1) of the CAA. In its January 3, 2001, approval of the Washington area nonattainment demonstration and 1996–1999 ROP plan (66 FR 607), the EPA posited that a state must ''consider all potentially available measures to determine whether they were reasonably available for implementation in the area, and whether they would advance the attainment date''. Furthermore, the EPA determined that states may ''reject measures as not being RACM because they would not advance the attainment date, would cause substantial widespread and long-term adverse impacts, or would be economically or technologically infeasible.'' Although the Circuit Court vacated the EPA's January 3, 2001, approval of the Washington area's attainment demonstration and 1996–1999 ROP plan, the Circuit Court upheld the EPA's definition of RACM. *See Sierra Club* v. *Whitman,* 294 F.3d at 162–63. However, the Circuit Court found that the EPA had not determined whether any measures for the Washington area fell within the EPA's definition and remanded the matter to the EPA to determine which measures, if any, are to be implemented as RACM. *Id.* at 163.

With respect to contingency measures, the Washington area attainment demonstration does not contain a contingency plan that identifies those measures that will be implemented should the area not attain the standard by November 15, 2005. Section 172(c)(9) of the CAA requires that specific measures must be undertaken if an area fails to make reasonable further progress, or to attain the NAAQS by the attainment date. Furthermore, such measures must be included in the SIP as contingency measures to take effect without further action by the State or the Administrator. As noted previously, the Circuit Court ruled that sections 172(c)(9) and 182(c)(9) of the CAA require that contingency measures must be included as an integral element in the attainment demonstration and ROP SIPs for the Washington area. The Circuit Court further determined that EPA lacked the authority to approve the Washington area attainment demonstration and ROP SIPs without contingency measures. Therefore, the jurisdictions in the Washington area have committed to submit to the EPA adopted contingency measures to be implemented if the Washington area does not attain the 1-hour ozone standard by November 15, 2005. These measures need to provide for at least a 3 percent reduction in base line emissions and be fully adopted rules or measures that can be implemented without further action by the States or EPA after November 15, 2005. The contingency measures must also meet all of the EPA's guidance and policy relating to contingency measures.

2. NO_X Reductions Consistent With the Modeling Demonstration

The EPA completed final rulemaking on the NO_X SIP Call on October 27, 1998, which required States to address transport of NO_X and ozone to other States. To address transport, the NO_X SIP Call established NO_X emissions budgets for 23 jurisdictions that are intended to reduce emissions in upwind States that significantly contribute to nonattainment problems. Emission reductions that will be achieved through the EPA's NO_X SIP Call will reduce the levels of ozone and ozone precursors entering nonattainment areas at their boundaries. For purposes of developing attainment demonstrations, States define local modeling domains that include both the nonattainment area and nearby surrounding areas. The ozone levels at the boundary of the local modeling domain are reflected in modeled attainment demonstrations and are referred to as boundary conditions. The 1-hour attainment demonstration for the Washington area relies, in part, on the NO_X SIP Call reductions for purposes of determining the boundary conditions of the modeling domain. Emission reductions assumed in the attainment demonstrations are modeled to occur both within the State and in upwind States; thus, intrastate reductions as well as reductions in other States impact the boundary conditions. If States assume control levels and emission reductions other than those of the NO_X SIP Call within their State but outside of the modeling domain, States must also adopt control measures to achieve those reductions in order to have an approvable plan.

Accordingly, States in which the nonattainment areas are located will not be required to adopt measures outside the modeling domain to achieve the NO_X SIP Call budgets prior to the time that all States are required to comply with the NO_X SIP Call. If the reductions from the NO_X SIP Call do not occur as planned, States will need to revise their SIPs to add additional local measures or obtain interstate reductions, or both, in order to provide sufficient reductions needed for attainment.

3. Motor Vehicle Emissions Budgets

The EPA believes that attainment demonstration SIPs must necessarily estimate the motor vehicle emissions that will be produced in the attainment year and demonstrate that this emissions level, when considered with emissions from all other sources, is consistent with attainment. This estimate of motor vehicle emissions is used to determine the conformity of transportation plans and programs to the SIP, as described by CAA section 176(c)(2)(A). For transportation conformity purposes, these estimates of motor vehicle emissions are known as the motor vehicle emissions budgets. The EPA believes that appropriately identified motor vehicle emissions budgets are a necessary part of an attainment demonstration SIP. A SIP cannot effectively demonstrate attainment unless it identifies the level of motor vehicle emissions that can be allowed while still demonstrating attainment.

4. Tier 2/Sulfur Program Benefits

On February 10, 2000 (65 FR 6698), the EPA published a final rule promulgating a major, comprehensive program designed to significantly reduce emissions from passenger cars and light trucks (including sport-utility vehicles, minivans, and pickup trucks) and to reduce sulfur in gasoline. Under this program, automakers would produce vehicles designed to have very low emissions when operated on low-sulfur gasoline, and oil refiners would provide that cleaner gasoline nationwide.

The final rule was supported by 1-hour ozone modeling and monitoring information that support the EPA's conclusion that the Tier 2/Sulfur program is necessary to help areas attain the 1-hour NAAQS. See 64 FR 35112, June 30, 1999, and 64 FR 57827, October 27, 1999. Under the final rule, NO_X and VOC emission reductions (as well as other reductions not directly relevant for attainment of the 1-hour ozone standard) would occur beginning in the 2004 ozone season. Nationwide, the Tier 2/Sulfur program is projected to result in emissions reductions of NO_X per year of approximately 856,000 tons per year by 2007 and 1,236,000 tons by 2010 tons (65 FR at 6698).

In the October 27, 1999, supplemental notice (64 FR at 57830), the EPA reported that the EPA's regional ozone modeling indicated that 17 metropolitan areas for which the 1-hour standard applies need the Tier 2/Sulfur program reductions to help attain the 1-hour ozone standard. The Washington area whose attainment demonstration the EPA is proposing to conditionally approve today is included on that list.

The EPA issued a memorandum that provides estimates of the emissions reductions associated with the Tier 2/Sulfur program proposal.[3] The memorandum provides the tonnage benefits for the Tier 2/Sulfur program in 2007 on a county-by-county basis for all counties within many serious and severe nonattainment areas and the 2005 tonnage benefits for the Tier 2/Sulfur program for each county for three areas.

The EPA also issued a memorandum which explains the connection between the Tier 2/Sulfur program, motor vehicle emissions budgets for conformity determinations, and timing for SIP revisions to account for the Tier 2/Sulfur program benefit.[4] This memorandum explains that conformity analyses in serious and severe ozone nonattainment areas can begin including Tier 2/Sulfur program benefits once the EPA's Tier 2 rule is promulgated, provided that the attainment demonstration SIPs and associated motor vehicle emissions budgets include the Tier 2 benefits. The motor vehicle emissions budgets in the February 2000 plans include Tier 2 benefits.

The District, Maryland and Virginia need to revise their motor vehicle emissions budgets in their attainment demonstration SIPs using the MOBILE6 model because the motor vehicle emissions budgets in the February 2000 plans to include the effects of the Tier 2/Sulfur program, which can not be accurately reflected with the MOBILE5 model. In addition, the budgets need to be revised using MOBILE6 even in an area that does not need the Tier 2/Sulfur program for attainment but decide to include its benefits in the motor vehicle emissions budgets anyway.

When we first proposed action on the attainment demonstration for the Washington area (64 FR 70460, December 16, 1999), the District, Maryland and Virginia needed to submit an enforceable commitment in the near term to revise their motor vehicle emissions budgets if the budgets include the effects of the Tier 2/Sulfur program within one year after the EPA's release of MOBILE6. When we released the Tier 2 guidance and policy in November 1999, we could not forecast the MOBILE6 release date in relation to final action on the attainment demonstration SIP revisions. Such release date could have been over one-year past the time we approved the attainment demonstration for an area, and therefore, a conditional approval would not have been a suitable approval option. Therefore, at that time, approval of an enforceable commitment would ensure the requirement to revise the motor vehicle emissions budgets could be enforced in court by the EPA or citizens. The enforceable commitment was to be submitted to the EPA along with the other commitments discussed elsewhere in this document, or alternatively, as part of the SIP revision that modified the motor vehicle emission inventories and budgets to include the Tier 2/Sulfur program benefits needed in order for the EPA to approve the SIP submittal. The MOBILE6 model was released on January 29, 2002 (67 FR 4254). Now that MOBILE6 has been released, the EPA may issue a conditional approval based on a State's commitment to expeditiously revise and submit not later than one-year after the EPA issues a conditional approval to the EPA an updated attainment demonstration SIP that reflects revised MOBILE6-based motor vehicle emissions budgets.

5. Mid-Course Review

A mid-course review (MCR) is a reassessment of modeling analyses and more recent monitored data to determine if a prescribed control strategy is resulting in emission reductions and air quality improvements needed to attain the ambient air quality standard for ozone as expeditiously as practicable but by no later than the statutory dates. The EPA believes that an enforceable commitment to perform a MCR is a critical element of the WOE analysis for the attainment demonstration on which the EPA is proposing to take action today. The State of Maryland, the Commonwealth of Virginia and the District submitted an enforceable commitment to perform a MCR as described here. However, an enforceable commitment to perform and submit a MCR is meaningless outside of the context of an approved attainment demonstration. For this reason, our conditional approval of the attainment

[3] Memorandum, ''1-Hour Ozone Attainment Demonstrations and Tier 2/Sulfur Rulemaking'' from Lydia Wegman, Office of Air Quality Planning and Standards and Merrylin Zaw-Mon, Office of Mobile Sources to the Air Division Directors, Regions I–IV, issued November 8, 1999. A copy of this memorandum may be found on the EPA's web site at *http://www.epa.gov/oms/transp/traqconf.htm.*

[4] Memorandum, ''Guidance on Motor Vehicle Emissions Budgets in One-Hour Ozone Attainment Demonstrations'', from Merrylin Zaw-Mon, Office of Mobile Sources, to Air Division Directors, Regions I–VI, issued November 3, 1999. A copy of this memorandum may be found on the EPA's web site at *http://www.epa.gov/oms/transp/traqconf.htm.*

demonstration includes the enforceable commitment to perform a mid-course review.

C. The EPA's Review and Analysis of the District's, Maryland's and Virginia's Submittals Against the EPA's Framework for Proposing Action on Attainment Demonstration SIPs

This section provides a review of Maryland's, Virginia's and the District's submittals and an analysis of how these submittals satisfy the frame work previously discussed.

As noted previously, the EPA addressed the sufficiency of the modeling demonstration of attainment in its previous notices regarding the Washington area attainment demonstration and incorporated by reference its prior proposal, the comments submitted thereon, and its response to those comments. *See* 64 FR 70460, December 16, 1999, and 66 FR 586, January 3, 2001. EPA is not reprinting that discussion here but will address any further comments submitted in response to this re-proposal of its approval of the modeling demonstration showing attainment of the Washington area by November 2005.

1. CAA Measures and Measures Relied on in the Current SIP Submission

Table 3 contains a summary of the CAA required ozone SIP elements for serious areas and any additional measures included in the attainment demonstration.

TABLE 3.—CONTROL MEASURES IN THE 1-HOUR OZONE 1996–1999 ROP PLAN AND ATTAINMENT PLANS FOR THE METROPOLITAN WASHINGTON NONATTAINMENT AREA

Control measure	Type of measure	Credited in 1996—1999 ROP plan	Credited in attainment plan
Enhanced Inspection & Maintenance	Approved SIP	Yes	Yes.
Federal Motor Vehicle Control program	Federal	Tier 1	Tier 1 and 2.
NLEV	Approved SIP opt-in	Yes	Yes[1].
Reformulated Gasoline (Phase 1 & 2)	State opt-in	Phase 1	Phase 2.
Transportation Control Measures (TCM)	Approved SIP	Yes	Yes.
Federal Non-road Gasoline Engine standards	Federal	Yes	Yes.
Federal Non-road Heavy Duty diesel engine standards	Federal	Yes	Yes.
Rail Road Locomotive Controls	Federal	No	Yes.
NO_X RACT	Approved SIP	Yes	Yes.
Non-CTG RACT to 50 tpy	Approved SIP	Yes	Yes.
VOC Point Source Regulations to 25 tons/year[2]	Approved SIP	Yes	Yes.
Stage II Vapor Recovery[3] & On-board Refueling Vapor Recovery (ORVR)	Approved SIP Federal	Yes	Yes.
AIM Surface Coatings	Federal	Yes	Yes.
Consumer & commercial products	Federal	Yes	Yes.
Autobody refinishing	Federal/State	Yes	Yes.
Surface Cleaning/Degreasing	Approved SIP	Yes	Yes.
Open Burning Ban[2]	Approved SIP	Yes	Yes.
Stage I Vapor Recovery[4]	Approved SIP	Yes	Yes.
Graphic Arts	Approved SIP	Yes	Yes.
Heavy Duty Diesel Engines (On-road)	Federal	No	Yes.
Beyond RACT NO_X Requirements on Utilities	Approved SIP	No	Yes.

Notes:
[1] To the extent NLEV not superceded by Tier 2.
[2] Maryland and Virginia only.
[3] Reduction credits calculated for Maryland and Virginia only. The District required implementation of Stage II in 1985 for most sources, and has claimed no reductions since 1990. (The District's Stage II regulation was amended after 1990 to comply with the requirements for Stage II controls set forth in the 1990 amendments to the Clean Air Act. The EPA has approved the District's rule into the SIP.
[4] Reductions in only in those additional areas in Maryland and Virginia that were added to the Metropolitan Washington DC area after 1990.

The MDE, VADEQ and DoH have submitted all measures relied on in the attainment demonstration and all required measures except RACM and specific contingency measures. All submitted measures have been approved to date with the exception of Transportation Control Measures (TCMs), which are as part of the Washington area attainment demonstration and 1996–1999 ROP plan that the EPA is proposing to conditionally approve in this document. TCMs are strategies to both reduce vehicle miles traveled (VMT) and decrease the amount of emissions per VMT. The CAA classifies TCMs as programs for improved transit, traffic flow, fringe parking facilities for multiple occupancy transit programs, high occupancy or share-ride programs, and support for bicycle and other non-automobile transit. The TCMs for Virginia and Maryland included projects programmed between fiscal years 1994–1999 in the transportation improvement plan (TIP) under the Congestion Mitigation and Air Quality (CMAQ) Improvement Program and funded for implementation in the Washington area. The specific projects that Virginia and Maryland are claiming credit for and the estimated benefits are listed in Appendix H of the 1996–1999 ROP plan and Appendix J of the February 2000 plans. TCMs are considered acceptable measures for states to use to achieve reductions and EPA has determined that the VOC and NO_X reductions attributable to these measures are creditable for the 1996–1999 ROP plan and attainment demonstration.

The EPA is also proposing to conditionally approve the attainment demonstration based on the District, Maryland and Virginia having committed to submit contingency measures that will be implemented if the area fails to attain the ozone standard by November 15, 2005. In addition, the District, Maryland and Virginia have committed to submitting to the EPA an appropriate RACM analysis and any revisions to the attainment demonstration necessitated by such an analysis, including revised emissions budgets as applicable.

2. NO_X Reductions Consistent With the Modeling Demonstration

Inside the Baltimore-Washington modeling domain, the District, Maryland and Virginia modeled only the measures indicated in Table 3. The only NO_X control measure beyond CAA requirements was an additional level of control beyond RACT at large stationary sources of NO_X in the District's and Maryland's portion of the Washington area. The status of all measures was discussed in the preceding section of this document.

3. Motor Vehicle Emissions Budgets

As discussed in section III.B.3 of this document, the motor vehicle emissions budgets are the estimate of motor vehicle emissions in the attainment year that when considered with emissions from all other sources is consistent with attainment. The attainment demonstrations for the Washington area contain levels of modeled emissions that the EPA concludes demonstrate attainment once transport from upwind areas is addressed. The basis for this conclusion will not be altered if the Washington area can demonstrate that the level of nonattainment area emissions in 2005 is equal to or less than the 1999 control strategy levels contained in the attainment demonstrations considering growth. Thus, Maryland, Virginia and the District have demonstrated that revised motor vehicle emissions budgets for 2005 in the attainment demonstrations for the Washington area are adequate by showing that overall emissions including the revised motor vehicle emissions budgets when considered with emissions from all other sources are less than the 1999 control strategy levels. In the February 2000 plans, the States submitted such a demonstration. The EPA has reviewed these submittals and found that all measures upon which the States relied are now in the approved SIP.

The EPA has interpreted the general adequacy criteria with respect to the 1-hour ozone attainment demonstrations to require the motor vehicle emissions budgets to include the effects of all motor vehicle controls, including Federal measures and the mobile source control measures assumed in the NO_X SIP Call, that will be in place in the attainment year. Therefore, the revised motor vehicle emissions budgets presumptively must include all currently promulgated Federal measures and State SIP measures and opt-ins shown in Table 4.

TABLE 4.—ON-ROAD MOBILE SOURCE CONTROL MEASURES CONTRIBUTING TO ATTAINMENT OF THE 1-HOUR OZONE NAAQS IN THE WASHINGTON NONATTAINMENT AREA IN 2005

Control measure	Implementation year	Assumed in local modeling demonstration?	In the 2005 motor vehicle emissions budget?
Federal Motor Vehicle Control Program (FMVCP):			
Tier 1	1994	Tier 1 FMVCP only	Yes.
Tier 2	2004		Yes.
High enhanced I/M (CAA Mandate)	1997	Yes	Yes.
Reformulated Gasoline (State Opt-in):			
Phase I	1995	Yes	Yes.
Phase II	2000	No	Yes.
Clean Fuel Fleets/National Low Emissions Vehicles (NLEV)	1999	No	Yes.
Federal Heavy-duty Diesel Vehicle (HDV) 2 gm std	2004	No	Yes.

4. Tier 2/Sulfur Program Benefits

The EPA concludes that based on the modeling and WOE that the Washington area would not need any additional emission reductions beyond those contained in the area attainment demonstration to ensure attainment of the ozone NAAQS by 2005. Like other areas that rely, in part or in full, on Tier 2 reductions in order to demonstrate attainment, the Washington area attainment demonstration was revised in the February 2000 plans to estimate the effects of Tier 2 according to our policy. However, as noted, this was done with the MOBILE5 model which is inaccurate and must be redone with the MOBILE6 model.

The EPA is proposing to conditionally approve the attainment demonstration SIP revisions which include the commitment found in section 9.1.1.2 of the March 2000 plans for the Washington area because the State of Maryland, Commonwealth of Virginia and the District of Columbia have committed to revise and submit to the EPA by April 17, 2004, an updated attainment demonstration SIP that reflects revised MOBILE6-based motor vehicle emissions budgets, including revisions to the attainment modeling and/or weight of evidence demonstration, as necessary, to demonstrate that the SIP continues to demonstrate attainment by November 15, 2005.

5. Mid-Course Review (MCR)

In accordance with the provisions of section III.B.5. of this document, the EPA must receive an enforceable commitment to include a MCR from each of the three Washington area States before their attainment demonstrations can be approved. Virginia, Maryland and the District submitted these commitments on February 9, 14 and 22, 2000, respectively. The EPA has concluded that the enforceable commitments found in February 2000 plans are acceptable. However, an enforceable commitment to perform a mid-course review is meaningless outside of the context of an approved attainment demonstration. For this reason, our proposal to conditionally approve the attainment demonstration includes the enforceable commitment to perform and submit the MCR contained within the February 2000 plans.

IV. Rate-of-Progress Plans

A. What Agencies and Organizations Developed the 1996–1999 ROP Plan for the Washington Area?

The District of Columbia, Virginia and Maryland must demonstrate reasonable further progress (RFP) for the Washington area. These jurisdictions, under the auspices of the Metropolitan Washington Air Quality Committee (MWAQC) (with the assistance of the Metropolitan Washington Council of Governments) collaborated on a coordinated 1996–1999 ROP plan for the Washington area. The MWAQC includes state and local elected officials and representatives of the DC

Department of Health, the Maryland Department of the Environment, the Virginia Department of Environmental Quality and the National Capital Region Transportation Planning Board (TPB). The Act provides for interstate coordination for multi-state nonattainment areas. Because ROP requirements such as the 1996–1999 ROP plan establish emission budgets for transportation improvement plans, municipal planning organizations have historically been involved in air quality planning in the Washington area. The MWAQC ensures consultation with the TPB during the development of the 1996–1999 ROP plan and emission budgets. As explained below, the regional 1996–1999 ROP plan determined the regional target level, regional projections of growth and finally the total amount of creditable reductions required under the 9 percent requirement in the Washington area. The District of Columbia, Maryland and Virginia agreed to apportion this total amount of required creditable reductions among themselves. Although the plan was developed by a regional approach, each jurisdiction is required to submit its portion of the 1996–1999 ROP plan to the EPA as a revision to its SIP.

B. What Are the Rate-of-Progress Requirements Applicable to the Washington Area?

The CAA requires that serious and above ozone nonattainment areas develop plans to reduce area-wide VOC emissions after 1996 by 3 percent per year until the year of the attainment date required for that classification of nonattainment area. In addition, section 172(c)(9) of the CAA requires the SIP to provide for specific measures to be undertaken if an area fails to make reasonable further progress. The Washington area is classified as a serious ozone nonattainment area with an attainment date of November 15, 1999. However, the EPA published its final rule reclassifying the Washington area to severe ozone nonattainment effective March 25, 2003. The statutory attainment date for severe areas is November 15, 2005. As a serious area, the 3 percent per year requirement is expressed as an average over consecutive 3-year periods; thus, the requirement is a 9 percent reduction by 1999. However, the Circuit Court ruling on the EPA's approval of the Washington area attainment demonstration and 1996–1999 ROP plan indicated that in addition to a nine percent reduction in baseline emissions from 1996 to 1999, an area with an attainment date in 2005 must submit a ROP plan for the Washington area that demonstrates additional ROP to 2005. 294 F. 3d at 163. The **Federal Register** notice reclassifying the Washington area to severe ozone nonattainment imposes additional requirements on the Washington area including, among other things, ROP plans that achieve an additional 18 percent reduction in base line emissions between 1999 and 2005. These new requirements, as well as all of the requirements for a severe ozone nonattainment SIP, must be submitted to the EPA by the date established in the reclassification final rule. This proposed action is confined to the 1996-1999 ROP requirements for a severe ozone nonattainment area that are currently pending before the Agency.

The ROP plans were to be submitted by November 15, 1994, and the first 9 percent reductions were required to be achieved within 9 years after enactment, that is, by November 15, 1999. This 9 percent reduction requirement is a continuation of the requirement for a 15 percent reduction in VOC by 1996. For the 1996–1999 ROP plan, the Act allows the substitution of NO_X emissions reductions for VOC emission reductions where equivalent air quality benefits are achieved as determined using the applicable EPA guidance. The 9 percent VOC/NO_X reduction required by November 15, 1999, is a demonstration of reasonable further progress in the Washington area. Our assessment of the 1996–1999 ROP plan is limited to whether or not the 9 percent reduction requirement is met.

C. How Is the 3 Percent per Year 1996–1999 Reduction Calculated?

A 1996–1999 ROP plan consists of a plan to achieve a target level of emissions. There are several important emission inventories and calculations associated with the plan. These include: The base year emission inventory, future year projection inventories, and target level calculations.

The EPA addressed the sufficiency of the 1996–1999 ROP plan base year emission inventory, future year projection inventories, and target level calculations in its previous notices regarding the Washington area attainment demonstration. *See* 65 FR 58243, September 28, 2000, and 65 FR 62658, October 19, 2000. Since the Circuit Court did not address issues regarding the adequacy of the base year emission inventory, future year projection inventories, and target level calculations, the EPA believes that it may approve these calculations at this time. EPA incorporates by reference herein its prior proposal, the comments submitted thereon, and its response to those comments. EPA is not reprinting that discussion here but will address any further comments submitted in response to this re-proposal of its approval of the base year emission inventory, future year projection inventories, and target level calculations.

D. Nonattainment Area-Wide Plan—Apportionment of Reduction Needs

The EPA must determine whether or not the Washington area 9 percent requirement has been met. In general, the emission reduction from a measure is the difference between the future year projected uncontrolled emissions and the future year controlled emissions, or is equal to a percentage of the future year projected uncontrolled emissions. For on-road mobile sources, the emission reductions from a measure or suite of measures are determined by the difference of projected future year emissions with and without new control measures.

The Washington area 1996–1999 ROP plan apportions among the District, Maryland and Virginia the amount of creditable emission reductions that each must achieve in order for the nonattainment area to achieve, as a region, the required 9 percent reduction in VOC net of growth. The 1996–1999 ROP plan identifies the amount of creditable emission reductions that each state must achieve for the nonattainment area-wide plan to get a 9 percent reduction accounting for any growth in emissions from 1990 to 1999. The District of Columbia, Maryland and Virginia each committed to achieving the necessary NO_X and VOC reductions, found in Table 5.

TABLE 5.—EMISSION REDUCTION COMMITMENTS FOR THE WASHINGTON AREA THROUGH 1999

[tons/day]

	District of Columbia	Maryland	Virginia	Area total
Total VOC reduction by 1999	10.6	63.7	57.2	131.5
Total NO_X reduction by 1999	7.2	96.8	46.6	150.6

The required VOC and NO_X emission reductions for each jurisdiction have been apportioned using a ratio of the regional reduction requirement to the claimed creditable measures for the nonattainment area. This result was then multiplied by each jurisdiction's total creditable measures to determine its emission reduction requirement. The EPA has determined that this apportionment of the emission reduction needed for ROP is approvable because the Act provides for interstate planning of SIPs, and because all three jurisdictions have committed to achieving, in the aggregate, sufficient reductions to achieve the 9 percent requirement in the entire nonattainment area.

E. What Control Strategies Are the District, Maryland and Virginia Including in the 1996–1999 ROP Plan?

The 1996–1999 ROP plan describes the emission reduction credits that the Washington area jurisdictions are claiming toward their 9 percent reduction requirement. We can credit reductions for the ROP requirement for rules promulgated by the EPA and for state measures in the approved SIP.

Transportation Control Measures (TCMs): TCMs are strategies to both reduce VMT and decrease the amount of emissions per VMT. The CAA classifies as TCMs programs for improved transit, traffic flow, fringe parking facilities for multiple occupancy transit programs, high occupancy or share-ride programs, and support for bicycle and other non-automobile transit. The 1996–1999 ROP plans for Virginia and Maryland included TCM projects programmed between fiscal years 1994–1999 in the transportation improvement plan (TIP) under the Congestion Mitigation and Air Quality (CMAQ) Improvement Program and funded for implementation in the Washington area. The specific projects that Virginia and Maryland are claiming credit for and the estimated benefits are listed in Appendix H of the 1996–1999 ROP plan and Appendix J of the February 2000 plans. TCMs are considered acceptable measures for states to use to achieve reductions and EPA has determined that the VOC and NO_X reductions attributable to these measures are creditable for the 1996–1999 ROP plan and attainment demonstration.

The 1996–1999 ROP plan control measures for the Washington area are listed in Table 3 of this document and described in more detail in the TSD for this rulemaking.

F. What Are the Total Reductions in the 1996–1999 ROP Plan?

Tables 6, 7 and 8 summarize the VOC and NO_X creditable measures in Maryland's, Virginia's and the District's 1996–1999 ROP plan for the Washington area.

TABLE 6.—CREDITABLE VOC EMISSION REDUCTIONS IN THE 1996–1999 ROP PLAN FOR THE METROPOLITAN WASHINGTON AREA

[tons/day]

Measure	District of Columbia	Maryland	Virginia
Tier 1 FMVCP	1.4	5.5	5.9
RFG Refueling Benefits	0.0	0.9	0.7
NLEV	0.2	0.6	1.3
Reformulated Gasoline (on/off road)	2.2	7.9	8.0
Surface Cleaning/Degreasing	0.0	2.9	0.0
Autobody Refinishing	0.5	3.8	2.7
AIM	1.6	6.6	5.6
Consumer Products	0.6	2.2	1.9
Seasonal Open Burning Ban	0.0	3.7	2.6
Graphic Arts	0.9	1.0	1.5
Landfill Regulations	0.0	0	0.3
Non-CTG RACT to 50 TPY	0.0	0.4	0.4
RACT on Additional Sources >25 TPY and <50 TPY	N/A	0.3	0
Stage II Vapor Recovery	0.0	8.9	7.9
Stage I Enhancement (excluding Loudoun County, VA)	0.0	0.9	0.3
Non-road Gasoline Engines Rule	0.9	6.3	6.8
TCMs	0.0	0.1	0.1
Enhanced I/M	3.9	18.0	17.9
Total Creditable Reductions	11.8	70.0	63.9

TABLE 7.—CREDITABLE NO_X EMISSION REDUCTIONS IN THE 1996–1999 ROP PLAN FOR THE METROPOLITAN WASHINGTON AREA

[tons/day]

Measure	District of Columbia	Maryland	Virginia
Enhanced I/M	2.4	14.8	16.9
Tier 1	2.5	13.7	14.7
NLEV	.2	0.3	1.5
Reformulated Gasoline (on-road)	0.0	0.1	0.1
Non-road Gasoline Engines	−0.1	−0.4	−0.5
Non-road Diesel Engines	0.4	3.7	3.2
State NO_X RACT	2.1	67.9	12.0
Open Burning Ban	0	0.8	0.6
TCMs	0	0.2	0.2
Total Creditable Reductions	7.5	101.1	48.7

TABLE 8.—CREDITABLE EMISSION REDUCTIONS VERSUS REDUCTION NEEDS FOR THE 1996–1999 ROP PLAN FOR THE METROPOLITAN WASHINGTON AREA

[tons/day]

	District of Columbia	Maryland	Virginia	Area-wide
VOC Reductions in Plan	11.8	70.0	63.9	145.7
Commitment/Area-wide Needs	10.6	63.7	57.2	131.5
Surplus	1.2	6.3	6.7	14.2
NO_X Reductions in Plan	7.5	101.1	48.7	157.3
Commitment/Area-wide Needs	7.2	96.8	46.6	150.6
Surplus	0.3	4.3	2.1	6.7

Section 172(c)(9) of the CAA requires that specific measures must be undertaken if an area fails to make reasonable further progress, or to attain the NAAQS by the attainment date. Furthermore, such measures must be included in the SIP as contingency measures to take effect without further action by the State or the Administrator. As noted previously, the Circuit Court ruled that sections 172(c)(9) and 182(c)(9) of the CAA require that contingency measures must be included as an element in the attainment demonstration and ROP SIPs for the Washington area. The Court further determined that EPA lacked the authority to approve attainment demonstration and ROP SIPs without contingency measures. Therefore, the jurisdictions in the Washington area have committed to submit contingency measures that will be implemented should EPA notify the Washington area jurisdictions that the area did not achieve the required 9 percent reductions by November 15, 1999. These measures need to provide for a 3 percent reduction in base line emissions and be fully adopted rules or measures that can implemented without further action by the States or EPA after November 15, 1999. Such contingency measures must also meet all of the EPA's guidance and policy relating to contingency measures.

V. Applicability of Revised Motor Vehicle Emissions Budgets

A. What Is the Background on Transportation Conformity?

1. What Is Transportation Conformity?

Transportation conformity is a Clean Air Act (CAA) requirement for metropolitan planning organizations and the U.S. Department of Transportation to ensure that federally supported highway and transit activities are consistent with (''conform to'') the SIP. Conformity to a SIP means that an action will not cause or contribute to new violations; worsen existing violations; or delay timely attainment. The conformity requirements are established by CAA section 176(c). We issued the transportation conformity rule (40 CFR part 93) to implement this CAA requirement.

2. What Are Motor Vehicle Emissions Budgets?

As described in CAA section 176(c)(2)(A), attainment demonstrations necessarily include estimates of motor vehicle emissions to help areas reach attainment. These estimates act as a budget or ceiling for emissions from motor vehicles, and are used in conformity to determine whether transportation plans and projects conform to the attainment SIP. In order for transportation plans and projects to conform, estimated emissions from transportation plans and projects must not exceed the emission budgets contained in the attainment demonstration.

3. Which Motor Vehicle Emissions Budgets Usually Apply?

According to the transportation conformity rule, motor vehicle emissions budgets in a submitted SIP apply for conformity purposes even before we have approved the SIP, under certain circumstances. First, there must not be any other approved SIP motor vehicle emissions budgets that have been established for the same time frame and with respect to the same CAA requirements. For example, if there is already an approved attainment demonstration SIP that establishes motor vehicle emissions budgets for the attainment date, and the State submits a revision to those motor vehicle emissions budgets, the newly submitted budgets do not apply for conformity purposes until we have approved them into the SIP.

Second, submitted SIP motor vehicle emissions budgets cannot be used before we have approved the SIP unless we have found that the submitted SIP motor

vehicle emissions budgets are adequate for conformity purposes. Our process for determining adequacy is explained at 40 CFR 93.118(e) and the EPA's May 14, 1999, memo entitled, ''Conformity Guidance on Implementation of March 2, 1999, Conformity Court Decision.''

For more details about the applicability of submitted and approved budgets, *see* 61 FR 36117 (July 9, 1996) and 62 FR 43783 (August 15, 1997).

B. What Is the EPA Proposing Today Regarding Clarification of the Applicability of Revised Motor Vehicle Emissions Budgets?

We are proposing to clarify this proposal with regard to applicability of revised budgets under a conditional approval of the attainment demonstration SIPs for the Washington area. The following discussion addresses this issue specifically pertaining to the motor vehicle emissions budgets in the attainment demonstration for the Washington area.

1. How Are We Proposing to Clarify the Applicability of Revised Budgets?

In this notice, we are proposing to clarify what occurs if we issue a conditional approval of any of the February 2000 plans based on a State commitment to revise the 2005 motor vehicle emissions budgets for the Washington area in the future. If this occurs, the approved SIP motor vehicle emissions budgets will apply for conformity purposes only until the revised motor vehicle emissions budgets have been submitted and we have found the submitted motor vehicle emissions budgets to be adequate for conformity purposes.

In other words, when the State submits revised motor vehicle emissions budgets as they have committed, those revised motor vehicle emissions budgets will apply for conformity purposes as soon as we have found those motor vehicle emissions budgets to be adequate for conformity purposes and our adequacy finding is effective. The revised motor vehicle emissions budgets would then replace the motor vehicle emissions budgets in the conditionally approved attainment demonstration SIP, provided that (as we expect) the revised motor vehicle emissions budgets are submitted as a revision to part of the attainment demonstration SIP and are established for the same year as those in the approved SIP.

2. Why Are We Proposing to Clarify the Applicability of Revised Budgets?

In this notice of proposed rulemaking, we are proposing that for reasons described in section III.C. we would not conditionally approve the attainment demonstration SIPs unless the States commit to revise the SIPs' budgets in the future. As described in prior sections of this preamble, the motor vehicle emissions budgets must be revised using MOBILE6 because the attainment year budgets that would be conditionally approved reflect the benefits of our Tier 2/Sulfur regulation. The budgets might also be revised as a result of the RACM analysis the area has committed to complete.

Since we are proposing to approve attainment year motor vehicle emissions budgets only because the States have committed to revise them, we want our approval of the budgets to last only until adequate revised budgets are submitted pursuant to the commitments. We believe the revised motor vehicle emissions budgets should apply as soon as we find them adequate; we do not believe it is appropriate to wait until we have fully approved the revised attainment demonstration SIP. This is because we already know that once we have confirmed that the revised motor vehicle emissions budgets are adequate, they will be more appropriate than the originally approved budgets for conformity purposes.

In addition, we know now that the area cannot estimate accurately the benefits of the Tier 2 program until they revise the budgets using the MOBILE6 model. We are proposing to conditionally approve motor vehicle emissions budgets based on interim approximations of Tier 2 benefits only because the States are committing to recalculate the budgets using MOBILE6 in a timely fashion.

Finally, we know now that if the area identifies any additional mobile source RACM, the budgets, as revised to include those measures, will more accurately reflect the emissions levels necessary to demonstrate attainment. If we do not clarify our proposed conditional approval of the motor vehicle emissions budgets, States will revise their budgets as they have committed, but they will not be able to start using them quickly for conformity purposes. This would defeat the purpose of our original requirements for the budgets to be revised quickly. In contrast, according to this proposal, the revised budgets could be used for conformity after we have completed our adequacy review process, which we have committed to complete within 90 days after revisions are submitted, provided they are adequate.

This notice does not propose any change to the existing transportation conformity rule or to the way it is normally implemented with respect to other submitted and approved SIPs, which do not contain commitments to revise the motor vehicle emissions budgets.

C. How Does the 18-Month Clock Apply With Respect to These Budget Revisions?

Section 93.104(e)(2) of the conformity rule requires conformity of the transportation plan and transportation improvement program (TIP) to be redetermined within 18 months following the date of a State's initial submission of each SIP establishing a budget.

As described at 60 FR 44792 (August 29, 1995), the first submission of a given type of SIP that establishes a motor vehicle emissions budget (*e.g.*, an ozone attainment demonstration) starts the 18-month clock for redetermining conformity. However, the 18-month clock is unaffected by subsequent changes to that submitted SIP.

Therefore, the revisions to the attainment demonstration SIPs to reflect MOBILE6 or any additional RACM will not start a new 18-month clock. Of course, whenever conformity is determined in the future (in accordance with the 18-month clock or for any other reason), the demonstration must use whatever motor vehicle emissions budgets are applicable at that time. If an initial submission starts the 18-month clock but then is changed and the revised motor vehicle emissions budgets are found adequate, any subsequent conformity determination must use the new, adequate budgets.

Section 93.104(e)(3) also requires conformity of the transportation plan and TIP to be redetermined 18 months following our approval of a SIP that establishes or revises a budget. If we conditionally approve an ozone attainment demonstration, an 18-month clock will be started on the effective date of our conditional approval. A subsequent conversion of the conditional approval to full approval will not start another 18-month clock, unless the motor vehicle emissions budgets we are approving have changed since the conditional approval.

D. What Are the Budgets in the Plans?

The motor vehicle emissions budgets in the 1996–1999 ROP plan and attainment demonstrations are area-wide budgets for the entire Washington area. The motor vehicle emissions budgets for 1999 in the 1996–1999 ROP plan are 196.4 tons per day of NO_X and 128.5 tons per day of VOC. The motor vehicle emissions budgets for 2005 in the attainment demonstration are 101.8

tons per day for VOC and 161.8 tons per day of NO_X.

E. What Is the Status of the 1999 Motor Vehicle Emission Budgets Contained in the 1996–1999 ROP Plan for the Area?

We are proposing to conditionally approve the 1996–1999 ROP plan for the area including the 1999 motor vehicle emission budgets, or in the alternative, to disapprove this SIP with a protective finding. It should be noted that the 1999 budgets in the ROP plan do not have to be revised using MOBILE6 since these budgets were established for a year prior to the implementation of the Tier 2/sulfur regulations.

VI. What Is the Basis for the Proposed Actions?

A. Conditional Approval

In the previous sections of this document, the EPA has presented our analysis of the 1996–1999 ROP plan and attainment demonstration plans submitted for the Washington area. The EPA has concluded that these submittals will be fully approvable once several deficiencies are corrected. Two of these deficiencies were identified by the Circuit Court, namely that the 1996–1999 ROP plan and the attainment demonstration lack contingency measures, and the attainment demonstration lacks an analysis showing that all RACM have been adopted for implementation in the Washington area. A third deficiency we have identified with the attainment demonstration is the lack of revised MOBILE6-based motor vehicle emissions budgets, including revisions to the attainment modeling and/or weight of evidence demonstration, as necessary, to show that the SIP continues to demonstrate attainment by November 15, 2005.

To cure these deficiencies and allow for full approval of the SIPs the States must undertake the actions set forth below. For contingency measures related to the attainment demonstration, the States need to identify which measures have been implemented since the area failed to attain by November 15, 1999. In addition, because the Washington area will on March 25, 2003, become a severe nonattainment area, the attainment demonstration for the Washington area must also include contingency measures if the area fails to attain by November 15, 2005. For the 1996–1999 ROP plan contingency requirement, the area needs to identify those adopted measures that qualify as contingency measures to be implemented if EPA notifies the states that the Washington area did not achieve the required 9 percent rate of progress reductions by November 15, 1999.

The deficiencies in the SIPS are due to the actual (or potential) lack of certain enforceable measures in the SIPs. Under section 110(k)(4) of the CAA, the EPA ''may approve a plan revision based on a commitment of the State to adopt specific enforceable measures by a date certain, but not later than 1 year after the date of approval of the plan revision. Any such conditional approval shall be treated as a disapproval if the State fails to comply with such commitment.''

The EPA concludes that the SIP revisions identified in the section of this document entitled ''I. What action is the EPA proposing today?'' can be conditionally approved because each of the States has committed to all of the following:

(1) Submit to the EPA by April 17, 2004, a contingency plan containing those adopted measures that qualify as contingency measures due to the failure of the Washington area to attain the one-hour ozone standard for serious areas by November 15, 1999, and also those adopted measures that qualify as contingency measures to be implemented if EPA notifies the states that the Washington area did not achieve the required 9 percent rate of progress reductions by November 15, 1999.

(2) Revise and submit to the EPA by April 17, 2004, an updated attainment demonstration SIP that reflects revised MOBILE6-based motor vehicle emissions budgets, including revisions to the attainment modeling and/or weight of evidence demonstration, as necessary, to show that the SIP continues to demonstrate attainment by November 15, 2005.

(3) Submit to the EPA by April 17, 2004, adopted contingency measures to be implemented if the Washington area does not attain the one-hour ozone NAAQS by November 15, 2005.

(4) Submit to the EPA by April 17, 2004, an appropriate RACM analysis for the Washington area, along with any revisions to the attainment demonstration SIP necessitated by such analysis, should there be any.

These commitments are embodied in the following letters:

(1) A letter, dated January 14, 2003, from Richard F. Pecora, Secretary, Maryland Department of the Environment, to Donald S. Welsh, Regional Administrator, EPA. Region III.

(2) A letter, dated January 14, 2003, from Robert G. Burnley, Director, Virginia Department of Environmental Quality, to Donald S. Welsh, Regional Administrator, EPA. Region III.

(3) A letter, dated January 14, 2003, from Theodore J. Gordon, Senior Deputy Director for Environmental Health Science and Regulation, Government of the District of Columbia Department of Health, to Donald S. Welsh, Regional Administrator, EPA. Region III.

These letters contain the commitments that are acceptable in form and substance to comply with sections 110(k)(3) and (4) of the Act.

Although each of the Washington area States has committed to submitting the RACM analysis, the contingency measures and the 2005 revised mobile vehicle emissions budgets to EPA by April 17, 2004, these three things are among the severe area SIP elements required by the reclassification of the Washington area to severe ozone nonattainment. Therefore, as a practical matter, these three elements will have to be submitted to EPA consistent with the schedule for submission of the severe area SIP revisions to EPA. Under the schedule set forth in the final rule reclassifying the Washington area, each of the three Washington area States must submit all of the severe area SIP revisions no later than March 1, 2004. (*See* 68 FR 3410). Notwithstanding the April 17, 2004, commitment date, failure of the States to submit these three elements by March 1, 2004, can have repercussions. If EPA makes a finding that any of the Washington area States have failed to submit any of the required severe area SIP elements by March 1, 2004, or if EPA makes a finding that any of the required submittals is incomplete in accordance with section 110(k)(1)(B) and 40 CFR part 51, Appendix V, section 179(a) provides for the imposition of two sanctions. *See* section 179(a) of the CAA and 40 CFR 52.31. Under EPA's sanctions regulations, 40 CFR 52.31, the first sanction would be 2:1 offsets for sources subject to the new source review requirements under section 173 of the CAA unless the EPA has determined the State has submitted the required SIP revisions meeting the completeness criteria section 110(k)(1)(B) and of 40 CFR part 51. If 6 months after the first sanction is imposed EPA has not determined that State has submitted the required SIP revisions meeting the completeness criteria section 110(k)(1)(B) and of 40 CFR part 51, the second sanction will apply. The second sanction is a limitation on the receipt of Federal highway funds.

However, as discussed previously in this document, because the commitment letter recites April 17, 2004, as the

controlling date for submission of the RACM analysis, the contingency measures and the 2005 revised mobile vehicle emissions budgets, any conditional approval issued pursuant to this proposed rulemaking shall convert to a disapproval only if the State fails to make the required submissions by April 17, 2004. If EPA disapproves a required SIP, such as an attainment demonstration SIP, section 179(a) provides for the imposition of two sanctions. In the event of a disapproval the two sanctions would be imposed in accordance with the EPA's sanctions regulation, 40 CFR 52.31, and in the same order as described in the preceding paragraph.

B. Disapproval in the Alternative

The EPA believes that the proposed conditional approval is consistent with sections 110(k)(3) and (4) of the Act and with rulings by the Circuit Court and the District Court cited previously in this document. We also believe that the proposed conditional approval is the most reasonable of the legally supported alternatives for allowing the Washington area to deal with the situation created by the two court rulings adverse to EPA. However, EPA is well aware that its past actions with respect to this area have been controversial and have resulted in separate actions in two different Federal courts. EPA is also well aware that it is under a District Court-ordered deadline to publish its final action on the Washington area attainment demonstration and ROP SIPs by no later than April 17, 2003. Because EPA anticipates that the proposed conditional approvals may receive adverse comment, we are also proposing in the alternative to disapprove either or both the attainment demonstration and ROPs SIPs. EPA believes that the proposed disapproval in the alternative is a prudent step to take to preserve the court-ordered schedule in the event that we cannot issue a timely final conditional approval for both the attainment demonstration and ROP SIP revisions.

In the event that we cannot issue a final conditional approval with respect to the attainment demonstration SIP revision, we propose to disapprove those submissions due to the following deficiencies: (1) Lack of contingency measures; (2) lack of an analysis showing that all RACM have been adopted for implementation in the Washington area; and, (3) lack of revised MOBILE6-based motor vehicle emissions budgets, including revisions to the attainment modeling and/or weight of evidence demonstration, as necessary, to show that the SIP continues to demonstrate attainment by November 15, 2005. With respect to the 1996–1999 ROP plan, in the event that we cannot issue a final conditional approval, we propose to disapprove the submissions because they lack contingency measures. As explained in the following paragraphs at VI.C. the EPA is proposing that disapproval of either the attainment demonstration or the 1996–1999 ROP plan will be made with a protective finding regarding their respective motor vehicle emissions budgets.

C. Proposed Protective Findings

Under the conformity rule if EPA disapproves any submitted control strategy implementation plan revision (with or without a protective finding), the conformity status of the transportation plan and transportation improvement plan (TIP) shall lapse on the date that highway sanctions as a result of the disapproval are imposed on the nonattainment area under section 179(b)(1) of the Clean Air Act.[5] No new transportation plan, TIP, or project may be found to conform until another control strategy implementation plan revision fulfilling the same Clean Air Act requirements is submitted and conformity to this submission is determined. *See* 40 CFR 93.120(a).

When the EPA disapproves a control strategy SIP the EPA has to determine whether to issue a protective finding. If the EPA does not issue a protective finding then the conformity freeze established by section 93.120(a)(2) of the conformity rule will occur on the effective date of the disapproval. *See* 40 CFR 93.120(a)(2).

Alternatively, when disapproving a control strategy implementation plan revision, the EPA would give a protective finding where a submitted plan contains adopted control measures or written commitments to adopt enforceable control measures that fully satisfy the emissions reductions requirements relevant to the statutory provision for which the implementation plan revision was submitted, such as reasonable further progress or attainment. *See* 40 CFR 93.120(a)(3).

In the preamble to the conformity rule, EPA explained the implications of a disapproval of a ROP plan or attainment demonstration and how a protective finding works. When disapproving a control strategy SIP revision the EPA may give the SIP a protective finding. If the EPA disapproves a SIP but gives a protective finding, the motor vehicle emissions budget in the disapproved SIP could still be used to demonstrate conformity. There would be no adverse conformity consequences unless highway sanctions were imposed, as is the case with respect to all other SIP planning failures. Highway sanctions would be imposed two years following the EPA's disapproval if the SIP deficiency had not been remedied. The conformity of the plan and TIP would lapse once highway sanctions were imposed. The EPA will make a protective finding only if a submitted SIP contains adopted control measures or commitments to adopt measures that fully satisfy the emissions reductions requirements relevant to the statutory provision for which the SIP was submitted, such as ROP. That is, the EPA will give such a submitted SIP a protective finding if it contains enough emissions reduction measures to achieve its purpose of either demonstrating ROP or attainment. The EPA will not make a protective finding with respect to a SIP that does not contain emission reduction measures or commitments adequate to achieve the required ROP or attainment. *See* 62 FR at 43796, August 15, 1997.

The EPA is proposing that based on the analysis discussed in section IV of this document that the 1996–1999 ROP plan meets the ROP requirement by providing enough reductions with the adopted measures to have achieved the 9 percent reduction requirement. The EPA believes that the ROP plan meets the requirement for a protective finding, however, the EPA will take final action with respect to this protective finding only if it finalizes the disapproval in the alternative option proposed in this document.

Likewise, the EPA is proposing that, based on the analysis discussed previously in this document, the attainment demonstration has demonstrated that the Washington area will attain the ozone NAAQS no later than November 15, 2005, by providing enough reductions with the adopted measures to demonstrate attainment. The EPA believes that the attainment demonstration meets the requirement for a protective finding, however, the EPA will take final action with respect to this protective finding only if it finalizes the disapproval in the alternative option proposed in this document.

[5] Under the conformity rule the term ''control strategy implementation plan revisions'' includes ROP and attainment demonstrations, or, more generally, those implementation plans which contain specific strategies for controlling the emissions of and reducing ambient levels of pollutants in order to satisfy CAA requirements for demonstrations of reasonable further progress and attainment (CAA sectons 182(b)(1), 182(c)(2)(A), 182(c)(2)(B), 187(a)(7), 189(a)(1)(B), and 189(b)(1)(A); and sections 192(a) and 192(b), for nitrogen dioxide).

Under this proposed protective finding the mobile source budgets that were established in the 1996–1999 ROP plan and attainment demonstration plans will be in effect for transportation planning and conformity purposes and can be used until such time that highway sanctions as required in accordance with 40 CFR 52.31 and would apply two years after the disapproval of the ROP plan, unless EPA takes final action to approve a revised plan correcting the deficiency within 2 years of EPA's findings. The 1999 mobile emissions budgets in the 1996–1999 ROP plan which would remain in place under the proposed protective finding are 196.8 tons of NO_X and 128.5 tons for VOC. The 2005 mobile emissions budgets in the attainment demonstration which would remain in place under the proposed protective finding are 101.8 tons of NO_X and 161.8 tons for VOC.

VII. Proposed Action

A. The District of Columbia—Rate-of-Progress Plan

EPA is proposing conditional approval of the District of Columbia's 1996–1999 ROP plan SIP revision for the Washington area which was submitted on November 3, 1997, and supplemented on May 25, 1999, and the transportation control measures in Appendix H of the May 25, 1999, submittal, because the District has committed to submit to the EPA by April 17, 2004, (a date that will not be later than 1 year after the date of approval of the plan revision) a contingency plan containing those adopted measures that qualify as contingency measures to be implemented if EPA notifies the states that the Washington area did not achieve the required 9 percent rate of progress reductions by November 15, 1999.

With respect to the 1996–1999 ROP plan, in the event that we cannot issue a final conditional approval, we propose in the alternative to disapprove the District of Columbia's 1996–1999 ROP plan SIP because it lacks contingency measures. The EPA is proposing disapproval in the alternative with a protective finding with respect to the 1999 ROP motor vehicle emissions budgets.

B. The District of Columbia—Attainment Demonstration

EPA is proposing conditional approval of the revisions to the State Implementation Plan submitted by the District of Columbia on April 24, 1998, October 27, 1998, and February 16, 2000, and only section 9.1.1.2 of the March 22, 2000, SIP supplement dealing with a commitment to revise the 2005 attainment motor vehicle emissions budgets within one-year of the EPA's release of the MOBILE6 model. EPA is proposing conditional approval because the District has committed to:

(1) Submit to the EPA by April 17, 2004, a contingency plan containing those adopted measures that qualify as contingency measures due to the failure of the Washington area to attain the one-hour ozone standard for serious areas by November 15, 1999;

(2) Revise and submit to the EPA by April 17, 2004, an updated attainment demonstration SIP that reflects revised MOBILE6-based motor vehicle emissions budgets, including revisions to the attainment modeling and/or weight of evidence demonstration, as necessary, to show that the SIP continues to demonstrate attainment by November 15, 2005;

(3) Submit to the EPA by April 17, 2004, adopted contingency measures to be implemented if the Washington area does not attain the one-hour ozone NAAQS by November 15, 2005; and

(4) Submit to the EPA by April 17, 2004, a revised RACM analysis and any revisions to the attainment demonstration SIP as necessitated by such analysis should there be any.

In the alternative, the EPA is proposing to disapprove the State Implementation Plan submitted by the District of Columbia on April 24, 1998, October 27, 1998, and February 16, 2000, and only section 9.1.1.2 of the March 22, 2000, SIP supplement, due to the following deficiencies: (1) Lack of contingency measures; (2) lack of an analysis showing that all RACM have been adopted for implementation in the Washington area; and, (3) lack of revised MOBILE6-based motor vehicle emissions budgets, including revisions to the attainment modeling and/or weight of evidence demonstration, as necessary, to show that the SIP continues to demonstrate attainment by November 15, 2005. The EPA is proposing disapproval with a protective finding with respect to the 2005 attainment motor vehicle emissions budgets.

C. The State of Maryland—Rate-of-Progress Plan

EPA is proposing conditional approval of the State of Maryland's 1996–1999 ROP plan SIP revision for the Washington area which was submitted on December 24, 1997, and supplemented on May 20, 1999, and the transportation control measures in Appendix H of the May 25, 1999, submittal because Maryland has committed to submit to the EPA by April 17, 2004, a contingency plan containing those adopted measures that qualify as contingency measures to be implemented if EPA notifies the states that the Washington area did not achieve the required 9 percent rate of progress reductions by November 15, 1999.

With respect to the 1996–1999 ROP plan, in the event that we cannot issue a final conditional approval, we propose in the alternative to disapprove the State of Maryland's 1996–1999 ROP plan SIP because it lacks contingency measures. The EPA is proposing disapproval in the alternative with a protective finding with respect to the 1999 ROP motor vehicle emissions budgets.

D. The State of Maryland—Attainment Demonstration

EPA is proposing conditional approval of the revisions to the State Implementation Plan submitted by the State of Maryland on April 29, 1998, August 17, 1998, and February 14, 2000, and the transportation control measures in Appendix J of the February 9, 2000, submittal and only section 9.1.1.2 of the March 31, 2000, SIP supplement dealing with a commitment to revise the 2005 attainment motor vehicle emissions budgets within one-year of the EPA's release of the MOBILE6 model. EPA is proposing conditional approval because Maryland has committed to:

(1) Submit to the EPA by April 17, 2004, a contingency plan containing those adopted measures that qualify as contingency measures due to the failure of the Washington area to attain the one-hour ozone standard for serious areas by November 15, 1999;

(2) Revise and submit to the EPA by April 17, 2004, an updated attainment demonstration SIP that reflects revised MOBILE6-based motor vehicle emissions budgets, including revisions to the attainment modeling and/or weight of evidence demonstration, as necessary, to show that the SIP continues to demonstrate attainment by November 15, 2005;

(3) Submit to the EPA by April 17, 2004, adopted contingency measures to be implemented if the Washington area does not attain the one-hour ozone NAAQS by November 15, 2005; and

(4) Submit to the EPA by April 17, 2004, a revised RACM analysis and any revisions to the attainment demonstration SIP as necessitated by such analysis should there be any.

In the alternative, the EPA is proposing to disapprove the State Implementation Plan submitted by the State of Maryland on April 29, 1998,

August 17, 1998, and February 14, 2000, and the transportation control measures in Appendix J of the February 9, 2000, submittal and only section 9.1.1.2 of the March 31, 2000 SIP supplement due to the following deficiencies: (1) Lack of contingency measures; (2) lack of an analysis showing that all RACM have been adopted for implementation in the Washington area; and, (3) lack of revised MOBILE6-based motor vehicle emissions budgets, including revisions to the attainment modeling and/or weight of evidence demonstration, as necessary, to show that the SIP continues to demonstrate attainment by November 15, 2005. The EPA is proposing disapproval with a protective finding with respect to the 2005 attainment motor vehicle emissions budgets.

E. The Commonwealth of Virginia—Rate-of-Progress Plan

EPA is proposing conditional approval of the Commonwealth of Virginia's 1996–1999 ROP plan SIP revision for the Washington area which was submitted on December 19, 1997, and supplemented on May 25, 1999, and the transportation control measures in Appendix H of the May 25, 1999, submittal because Virginia has committed to submit to the EPA by April 17, 2004, a contingency plan containing those adopted measures that qualify as contingency measures to be implemented if EPA notifies the states that the Washington area did not achieve the required 9 percent rate of progress reductions by November 15, 1999.

With respect to the 1996–1999 ROP plan, in the event that we cannot issue a final conditional approval, we propose in the alternative to disapprove the Commonwealth of Virginia's 1996–1999 ROP plan SIP because it lacks contingency measures. The EPA is proposing disapproval in the alternative with a protective finding with respect to the 1999 ROP motor vehicle emissions budgets.

F. The Commonwealth of Virginia—Attainment Demonstration

EPA is proposing conditional approval of the revisions to the State Implementation Plan submitted by the Commonwealth of Virginia on April 29, 1998, August 18, 1998, and February 9, 2000, and the transportation control measures in Appendix J of the February 9, 2000, submittal, and only section 9.1.1.2 of the March 31, 2000, SIP supplement dealing with a commitment to revise the 2005 attainment motor vehicle emissions budgets within one-year of the EPA's release of the MOBILE6 model. EPA is proposing conditional approval because Virginia has committed to:

(1) Submit to the EPA by April 17, 2004, a contingency plan containing those adopted measures that qualify as contingency measures due to the failure of the Washington area to attain the one-hour ozone standard for serious areas by November 15, 1999;

(2) Revise and submit to the EPA by April 17, 2004, an updated attainment demonstration SIP that reflects revised MOBILE6-based motor vehicle emissions budgets, including revisions to the attainment modeling and/or weight of evidence demonstration, as necessary, to show that the SIP continues to demonstrate attainment by November 15, 2005;

(3) Submit to the EPA by April 17, 2004, adopted contingency measures to be implemented if the Washington area does not attain the one-hour ozone NAAQS by November 15, 2005; and

(4) Submit to the EPA by April 17, 2004, a revised RACM analysis and any revisions to the attainment demonstration SIP as necessitated by such analysis should there be any.

In the alternative, the EPA is proposing to disapprove the State Implementation Plan submitted by the Commonwealth of Virginia on April 29, 1998, August 18, 1998, and February 9, 2000, and the transportation control measures in Appendix J of the February 9, 2000, submittal, and only section 9.1.1.2 of the March 31, 2000, SIP supplement due to the following deficiencies: (1) Lack of contingency measures; (2) lack of an analysis showing that all RACM have been adopted for implementation in the Washington area; and, (3) lack of revised MOBILE6-based motor vehicle emissions budgets, including revisions to the attainment modeling and/or weight of evidence demonstration, as necessary, to show that the SIP continues to demonstrate attainment by November 15, 2005. The EPA is proposing disapproval with a protective finding with respect to the 2005 attainment motor vehicle emissions budgets.

G. Applicability of Revised Motor Vehicle Emissions Budgets

In this notice, we are proposing to clarify what occurs if we issue a conditional approval of any of the February 2000 plans based on a State commitment to revise the 2005 motor vehicle emissions budgets for the Washington area in the future. If this occurs, the conditionally approved 2005 motor vehicle emissions budgets will apply for conformity purposes only until the revised motor vehicle emissions budgets have been submitted and we have found the submitted motor vehicle emissions budgets to be adequate for conformity purposes.

The EPA is soliciting public comments on the issues discussed in this document and any other relevant issues regarding the attainment demonstration for the Washington area. These comments will be considered before taking final action. Interested parties may participate in the Federal rulemaking procedure by submitting written comments to the EPA Regional Office listed in the **ADDRESSES** section of this document. A more detailed description of the state submittal and the EPA's evaluation are included in a Technical Support Document (TSD) prepared in support of this rulemaking action. A copy of the TSD is available upon request from the EPA Regional Office listed in the **ADDRESSES** section of this document.

In 1995, Virginia adopted legislation that provides, subject to certain conditions, for an environmental assessment (audit) ''privilege'' for voluntary compliance evaluations performed by a regulated entity. The legislation further addresses the relative burden of proof for parties either asserting the privilege or seeking disclosure of documents for which the privilege is claimed. Virginia's legislation also provides, subject to certain conditions, for a penalty waiver for violations of environmental laws when a regulated entity discovers such violations pursuant to a voluntary compliance evaluation and voluntarily discloses such violations to the Commonwealth and takes prompt and appropriate measures to remedy the violations. Virginia's Voluntary Environmental Assessment Privilege Law, Va. Code sec. 10.1–1198, provides a privilege that protects from disclosure documents and information about the content of those documents that are the product of a voluntary environmental assessment. The Privilege Law does not extend to documents or information (1) that are generated or developed before the commencement of a voluntary environmental assessment; (2) that are prepared independently of the assessment process; (3) that demonstrate a clear, imminent and substantial danger to the public health or environment; or (4) that are required by law.

On January 12, 1997, the Commonwealth of Virginia Office of the Attorney General provided a legal opinion that states that the Privilege law, Va. Code sec. 10.1–1198, precludes granting a privilege to documents and

information ''required by law,'' including documents and information ''required by Federal law to maintain program delegation, authorization or approval,'' since Virginia must ''enforce Federally authorized environmental programs in a manner that is no less stringent than their Federal counterparts. * * *'' The opinion concludes that ''[r]egarding § 10.1–1198, therefore, documents or other information needed for civil or criminal enforcement under one of these programs could not be privileged because such documents and information are essential to pursuing enforcement in a manner required by Federal law to maintain program delegation, authorization or approval.''

Virginia's Immunity law, Va. Code sec. 10.1–1199, provides that ''[t]o the extent consistent with requirements imposed by Federal law,'' any person making a voluntary disclosure of information to a state agency regarding a violation of an environmental statute, regulation, permit, or administrative order is granted immunity from administrative or civil penalty. The Attorney General's January 12, 1997 opinion states that the quoted language renders this statute inapplicable to enforcement of any Federally authorized programs, since ''no immunity could be afforded from administrative, civil, or criminal penalties because granting such immunity would not be consistent with Federal law, which is one of the criteria for immunity.''

Therefore, the EPA has determined that Virginia's Privilege and Immunity statutes will not preclude the Commonwealth from enforcing its program consistent with the Federal requirements. In any event, because the EPA has also determined that a State audit privilege and immunity law can affect only State enforcement and cannot have any impact on Federal enforcement authorities, the EPA may at any time invoke its authority under the Clean Air Act, including, for example, sections 113, 167, 205, 211 or 213, to enforce the requirements or prohibitions of the State plan, independently of any State enforcement effort. In addition, citizen enforcement under section 304 of the Clean Air Act is likewise unaffected by this, or any, State audit privilege or immunity law.

VIII. Statutory and Executive Order Reviews

A. Executive Order 12866

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

B. Executive Order 13045

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

This proposed rule is not subject to Executive Order 13045 because it does not involve decisions intended to mitigate environmental health or safety risks.

C. Executive Order 13132

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

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, as specified in Executive Order 13132 (64 FR 43255, August 10, 1999), because it merely approves a state rule implementing a Federal standard, and does not alter the relationship or the distribution of power and responsibilities established in the Clean Air Act. Thus, the requirements of section 6 of the Executive Order do not apply to this rule.

D. Executive Order 13175

This proposed rule also does not have tribal implications because it will not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal government and Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes, as specified by Executive Order 13175 (65 FR 67249, November 9, 2000).

E. Executive Order 13211

This action is also not subject to Executive Order 13211, ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001). This action merely approves state law as meeting Federal requirements and imposes no additional requirements beyond those imposed by state law.

F. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) generally requires an agency to conduct a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Small entities include small businesses, small not-for-profit enterprises, and small governmental jurisdictions. This proposed rule will not have a significant impact on a substantial number of small entities because conditional approvals of SIP submittals under section 110 and subchapter I, part D of the CAA do not create any new requirements but simply approve requirements that the State is already imposing. Therefore, because the Federal SIP approval does not impose any new requirements, I certify that it does not have a significant impact on any small entities affected. Moreover, due to the nature of the Federal-State relationship under the Clean Air Act, preparation of a flexibility analysis would constitute Federal inquiry into the economic reasonableness of state action. The Clean Air Act forbids EPA

to base its actions concerning SIPs on such grounds. *Union Electric Co.* v. *U.S. EPA*, 427 U.S. 246, 255–66 (1976); 42 U.S.C. 7410(a)(2).

If the conditional approval is converted to a disapproval under section 110(k), based on the State's failure to meet the commitment, it will not affect any existing state requirements applicable to small entities. Federal disapproval of the state submittal does not affect its state-enforceability. Moreover, EPA's disapproval of the submittal does not impose a new Federal requirement. Therefore, I certify that this proposed disapproval action does not have a significant impact on a substantial number of small entities because it does not remove existing requirements nor does it substitute a new Federal requirement.

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

G. Unfunded Mandates

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

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

Sections 202 and 205 do not apply to the proposed disapproval because the proposed disapproval of the SIP submittal would not, in and of itself, constitute a Federal mandate because it would not impose an enforceable duty on any entity. In addition, the Act does not permit EPA to consider the types of analyses described in section 202 in determining whether a SIP submittal meets the CAA. Finally, section 203 does not apply to the proposed disapproval because it would affect only the District of Columbia, the State of Maryland and the Commonwealth of Virginia, which are not small governments.

H. National Technology Transfer and Advancement Act

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

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

This proposed rule regarding the 1-hour ozone attainment demonstration and the 1996–1999 ROP plan for the Washington area does not impose an information collection burden under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Intergovernmental relations, Nitrogen dioxide, Ozone, Volatile organic compounds.

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

Dated: January 24, 2003.

James J. Burke,

Acting Regional Administrator, Region III.

[FR Doc. 03–2333 Filed 1–31–03; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[MD129/130–3089b; FRL–7437–6]

Approval and Promulgation of Air Quality Implementation Plans; Maryland; Amendments to Volatile Organic Compound Requirements From Specific Processes

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA proposes to approve the State Implementation Plan (SIP) revision submitted by the State of Maryland for the purpose of establishing two (2) amendments to COMAR 26.11.19, from specific processes on volatile organic compound (VOC) requirements. In the Final Rules section of this **Federal Register**, EPA is approving the State's SIP submittal as a direct final rule without prior proposal because the Agency views this as a noncontroversial submittal and anticipates no adverse comments. A detailed rationale for the approval is set forth in the direct final rule. If no adverse comments are received in response to this action, no further activity is contemplated. If EPA receives adverse comments, the direct final rule will be withdrawn and all public comments received will be addressed in a subsequent final rule based on this proposed rule. EPA will not institute a second comment period. Any parties interested in commenting on this action should do so at this time.

DATES: Comments must be received in writing by March 5, 2003.

ADDRESSES: Written comments should be addressed to Walter K. Wilkie. Acting Chief, Air Quality Planning and Information Services Branch, Mailcode 3AP21, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103. Copies of the documents relevant to this action are available for public inspection during normal business hours at the Air Protection Division, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103; and the Maryland Department of the Environment, 1800 Washington Blvd., Suite 730, Baltimore, Maryland 21224.

FOR FURTHER INFORMATION CONTACT: Betty Harris at (215) 814–2168, at the EPA Region III address above, or by e-mail at *harris.betty@epa.gov*. Please note that while questions may be posed via telephone and e-mail, formal comments

must be submitted in writing, as indicated in the **ADDRESSES** section of this document.

SUPPLEMENTARY INFORMATION: For further information, please see the information provided in the direct final action for Maryland's amendments to the VOC requirements from specific processes, that is located in the ''Rules and Regulations'' section of this **Federal Register** publication. Please note that if EPA receives adverse comment on an amendment, paragraph, or section of this rule and if that provision may be severed from the remainder of the rule, EPA may adopt as final those provisions of the rule that are not the subject of an adverse comment.

Dated: December 31, 2002.

Thomas C. Voltaggio,

Acting Regional Administrator, Region III.

[FR Doc. 03–2433 Filed 1–31–03; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL EMERGENCY MANAGEMENT AGENCY

44 CFR Part 61

RIN 3067–AD34

National Flood Insurance Program (NFIP); Increased Rates for Flood Coverage

AGENCY: Federal Emergency Management Agency (FEMA).

ACTION: Proposed Rule.

SUMMARY: We (the Federal Insurance and Mitigation Administration of FEMA) propose to change the way premiums are calculated for policyholders who purchase flood insurance coverage under the NFIP for ''Pre-FIRM'' buildings in Special Flood Hazard Areas (SFHAs). (The term ''Pre-FIRM buildings'' means buildings whose construction began on or before December 31, 1974, or before the effective date of the community's Flood Insurance Rate Map (FIRM), whichever date is later. Most Pre-FIRM buildings and their contents are eligible for subsidized rates under the NFIP.)

We are planning to increase flood insurance rates to be implemented in coordination with the elimination of the Expense Constant, a flat charge that the policyholder currently pays to defray certain expenses of the Federal Government related to flood insurance. As part of this planned increase in rates, we are proposing to increase Pre-FIRM subsidized rates. As a result of this change, the same amount of premium revenue will still be collected to cover those expenses currently generated by the Expense Constant; however, policyholders will pay for those expenses through premiums that vary by the amount of insurance that they purchase, instead of a flat charge per policy. The end result will be revenue neutral.

DATES: We invite comments on this proposed rule, which we should receive on or before March 5, 2003.

ADDRESSES: Please submit any written comments to the Rules Docket Clerk, Office of the General Counsel, Federal Emergency Management Agency, 500 C Street, SW., room 840, Washington, DC 20472, (facsimile) 202–646–4536, or (e-mail) *rules@fema.gov.*

FOR FURTHER INFORMATION CONTACT: Thomas Hayes, Federal Emergency Management Agency, Federal Insurance and Mitigation Administration, 500 C Street SW., Washington, DC 20472, 202–646–3419, (facsimile) 202–646–7970, or (e-mail) *Thomas.Hayes@fema.gov.*

SUPPLEMENTARY INFORMATION:

Background

The Flood Disaster Protection Act of 1973 requires us to charge full-risk premiums for flood insurance coverage on buildings when their construction began after December 31, 1974, or on or after the effective date of the Flood Insurance Rate Map, if the second date is later. (We call such construction ''Post-FIRM'' construction.)

The Flood Disaster Protection Act of 1973 also authorizes us to apply chargeable premiums to Pre-FIRM property and gives FEMA flexibility to set the flood insurance rates for such property. The legislation calls for us to balance the need to offer reasonable rates that encourage people to buy flood insurance with the statutory goal to distribute burdens fairly between all who will be protected by flood insurance and the general public.

Through the years, FIMA has increased these rates five times with the latest being the final rule 67 FR 8902, published February 27, 2002. Each of the prior changes has been implemented in order to distribute burdens fairly among all who will be protected by flood insurance and to reduce the burden on the general public.

However, with this rule, the proposed rate increase will simply offset the revenue that the Program would otherwise forego through the elimination of the Expense Constant, as explained in the next section. This rule is revenue-neutral, whereas the previous rules resulted in premium increases for the class of Pre-FIRM SFHA policyholders.

While this proposed change to offset the elimination of the Expense Constant will be premium-neutral for the class of Pre-FIRM SFHA policyholders, it will result in slightly different premiums for individual policyholders. For residential structures, the largest net premium increase for any policyholder will be $24, while policyholders that purchase either Contents-only (*e.g.*, renters) or building-only coverage will see net premium decreases of at least $10. Non-Residential policyholders will have slightly different results.

Section 572 of the National Flood Insurance Reform Act of 1994, Pub. L. 103–325, 42 U.S.C. 4015, however, imposes the following annual limitation on rate increases under the NFIP:

''Notwithstanding any other provision of this title, the chargeable risk premium rates for flood insurance under this title for any properties within any single risk classification may not be increased by an amount that would result in the average of such rate increases for properties within the risk classification during any 12-month period exceeding 10 percent of the average of the risk premium rates for properties within the risk classification upon commencement of such 12-month period.''

This regulation complies with this statutory limitation on annual rate increase under the NFIP, since it will be revenue neutral.

Proposed Changes and Their Purposes

We are proposing to increase the rates for Pre-FIRM SFHA policies to offset the revenue that the Program would otherwise forego through the elimination of the Expense Constant. The Expense Constant is a flat charge that the policyholder currently pays to defray certain expenses of the Federal Government related to flood insurance. This proposed change will be premium-neutral for the class of Pre-FIRM SFHA policyholders.

FIMA believes that eliminating the Expense Constant will help us further the goals of the flood program, especially in regard to policy growth. Currently, policyholders see two flat charges on their flood insurance premium bills—$50 for the Expense Constant, and $30 for the Federal Policy Fee (a statutorily-mandated fee to cover certain administrative expenses of the National Flood Insurance Program that are not covered by the Expense Constant). Our marketing research has indicated that this is viewed very unfavorably by prospective insureds. They view it as having to pay $80 before they can even purchase any flood insurance coverage. By eliminating the expense constant, we can hopefully

overcome an objection at the point of sale, while still generating the same average revenue per policy. Although we are unable to quantify the expected impact of this proposal on future policy sales, we expect it to help the program generate a modest increase in policies in force.

As an additional benefit, this will bring the NFIP in closer conformity with the insurance industry standard of practice for property insurance where expense constants are rarely used. This proposal will make the NFIP's premium calculation more like that for other property lines. As such, it should also make it more intuitive for insurance agents to process flood insurance.

Comparison of Proposed Rate Increases with Current Rates

The following chart compares the current rates we charge for Pre-FIRM SFHA properties with the proposed rate increases for Pre-FIRM, SFHA properties. Also these proposed increases apply only to the rates charged for the ''first layer'' of flood insurance coverage set by Congress in Section 1306 of the National Flood Insurance Act of 1968, as amended (Pub. L. 90–448):

Type of structure	Current A zone [1] rates per year per $100 coverage on—		Proposed A zone [1] rates per year per $100 coverage on—			
			Structure			Contents
	Structure	Contents	RCBAP [2]		All other	
			High rise	Low rise		
1. Residential:						
No Basement or Enclosure	.68	.79	.85	.70	.76	.96
With Basement or Enclosure	.73	.79	.90	.75	.81	.96
2. All other including hotels and motels with normal occupancy of less than 6 months duration:						
No basement or Enclosure	.79	1.58	N/A	N/A	.83	1.62
With basement or Enclosure	.84	1.58	N/A	N/A	.88	1.62

[1] A zones are zones A1–A30, AE, AO, AH, and unnumbered A zones.
[2] Residential Condominium Building Association Policies (RCBAP) are distinguished between High Rise (those structures that have 3 or more floors and 5 or more units) and Low Rise (those structures that have either less than 3 floors or less than 5 units).

Type of structure	Current V zone [1] rates per year per $100 coverage on—		Proposed V zone [1] rates per year per $100 coverage on—			
			Structure			Contents
	Structure	Contents	RCBAP [2]		All other	
			High rise	Low rise		
1. Residential:						
No Basement or Enclosure	.91	1.06	1.08	.93	.99	1.23
With Basement or Enclosure	.98	1.06	1.15	1.00	1.06	1.23
2. All other including hotels and motels with normal occupancy of less than 6 months duration:						
No basement or Enclosure	1.06	2.10	N/A	N/A	1.10	2.14
With basement or Enclosure	1.12	2.10	N/A	N/A	1.16	2.14

[1] V zones are zones V1–V30, VE, and unnumbered V zones.
[2] Residential Condominium Building Association Policies (RCBAP) are distinguished between High Rise (those structures that have 3 or more floors and 5 or more units) and Low Rise (those structures that have either less than 3 floors or less than 5 units).

Prior to this change, as shown in the Current A Zone and Current V Zone table, RCBAP policyholders were always charged the same building rates as everyone else. In order to accomplish the elimination of the Expense Constant in a revenue-neutral manner, it is now necessary to vary the rates as shown in the Proposed tables.

National Environmental Policy Act (NEPA)

Pursuant to section 102(2) (C) of the National Environmental Policy Act (NEPA) of 1969, 42 U.S.C. 4317 *et seq.*, we are conducting an environmental assessment of this proposed rule. The assessment will be available for inspection through the Rules Docket Clerk, Federal Emergency Management Agency, room 840, 500 C St. SW., Washington, DC 20472.

Executive Order 12866, Regulatory Planning and Review

We have prepared and reviewed this proposed rule under the provisions of E.O. 12866, Regulatory Planning and Review. Under Executive Order 12866, 58 FR 51735, October 4, 1993, a significant regulatory action is subject to OMB review and the requirements of the Executive Order. The Executive Order defines ''significant regulatory action'' as one that is likely to result in a rule that may:

(1) Have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities;

(2) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;

(3) materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or

(4) raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

For the reasons that follow we have concluded that the proposed rule is

neither an economically significant nor a significant regulatory action under the Executive Order. The rule will be premium neutral for the National Flood Insurance Fund. The adjustment in premiums rates will be offset by the elimination of the Expense Constant. It would not have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, the insurance sector, competition, or other sectors of the economy. It would create no serious inconsistency or otherwise interfere with an action taken or planned by another agency. It would not materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof. Nor does it raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

The Office of Management and Budget has not reviewed this proposed rule under the provisions of Executive Order 12866.

Paperwork Reduction Act

This rule does not contain a collection of information and is therefore not subject to the provisions of the Paperwork Reduction Act.

Executive Order 13132, Federalism

Executive Order 13132 sets forth principles and criteria that agencies must adhere to in formulating and implementing policies that have federalism implications, that is, regulations that have substantial direct effects on the States, or on the distribution of power and responsibilities among the various levels of government. Federal agencies must closely examine the statutory authority supporting any action that would limit the policymaking discretion of the States, and to the extent practicable, must consult with State and local officials before implementing any such action.

We have reviewed this proposed rule under E.O.13132 and have determined that the rule does not have federalism implications as defined by the Executive Order. The rule would adjust the premiums for buildings in Pre-FIRM Special Flood Hazard Areas. The rule in no way that we foresee affects the distribution of power and responsibilities among the various levels of government or limits the policymaking discretion of the States.

List of Subjects in 44 CFR Part 61

Flood insurance.

Accordingly, we propose to amend 44 CFR Part 61 as follows:

PART 61—INSURANCE COVERAGE AND RATES

1. The authority citation for part 61 continues to read as follows:

Authority: 42 U.S.C. 4001 *et seq.;* Reorganization Plan No. 3 of 1978, 43 FR 41943, 3 CFR, 1978 Comp., p. 329; E.O. 12127 of Mar. 31, 1979, 44 FR 19367, 3 CFR, 1979 Comp., p.376.

2. Revise §61.9 (a) to read as follows:

§ 61.9 Establishment of chargeable rates.

(a) Under section 1308 of the Act, we are establishing annual chargeable rates for each $100 of flood insurance coverage as follows for Pre-FIRM, A zone properties, Pre-FIRM, V-zone properties, and emergency program properties.

Type of structure	Proposed A zone [1] rates per year per $100 coverage on—				Proposed V zone [2] rates per year per $100 coverage on—			
	Structure			Contents	Structure			Contents
	RCBAP [3]		All other		RCBAP [3]		All other	
	High rise	Low rise			High rise	Low Rise		
1. Residential:								
No Basement or Enclosure	.85	.70	.76	.96	1.08	.93	.99	1.23
With Basement or Enclosure	.90	.75	.81	.96	1.15	1.00	1.06	1.23
2. All other including hotels and motels with normal occupancy of less than 6 months duration:								
No basement or Enclosure	N/A	N/A	.83	1.62	N/A	N/A	1.10	2.14
With basement or Enclosure	N/A	N/A	.88	1.62	N/A	N/A	1.16	2.14

[1] A zones are zones A1–A30, AE, AO, AH, and unnumbered A zones.
[2] V zones are zones V1–V30, VE, and unnumbered V zones.
[3] Residential Condominium Building Association Policies (RCBAP) are distinguished between High Rise (those structures that have 3 or more floors and 5 or more units) and Low Rise (those structures that have either less than 3 floors or less than 5 units).

* * * * *

Dated: January 23, 2003.

Anthony S. Lowe,

Administrator, Federal Insurance and Mitigation Administration.

[FR Doc. 03–2453 Filed 1–31–03; 8:45 am]

BILLING CODE 6718–03–P

Notices

Federal Register
Vol. 68, No. 22
Monday, February 3, 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.

DEPARTMENT OF AGRICULTURE

Forest Service

Notice of Intent To Prepare an Environmental Impact Statement for the Emigrant Wilderness Dams on the Stanislaus National Forest, Tuolumne County, CA

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) on a proposal to reconstruct, operate, and maintain 12 dams, to allow 6 dams to deteriorate naturally, and to restore 50–100 feet of the channel downstream from unit #7 on Long Lake in the Emigrant Wilderness on National Forest land in the county of Tuolumne.

The Stanislaus National Forest issued an EIS, ROD, and Forest Plan Amendment for the Emigrant Wilderness Management Direction on April 8, 1998. Because of subsequent administrative appeals, the Regional Forester later issued an appeal review decision. The ''Emigrant Wilderness Management Direction'' (April 2002) presents the current Emigrant Wilderness Management Direction, based on the original Forest Plan Amendment as modified through the appeal review process. In order to implement the Stanislaus National Forest Plan, specifically the Emigrant Wilderness Management Direction, there is a need to complete site-specific analyses and to determine if and how the 18 dams should be maintained or not maintained.

DATES: Submit comments on or before March 5, 2003.

The Draft EIS is expected to be filed with the Environmental Protection Agency (EPA) and to be available for public review during the fall of 2003. At that time, EPA will publish a Notice of Availability of the Draft EIS in the **Federal Register**. The comment period on the Draft EIS will be 45 days from the date the EPA publishes the Notice of Availability in the **Federal Register**. The Final EIS is scheduled to be completed in the winter of 2004.

ADDRESSES: Address all comments concerning this notice to the Stanislaus National Forest, ATTN: Emigrant Dams, 19777 Greenley Road, Sonora, CA 95370. E-mail comments may be sent to *jmaschi@fs.fed.us.*

FOR FURTHER INFORMATION CONTACT: John Maschi, Forest Planner, Stanislaus National Forest, (209) 532–3671 ext. 317.

SUPPLEMENTARY INFORMATION: The information presented in this notice is included to help the reviewer determine if they are interested in or potentially affected by the proposed action.

Background

Congress designated the 113,000 acre Emigrant Wilderness on January 3, 1975. Its borders include Yosemite National Park on the south, the Toiyabe National Forest on the east, and State Highway 108 on the north. The Emigrant Wilderness is an elongated area that trends northeast about 25 miles in length and up to 15 miles in width. Watersheds drain to the Stanislaus and Tuolumne rivers. The Wilderness is entirely within Tuolumne County.

Eighteen water control structures (dams) existed in the Emigrant Wilderness before its designation in 1975. Most of the dams were constructed in the 1920's and 1930's to develop a resident fishery. Prior to fish stocking by cattlemen during the 1890's, these high elevation lakes were naturally fishless. The original intent of most of the dams was to enhance downstream flows for fish habitat, not necessarily to promote lake fisheries. The remaining Emigrant Wilderness dams were built as late as 1951. The dams are composed mostly of rock and mortar (with the exception of one earth-filled dam). Because of the age and theme of some dams, seven are now eligible for the National Register of Historic Places.

Purpose and Need for Action

The Stanislaus National Forest issued an EIS, ROD, and Forest Plan Amendment for the Emigrant Wilderness Management Direction on April 8, 1998. Because of subsequent administrative appeals, the Regional Forester later issued an appeal review decision. The ''Emigrant Wilderness Management Direction'' (April 2002) presents the current Emigrant Wilderness Management Direction, based on the original Forest Plan Amendment as modified through the appeal review process.

In order to implement the Stanislaus National Forest Plan, specifically the Emigrant Wilderness Management Direction, there is a need to complete site-specific analyses and to determine if and how 18 dams should be maintained or not maintained.

Proposed Action

The Stanislaus National Forest proposes to reconstruct, operate, and maintain 12 dams in the Emigrant Wilderness. In addition, the Forest proposes to restore 50–100 feet of the channel downstream of Unit #7 on Long Lake. The Forest also proposes not to maintain six dams. These dams would be allowed to deteriorate naturally in order to restore natural processes. Attachment 1 provides a listing of the dams to be maintained and not maintained.

Reconstruction and standard maintenance would be completed using minimum tool and pack-it-in/pack-it-out philosophy and use native materials from the immediate vicinity (if available). No mechanized or motorized equipment would be used, materials would be packed in using livestock, and hand labor would be used for maintenance and reconstruction needs. Any temporary access routes to project sites would be designated by the Forest Service and decommissioned immediately following completion of the work. All activities would be conducted according to existing Forest Service law, regulation, policy, and direction (*e.g.* group size limits and campfire restrictions).

Standard maintenance of the 12 dams would also include, but not be limited to, log removal if the integrity of the structure were threatened, mortar replacement on the upstream face of the structure, and minor rock replacement.

Because no special funding is expected for this project, implementation would depend upon obtaining funds other than normal Forest Service appropriated dollars. Maintenance and reconstruction would

depend on funding and participation from interested partners, volunteers, etc.

The information below provides a summary of the proposed action which lists each of the 18 dams followed by:

a. Whether the dam is proposed to be maintained,

b. The initial activities proposed for the dam, and

c. Preliminary issues associated with the dam.

1. Cooper Meadow Dam

a. No maintenance.
b. No activities proposed.
c. Returning the area to natural processes.

2. Whitesides Meadow Dam

a. No maintenance.
b. No activities proposed.
c. Returning the area to natural processes.

3. Y-Meadow Dam

a. Maintain.
b. Replace outlet valve, control shaft/wheel, and sleeve outlet conduit and seal mortar on upstream face.
c. Habitat for Mountain yellow-legged frog (MYLF) and values of the proposed Wild & Scenic River (W&SR).

4. Bear Lake Dam

a. No maintenance.
b. No activities proposed.
c. Returning the area to natural processes, values of proposed W&SR, and wild trout fishery on Lower Clavey.

5. Long Lake Dam

a. Maintain.
b. Replace outlet valve, control shaft/wheel, and sleeve outlet conduit, repair control works well shaft, stabilize downstream base of Unit #7, and seal mortar on upstream face.
c. Historic values, recreational lake fishery, habitat for MYLF, and downstream flows for rainbow trout recruitment.

6. Lower Buck Lake Dam

a. Maintain.
b. Replace outlet valve, control shaft/wheel, and sleeve outlet conduit, log removal, and seal mortar on upstream face.
c. Historic values, downstream flows for rainbow trout recruitment, recreational lake fishery, and habitat for MYLF.

7. Red Can Lake Dam

a. No maintenance.
b. No activities proposed.
c. Returning the area to natural processes.

8. Leighton Lake Dam

a. Maintain.
b. Replace outlet valve, control shaft/wheel, and sleeve outlet conduit, disassemble and rebuild dam, construct control works well shaft, and seal mortar on upstream face.
c. Historic values and downstream self-sustaining fishery.

9. Yellowhammer Lake Dam

a. No maintenance.
b. No activities proposed.
c. Returning the area to natural processes.

10. High Emigrant Lake Dam

a. Maintain.
b. Replace outlet valve, control shaft/wheel, and sleeve outlet conduit, rebuild outlet control works well shaft, and seal mortar on upstream face.
c. Habitat for Yosemite toad (YT) and downstream flows for rainbow trout recruitment.

11. Emigrant Meadow Dam

a. Maintain.
b. Replace outlet valve, replace control shaft/wheel, insert plastic pipe into existing outlet conduit, and seal mortar on upstream face.
c. Historic values, habitat for YT, recreational lake fishery, and self-sustaining lake fishery.

12. Middle Emigrant Lake Dam

a. Maintain.
b. Rebuild failed left side of dam, insert plastic pipe into existing outlet conduit, replace outlet valve, and seal mortar on upstream face.
c. Habitat for MYLF, downstream flows for rainbow trout recruitment, and self-sustaining lake fishery.

13. Emigrant Lake Dam

a. Maintain.
b. Stabilize mortar downstream face of dam, repair spillway dike, and seal mortar on upstream face.
c. Historic values, recreational lake fishery, self-sustaining lake fishery, and downstream flows for rainbow trout recruitment.

14. Cow Meadow Lake Dam

a. Maintain.
b. Reconstruct entire Unit #1.
c. Habitat for MYLF and self-sustaining lake fishery.

15. Snow Lake Dam

a. Maintain.
b. Replace outlet valve, control shaft/wheel, and sleeve outlet conduit and seal mortar on upstream face.
c. Downstream self-sustaining fishery, recreational lake fishery, and habitat for MYLF.

16. Horse Meadow Dam

a. No maintenance.
b. No activities proposed.
c. Returning the area to natural processes.

17. Bigelow Lake Dam

a. Maintain.
b. Replace outlet valve, control shaft/wheel and sleeve outlet conduit, replace missing rocks, and seal mortar on upstream face.
c. Historic values, recreational lake fishery, and downstream flows for rainbow trout recruitment.

18. Huckleberry Lake Dam

a. Maintain.
b. Replace outlet valve, control shaft/wheel and sleeve outlet conduit, replace missing rocks, and seal mortar on upstream face.
c. Recreational lake fishery, self-sustaining lake fishery, and downstream recreational fishery.

Responsible Official

The Forest Supervisor, Stanislaus National Forest, is the Responsible Official.

Nature of Decision To Be Made

The Forest Supervisor, as Responsible Official, may decide to: (1) Select the proposed action, (2) select one of the alternatives, (3) select one of the alternatives after modifying the alternative with additional mitigating measures or combinations of activities from other alternatives, or (4) select the no action alternative and take no action at this time.

Comment Requested

The Forest Service would like to know of any issues, concerns, and suggestions you may have about this proposal. Comments should be as fully formed as possible to assist us in the analysis. If you have any questions, or if something is unclear, contact John Maschi at 209.532.3671 ext. 317 before submitting your comments. Although comments are welcome at any time, they will be most effective if received by March 5, 2003. Send comments to:

Stanislaus National Forest, ATTN: Emigrant Dams, 19777 Greenly Road, Sonora, CA 95370.

Alternately, e-mail your comments to *jmaschi@fs.fed.us.*

Authorization

National Environmental Policy Act of 1969 as amended (42 U.S.C. 4321–4346); Council on Environmental Quality Regulations (40 CFR parts 1500–1508); U.S. Department of Agriculture NEPA Policies and Procedures (7 CFR part 1b).

Reviewer's Obligation

The Forest Service believes, at this early stage, it is important to give reviewers notice of several court rulings related to public participation in the environmental review process. First, reviewers of draft environmental impact statements must structure their participation in the environmental review of the proposal so that it is meaningful and alerts the 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 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. Wisc. 1980). Because of these court rulings, it is very important that those interested in this proposed action participate by the close of the comment period so that substantive comments and objections are made available to the Forest Service at the 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 may also address the adequacy of the draft environmental impact statement or the merits of the alternatives formulated and discussed in the statement. Reviewer may wish to refer to the Council on Environmental Quality Regulations for implementing the procedural provisions of the National Environmental Policy Act at 40 CFR 1503.3 in addressing these points (Authority: 40 CFR 1501.7 and 1508.22; Forest Service Handbook 1909.15, Section 21).

Dated: January 24, 2003.

Tom Quinn,

Forest Supervisor, Stanislaus National Forest.

[FR Doc. 03–2275 Filed 1–31–03; 8:45 am]

BILLING CODE 3410–11–P

DEPARTMENT OF COMMERCE

Census Bureau

Manufacturers' Shipments, Inventories, and Orders (M3) Survey

ACTION: Proposed collection; comment request

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 April 4, 2003.

ADDRESSES: Direct all written comments to Diana Hynek, Departmental Paperwork Clearance Officer, Department of Commerce, 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 instrument and instructions should be directed to G. Daniel Sansbury, Census Bureau, FOB #4 Room 2232, Washington, DC 20233–6913, (301) 763–4834 or via the Internet at *g.daniel.sansbury@census.gov.*

SUPPLEMENTARY INFORMATION:

I. Abstract

The Manufacturers' Shipments, Inventories, and Orders (M3) survey requests data from domestic manufacturers on form M–3(SD), which will be mailed at the end of each month. Data requested are shipments, new orders, unfilled orders, total inventory, materials and supplies, work-in-process, and finished goods. It is currently the only survey that provides broad-based monthly statistical data on the economic conditions in the domestic manufacturing sector.

The M3 survey is designed to measure current industrial activity and to provide an indication of future production commitments. The value of shipments measures the value of goods delivered during the month by domestic manufacturers. Estimates of new orders serve as an indicator of future production commitments and represent the current sales value of new orders received during the month, net of cancellations. Substantial accumulation or depletion of unfilled orders measures excess or deficient demand for manufactured products. The level of inventories, especially in relation to shipments, is frequently used to monitor the business cycle.

The estimated total annual burden hours have decreased from 24,000 to 13,860 due to a decrease in the number of respondents.

II. Method of Collection

Respondents submit data on form M–3(SD) via mail, facsimile machine, Touchtone Data Entry (TDE), Voice Recognition Entry (VRE), or via the Internet. Analysts call cooperative respondents who have not reported in time for preparing the monthly estimates.

III. Data

OMB Number: 0607–0008.

Form Number: M–3(SD).

Type of Review: Regular.

Affected Public: Businesses, large and small, or other for profit.

Estimated Number of Respondents: 3,500.

Estimated Time Per Response: .33 hour.

Estimated Total Annual Burden Hours: 13,860.

Estimated Total Annual Cost: $302,425.

Respondent's Obligation: Voluntary.

Legal Authority: Title 13, United States Code, sections 131 and 182.

IV. Request for Comments

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden (including hours and cost) of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, 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: January 28, 2003.

Madeleine Clayton,

Management Analyst, Office of the Chief Information Officer.

[FR Doc. 03–2362 Filed 1–31–03; 8:45 am]

BILLING CODE 3510–70–P

DEPARTMENT OF COMMERCE

Census Bureau

Survey of Income and Program Participation (SIPP) Wave 9 of the 2001 Panel

ACTION: Proposed collection; comment request.

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 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 April 4, 2003.

ADDRESSES: Direct all written comments to Diana Hynek, Departmental Paperwork Clearance Officer, Department of Commerce, 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 instrument(s) and instructions should be directed to Judith H. Eargle, Census Bureau, FOB 3, Room 3387, Washington, DC 20233–0001, (301) 763–3819.

SUPPLEMENTARY INFORMATION:

I. Abstract

The Census Bureau conducts the SIPP which is a household-based survey designed as a continuous series of national panels. New panels are introduced every few years with each panel usually having durations of one to four years. Respondents are interviewed at 4-month intervals or ''waves'' over the life of the panel. The survey is molded around a central ''core'' of labor force and income questions that remain fixed throughout the life of the panel. The core is supplemented with questions designed to address specific needs, such as obtaining information about assets and liabilities, as well as expenses related to work, health care, and child support. These supplemental questions are included with the core and are referred to as ''topical modules.''

The SIPP represents a source of information for a wide variety of topics and allows information for separate topics to be integrated to form a single, unified database so that the interaction between tax, transfer, and other government and private policies can be examined. Government domestic-policy formulators depend heavily upon the SIPP information concerning the distribution of income received directly as money or indirectly as in-kind benefits and the effect of tax and transfer programs on this distribution. They also need improved and expanded data on the income and general economic and financial situation of the U.S. population. The SIPP has provided these kinds of data on a continuing basis since 1983 permitting levels of economic well-being and changes in these levels to be measured over time.

The 2001 Panel is currently scheduled for three years and will include nine waves of interviewing beginning February 2001. Approximately 50,000 households will be selected for the 2001 Panel, of which 37,500 are expected to be interviewed. We estimate that each household will contain 2.1 people, yielding 78,750 interviews in Wave 1 and subsequent waves. Interviews take 30 minutes on average. One wave of interviewing will occur in the 2001 SIPP Panel during FY 2004. The total annual burden for the 2001 Panel SIPP interviews would be 39,375 hours in FY 2004.

The topical modules for the 2001 Panel Wave 9 collect information about:

- Medical Expenses and Utilization of Health Care (Adults and Children).
- Work Related Expenses and Child Support Paid.
- Assets, Liabilities, and Eligibility.

Wave 9 interviews will be conducted from October 2003 through January 2004.

A 10-minute reinterview of 2,500 people is conducted at each wave to ensure accuracy of responses. Reinterviews would require an additional 418 burden hours in FY 2004.

II. Method of Collection

The SIPP is designed as a continuing series of national panels of interviewed households that are introduced every few years with each panel having durations of one to four years. All household members 15 years old or over are interviewed using regular proxy-respondent rules. During the 2001 Panel, respondents are interviewed a total of nine times (nine waves) at 4-month intervals making the SIPP a longitudinal survey. Sample people (all household members present at the time of the first interview) who move within the country and reasonably close to a SIPP primary sampling unit will be followed and interviewed at their new address. Individuals 15 years old or over who enter the household after Wave 1 will be interviewed; however, if these individuals move, they are not followed unless they happen to move along with a Wave 1 sample individual.

III. Data

OMB Number: 0607–0875.

Form Number: SIPP/CAPI Automated Instrument.

Type of Review: Regular.

Affected Public: Individuals or households.

Estimated Number of Respondents: 78,750 people per wave.

Estimated Time Per Response: 30 minutes per person, on average.

Estimated Total Annual Burden Hours: 39,793.

Estimated Total Annual Cost: The only cost to respondents is their time.

Respondent's Obligation: Voluntary.

Legal Authority: Title 13, United States Code, section 182.

IV. Request for Comments

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden (including hours and cost) of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized or included in the request for the Office of Management and Budget approval of this information collection. They also will become a matter of public record.

Dated: January 28, 2003.

Madeleine Clayton,

Management Analyst, Office of the Chief Information Officer.

[FR Doc. 03–2363 Filed 1–31–03; 8:45 am]

BILLING CODE 3510–07–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[Docket 50–2002]

Foreign-Trade Zone No. 2, Application for Expansion, Amendment of Application

Notice is hereby given that the application of the Board of Commissioners of the Port of New Orleans (the Port), grantee of FTZ 2, for

authority to expand FTZ 2 in the New Orleans, Louisiana area (Doc. 50–2002, 67 FR 70047, 11/20/02), has been amended to include 3 new parcels (6 acres total) located at 1883 Tchoupitoulas Street (2 acres), 2311 Tchoupitoulas Street (2 acres), and 2940 Royal Street (2 acres) New Orleans, Louisiana. The new parcels will be designated as Site 5—Parcels 33, 34, and 35, respectively, and will be operated by Port Cargo Services, Inc. The application otherwise remains unchanged.

Comments on the change may be submitted to the Foreign-Trade-Zones Board, U.S. Department of Commerce, FCB—Suite 4100W, 1401 Constitution Ave., NW., Washington, DC 20230, by February 18, 2003.

Dated: January 22, 2003.

Dennis Puccinelli,

Executive Secretary.

[FR Doc. 03–2439 Filed 1–31–03; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[Docket 6–2003]

Foreign-Trade Zone 40—Cleveland, OH, Area Application for Expansion

An application has been submitted to the Foreign-Trade Zones (FTZ) Board (the Board), by the Cleveland-Cuyahoga County Port Authority, grantee of Foreign-Trade Zone 40, requesting authority to expand its zone in the Cleveland, Ohio, area, within the Cleveland Customs port of entry. The application was submitted pursuant to the provisions of the Foreign-Trade Zones Act, as amended (19 U.S.C. 81a–81u), and the regulations of the Board (15 CFR part 400). It was formally filed on January 23, 2003.

FTZ 40 was approved on September 29, 1978 (Board Order 135, 43 FR 46886, 10/11/78) and expanded in June 1982 (Board Order 194, 47 FR 27579, 6/25/82); April 1992 (Board Order 574, 57 FR 13694, 4/17/92); February 1997 (Board Order 870, 62 FR 7750, 2/20/97); June 1999 (Board Order 1040, 64 FR 33242, 6/22/99); and, April 2002 (Board Order 1224, 67 FR 20087, 4/15/02). The general-purpose zone project currently consists of the following sites in the Cleveland, Ohio, area: *Site 1* (94 acres)—Port of Cleveland complex on Lake Erie at the mouth of the Cuyahoga River, Cleveland; *Site 2* (175 acres)—the IX Center (formerly the ''Cleveland Tank Plant''), in Brook Park, adjacent to the Cleveland Hopkins International Airport; *Site 3* (1,900 acres)—Cleveland Hopkins International Airport complex; *Site 4* (450 acres)—Burke Lakefront Airport, 1501 North Marginal Road, Cleveland; *Site 5* (298 acres)—Emerald Valley Business Park, Cochran Road and Beaver Meadow Parkway, Glenwillow; *Site 6* (30 acres)—Collinwood site, South Waterloo (South Marginal) Road and East 152nd Street, Cleveland; *Site 7* (47 acres)—Water Tower Industrial Park, Coit Road and East 140th Street, Cleveland; *Site 8* (83 acres)—Strongsville Industrial Park, Royalton Road (State Route 82), Strongsville; *Site 9* (13 acres)—East 40th Street between Kelley & Perkins Avenues (3830 Kelley Avenue), Cleveland; and, *Site 10* (15 acres)—Frane Industrial Park, Forman Road, Ashtabula. An application is pending with the FTZ Board to expand existing Site 3 to include the contiguous Snow Road Industrial Park (Docket 38–2002).

The applicant is now requesting authority to expand existing Site 1 by adding two non-contiguous public warehouse/distribution and manufacturing facilities: *Proposed Site 1b* (45 acres)—Cleveland Bulk Terminal (owned by the applicant), 5500 Whiskey Island Drive, Cleveland; and, *Proposed Site 1c* (1,200 acres)—Tow Path Valley Business Park, located on both the east and west banks of the Cuyahoga River, with its borders extending approximately between Jennings Road on the south, to Upper Campbell Road on the east, to I–490/I–77/Dille Road on the north, to W. 14th Street to the west, Cleveland. (Existing Site 1 would be redesignated as Site 1a.) Proposed Site 1b functions as an adjunct of the primary break-bulk and vessel container operations of the maritime facilities of the Port of Cleveland. Proposed Site 1c is a new industrial park related to an inner-city industrial redevelopment project at the former facilities of the LTV Steel Company. No steel-making or steel processing facilities are included within this proposal. The Tow Path Valley Business Park Development Company is the developer and operator of the site. Both sites will provide public warehousing and distribution services to area businesses. The Tow Path site will also offer sites suitable for manufacturing activity, though no specific manufacturing requests are being made at this time. Such requests would be made to the Board on a case-by-case basis.

In accordance with the Board's regulations, a member of the FTZ Staff has been designated examiner to investigate the application and report to the Board.

Public comment on the application is invited from interested parties. Submissions (original and 3 copies) shall be addressed to the Board's Executive Secretary at one of the following addresses:

1. Submissions via Express/Package Delivery Services: Foreign-Trade Zones Board, U.S. Department of Commerce, Franklin Court Building, Suite 4100W, 1099 14th Street, NW., Washington, DC 20005.

2. Submissions via the U.S. Postal Service: Foreign-Trade Zones Board, U.S. Department of Commerce, FCB-Suite 4100W, 1401 Constitution Avenue, NW., Washington, DC 20230.

The closing period for their receipt is April 4, 2003. Rebuttal comments in response to material submitted during the foregoing period may be submitted during the subsequent 15-day period (to April 21, 2003).

A copy of the application and accompanying exhibits will be available during this time for public inspection at address Number 1 listed above, and at the U.S. Department of Commerce Export Assistance Center, 600 Superior Avenue East, Suite 700, Cleveland, OH 44114.

Dated: January 23, 2003.

Dennis Puccinelli,

Executive Secretary.

[FR Doc. 03–2441 Filed 1–31–03; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[Order No. 1266]

Expansion of Foreign-Trade Zone 12, McAllen, Texas

Pursuant to its authority under the Foreign-Trade Zones Act of June 18, 1934, as amended (19 U.S.C. 81a–81u), the Foreign-Trade Zones Board (the Board) adopts the following Order:

Whereas, the McAllen Economic Development Corporation, grantee of Foreign-Trade Zone 12, submitted an application to the Board for authority to expand FTZ 12-Site 1 to include two additional parcels (90 acres) at the McAllen Southwest Industrial Area in Hidalgo County, Texas, within the Hidalgo/Pharr Customs port of entry (FTZ Docket 27–2002; filed 6/11/02);

Whereas, notice inviting public comment was given in the **Federal Register** (67 FR 41394, 6/18/02) and the application has been processed pursuant to the FTZ Act and the Board's regulations; and,

Whereas, the Board adopts the findings and recommendations of the examiner's report, and finds that the requirements of the FTZ Act and Board's regulations are satisfied, and that the proposal is in the public interest;

Now, therefore, the Board hereby orders:

The application to expand FTZ 12–Site 1 is approved, subject to the Act and the Board's regulations, including Section 400.28.

Signed at Washington, DC, this 21st day of January 2003.

Faryar Shirzad,

Assistant Secretary of Commerce for Import Administration, Alternate Chairman, Foreign-Trade Zones Board.

Dennis Puccinelli,

Executive Secretary.

[FR Doc. 03–2442 Filed 1–31–03; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[Docket 8–2003]

Foreign-Trade Zone 62—Brownsville, Texas; Application for Expansion

An application has been submitted to the Foreign-Trade Zones Board (the Board) by the Brownsville Navigation District, grantee of Foreign-Trade Zone 62, requesting authority to expand its zone to include an additional site in the Brownsville, Texas, area, within the Brownsville/Los Indios Customs port of entry. The application was submitted pursuant to the provisions of the Foreign-Trade Zones Act, as amended (19 U.S.C. 81a–81u), and the regulations of the Board (15 CFR Part 400). It was formally filed on January 24, 2003.

FTZ 62 was approved on October 20, 1980 (Board Order 166, 45 FR 71638, 10/29/80) and expanded on September 30, 1983 (Board Order 226, 48 FR 45814, 10/7/83) and on October 24, 1989 (Board Order 444, 54 FR 46098, 11/1/89). The zone project currently consists of three sites (2,281 acres) in the Brownsville area: *Site 1* (1,971 acres) within the 21,000-acre developable portion of the 42,000-acre Brownsville Navigation District (includes the 71-acre NAFTA Industrial Park, located at 6984 N. FM 511); *Site 2* (3 parcels, 193 acres) within the Valley International Airport located on Rio Hondo Road, Harlingen: Parcel A (123 acres) within the Harlingen Industrial Airpark; and, Parcel B (55 acres) & Parcel C (15 acres) located on the west side of the airport; *Site 3* (3 parcels, 117 acres) within the 3,000-acre Harlingen Industrial Park II, Harlingen: Parcel A (91 acres) located at FM 106 and FM 1595; and, Parcel B (7 acres) & Parcel C (18 acres) located at FM 106; and, a *Temporary Site* (8 acres) located at 1101 Joaquin Cavazos Road, within the FINSA Industrial Park, Los Indios (expires 4/1/03).

The applicant is now requesting authority to expand the general-purpose zone to include an additional site at the FINSA Industrial Park (*Proposed Site 4*—4 parcels, 758 acres) located at 1101 Joaquin Cavazos Road, Los Indios. The proposed site will also include the temporary site. The applicant is also requesting that 10 acres at Site 2–Parcel A (Harlingen Industrial Airpark) be restored to zone status. No specific manufacturing authority is being requested at this time. Such requests would be made to the Board on a case-by-case basis.

In accordance with the Board's regulations, a member of the FTZ Staff has been designated examiner to investigate the application and report to the Board.

Public comment on the application is invited from interested parties. Submissions (original and 3 copies) shall be addressed to the Board's Executive Secretary at one of the addresses below: ZZzx

1. *Submissions via Express/Package Delivery Services:* Foreign-Trade Zones Board, U.S. Department of Commerce, Franklin Court Building—Suite 4100W, 1099 14th Street, NW., Washington, DC 20005; or

2. *Submissions via the U.S. Postal Service:* Foreign-Trade Zones Board, U.S. Department of Commerce, FCB—Suite 4100W, 1401 Constitution Avenue, NW., Washington, DC 20230.

The closing period for their receipt is April 4, 2003. Rebuttal comments in response to material submitted during the foregoing period may be submitted during the subsequent 15-day period (to April 21, 2003).

A copy of the application and accompanying exhibits will be available for public inspection at the Office of the Foreign-Trade Zones Board's Executive Secretary at the first address listed above, and at the Port of Brownsville, Brownsville Navigation District, 1000 Foust Road, Brownsville, TX 78521.

Dated: January 24, 2003.

Dennis Puccinelli,

Executive Secretary.

[FR Doc. 03–2440 Filed 1–31–03; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation; Opportunity To Request Administrative Review

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

ACTION: Notice of Opportunity to Request Administrative Review of Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation.

Background

Each year during the anniversary month of the publication of an antidumping or countervailing duty order, finding, or suspension of investigation, an interested party, as defined in section 771(9) of the Tariff Act of 1930, as amended (the Act), may request, in accordance with section 351.213(2002) of the Department of Commerce (the Department) Regulations, that the Department conduct an administrative review of that antidumping or countervailing duty order, finding, or suspended investigation.

Opportunity To Request a Review

Not later than the last day of February 2003, interested parties may request administrative review of the following orders, findings, or suspended investigations, with anniversary dates in February for the following periods:

	Period
Antidumping Duty Proceedings Period	
Brazil: Stainless Steel Bar, A–351–825	2/1/02—1/31/03
France:	
Certain Cut-to-Length Carbon-Quality Steel Plate, A–427–816	2/1/02—1/31/03
Low Enriched Uranium, A–427–818	7/13/01—1/31/03
Germany: Sodium Thiosulfate, A–428–807	2/1/02—1/31/03
India:	

	Period
Certain Cut-to-Length Carbon-Quality Steel Plate, A–533–817	2/1/02—1/31/03
Forged Stainless Steel Flanges, A–533–809	2/1/02—1/31/03
Stainless Steel Bar, A–533–810	2/1/02—1/31/03
Certain Preserved Mushrooms, A–533–813	2/1/02—1/31/03
Indonesia:	
Certain Cut-to-Length Carbon-Quality Steel Plate, A–560–805	2/1/02—1/31/03
Certain Preserved Mushrooms, A–560–802	2/1/02—1/31/03
Italy:	
Certain Cut-to-Length Carbon-Quality Steel Plate, A–475–826	2/1/02—1/31/03
Stainless Steel Butt-Weld Pipe Fittings, A–475–828	2/1/02—1/31/03
Japan:	
Carbon Steel Butt-Weld Pipe Fittings, A–588–602	2/1/02—1/31/03
Certain Cut-to-Length Carbon-Quality Steel Plate, A–588–847	2/1/02—1/31/03
Mechanical Transfer Presses, A–588–810	2/1/02—1/31/03
Melamine In Crystal Form, A–588–056	2/1/02—1/31/03
Stainless Steel Bar, A–588–833	2/1/02—1/31/03
Malaysia: Stainless Steel Butt-Weld Pipe Fittings, A–557–809	2/1/02—1/31/03
Mexico: Welded Large Diameter Line Pipe, A–201–828	8/15/01—1/31/03
Philippines: Stainless Steel Butt-Weld Pipe Fittings, A–565–801	2/1/02—1/31/03
Republic of Korea:	
Certain Cut-to-Length Carbon-Quality Steel Plate, A–580–836	2/1/02—1/31/03
Stainless Steel Butt-Weld Pipe Fittings, A–580–813	2/1/02—1/31/03
Taiwan: Forged Stainless Steel Flanges, A–583–821	2/1/02—1/31/03
The People's Republic of China:	
Axes/adzes, A–570–803	2/1/02—1/31/03
Bars/wedges, A–570–803	2/1/02—1/31/03
Certain Preserved Mushrooms, A–570–851	2/1/02—1/31/03
Coumarin, A–570–830	2/1/02—1/31/03
Creatine Monohydrate, A–570–852	2/1/02—1/31/03
Hammers/sledges, A–570–803	2/1/02—1/31/03
Natural Bristle Paint Brushes and Brush Heads, A–570–501	2/1/02—1/31/03
Picks/mattocks, A–570–803	2/1/02—1/31/03
Sodium Thiosulfate, A–570–805	2/1/02—1/31/03
The United Kingdom: Sodium Thiosulfate, A–412–805	2/1/02—1/31/03
Countervailing Duty Proceedings	
France:	
Certain Cut-to Length Carbon Quality Steel Plate, C–427–817	1/1/02—12/31/02
Low Enriched Uranium, C–427–819	5/14/01—12/31/02
Germany: Low Enriched Uranium, C–428–829	5/14/01—12/31/02
India: Certain Cut-to-Length Carbon-Quality Steel Plate, C–533–818	1/1/02—12/31/02
Indonesia: Certain Cut-to-Length Carbon-Quality Steel Plate, C–560–806	1/1/02—12/31/02
Italy: Certain Cut-to-Length Carbon-Quality Steel Plate, C–475–827	1/1/02—12/31/02
Netherlands: Low Enriched Uranium, C–421–809	5/14/01—12/31/02
Republic of Korea: Certain Cut-to-Length Carbon-Quality Steel Plate, C–580–837	1/1/02—12/31/02
The United Kingdom: Low Enriched Uranium, C–412–821	5/14/01—12/31/02
Suspension Agreements	
None.	

In accordance with section 351.213(b) of the regulations, an interested party as defined by section 771(9) of the Act, may request in writing that the Secretary conduct an administrative review. For both antidumping and countervailing duty reviews, the interested party must specify the individual producers or exporters covered by an antidumping finding or an antidumping or countervailing duty order or suspension agreement for which it is requesting a review, and the requesting party must state why it desires the Secretary to review those particular producers or exporters. If the interested party intends for the Secretary to review sales of merchandise by an exporter (or a producer if that producer also exports merchandise from other suppliers) which were produced in more than one country of origin and each country of origin is subject to a separate order, then the interested party must state specifically, on an order-by-order basis, which exporter(s) the request is intended to cover.

Six copies of the request should be submitted to the Assistant Secretary for Import Administration, International Trade Administration, Room 1870, U.S. Department of Commerce, 14th Street & Constitution Avenue, NW, Washington, DC 20230. The Department also asks parties to serve a copy of their requests to the Office of Antidumping/Countervailing Enforcement, Attention: Sheila Forbes, in room 3065 of the main Commerce Building. Further, in accordance with section 351.303(f)(l)(i) of the regulations, a copy of each request must be served on every party on the Department's service list.

The Department will publish in the **Federal Register** a notice of ''Initiation of Administrative Review of Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation'' for requests received by the last day of February 2003. If the Department does not receive, by the last day of February 2003, a request for review of entries covered by an order, finding, or suspended investigation listed in this notice and for the period identified above, the Department will instruct the Customs Service to assess antidumping or countervailing duties on those entries at a rate equal to the cash deposit of (or bond for) estimated antidumping or countervailing duties required on those entries at the time of

entry, or withdrawal from warehouse, for consumption and to continue to collect the cash deposit previously ordered.

This notice is not required by statute but is published as a service to the international trading community.

Dated: January 29, 2003.

Holly A. Kuga,

Senior Office Director, Group II, Office 4, Import Administration.

[FR Doc. 03–2446 Filed 1–31–03; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

Howard Hughes Medical Institute; Notice of Decision on Application for Duty-Free Entry of Scientific Instrument

This decision is made pursuant to section 6(c) of the Educational, Scientific, and Cultural Materials Importation Act of 1966 (Pub. L. 89–651, 80 Stat. 897; 15 CFR part 301). Related records can be viewed between 8:30 A.M. and 5 P.M. in Suite 4100W, U.S. Department of Commerce, Franklin Court Building, 1099 14th Street, NW., Washington, DC.

Docket Number: 02–049. *Applicant:* Howard Hughes Medical Institute at New York University, New York, NY 10003. *Instrument:* Multisync Clinton Monoray monitor and FE–1 Goggles. *Manufacturer:* Cambridge Research Systems Ltd., United Kingdom. *Intended Use:* See notice at 67 FR 77749, December 19, 2002.

Comments: None received. *Decision:* Approved. No instrument of equivalent scientific value to the foreign instrument, for such purposes as it is intended to be used, is being manufactured in the United States. *Reasons:* The foreign instrument provides special goggles with rapid response time and a matched CRT display with very fast phosphors to obtain right eye/left eye image extinction values below 0.1% for study of stereopsis. The National Institutes of Health advises in its memorandum of December 10, 2002 that (1) this capability is pertinent to the applicant's intended purpose and (2) it knows of no domestic instrument or apparatus of equivalent scientific value to the foreign instrument for the applicant's intended use.

We know of no other instrument or apparatus of equivalent scientific value to the foreign instrument which is being manufactured in the United States.

Gerald A. Zerdy,

Program Manager, Statutory Import Programs Staff.

[FR Doc. 03–2447 Filed 1–31–03; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

National Institutes of Health—Bethesda, MD; Notice of Decision on Application for Duty-Free Entry of Electron Microscope

This is a decision pursuant to section 6(c) of the Educational, Scientific, and Cultural Materials Importation Act of 1966 (Pub. L. 89–651, 80 Stat. 897; 15 CFR part 301). Related records can be viewed between 8:30 A.M. and 5 P.M. in Suite 4100W, U.S. Department of Commerce, Franklin Court Building, 1099 14th Street, NW., Washington, DC.

Docket Number: 02–047. *Applicant:* National Institutes of Health, Bethesda, MD 20892–8025. *Instrument:* Electron Microscope, Model Tecnai 12 TWIN. *Manufacturer:* FEI Company, The Netherlands. *Intended Use:* See notice at 67 FR 77749, December 19, 2002. *Order Date:* September 16, 2002.

Comments: None received. *Decision:* Approved. No instrument of equivalent scientific value to the foreign instrument, for such purposes as the instrument is intended to be used, was being manufactured in the United States at the time the instrument was ordered. *Reasons:* The foreign instrument is a conventional transmission electron microscope (CTEM) and is intended for research or scientific educational uses requiring a CTEM. We know of no CTEM, or any other instrument suited to these purposes, which was being manufactured in the United States at the time of order of the instrument.

Gerald A. Zerdy,

Program Manager, Statutory Import Programs Staff.

[FR Doc. 03–2448 Filed 1–31–03; 8:45 am]

BILLING CODE 3510–DS–P

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 January 27, 2003, CEMEX, S.A. de C.V. (''CEMEX'') filed a first request for panel review with the United States Section of the NAFTA Secretariat pursuant to Article 1904 of the North American Free Trade Agreement. Panel review was requested of the 11th administrative review made by the International Trade Administration, respecting Gray Portland Cement and Clinker from Mexico. This determination was published in the **Federal Register** (68 FR 1816) on January 14, 2003. The NAFTA Secretariat has assigned Case Number USA–MEX–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 United States Section of the NAFTA Secretariat, pursuant to Article 1904 of the Agreement, on January 27, 2003, requesting panel review of the 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 February 26, 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 March 13, 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: January 28, 2003.

Caratina L. Alston,

United States Secretary, NAFTA Secretariat.

[FR Doc. 03–2361 Filed 1–31–03; 8:45 am]

BILLING CODE 3510–GT–U

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[I.D. 010603D]

Endangered and Threatened Species; Take of Anadromous Fish

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

ACTION: Issuance of permit 1413 to Charlotte Ambrose.

SUMMARY: Notice is given that NMFS has issued permit 1413 to Charlotte Ambrose, of the NMFS Protected Resources Division in Santa Rosa, California, that authorizes takes of Endangered Species Act-listed anadromous fish species for research purposes, subject to certain conditions set forth therein.

ADDRESSES: The applications and related documents are available for review in the following offices, by appointment:

For permit 1413: Protected Resources Division, NMFS, 777 Sonoma Avenue, Room 325, Santa Rosa, CA 95404–6528.

FOR FURTHER INFORMATION CONTACT: For permit 1413: Daniel Logan, Protected Resources Division, NMFS, Santa Rosa, CA, (707) 575–6053, or e-mail: *dan.logan@noaa.gov.*

SUPPLEMENTARY INFORMATION:

Species Covered in This Notice:

The following species and evolutionarily significant units (ESU's) are covered in this notice: Chinook salmon (*Oncorhynchus tshawytscha*), coho salmon (*O. kisutch*), and steelhead (*O. mykiss*).

Issuance of this permit, as required by the ESA, was based on a finding that such modification was: (1) applied for in good faith; (2) would not operate to the disadvantage of the listed species which are the subject of the permit; and (3) are consistent with the purposes and policies set forth in section 2 of the ESA. This permit was issued in accordance with and is subject to part 222 of title 50 CFR, the NMFS regulations governing listed species permits.

The applicant's proposed activities are in support of a potential ESA violation enforcement action. The applicant proposes field investigations to document the potential harm or injury to ESA-listed salmonids within the California Coastal (CC) Chinook salmon Evolutionarily Significant Unit (ESU), the Southern Oregon/Northern California Coasts (SONCC) coho salmon ESU, and the Northern California (NC) steelhead ESU.

The NMFS SWR believes that because the health and life of the animals are in danger, the issuance of permit 1413 is an urgent action and sufficient to qualify as an emergency situation consistent with CFR 222.303(g).

Permit Issued

Permit 1413 was issued on December 11, 2002.

Charlotte Ambrose is authorized to capture and handle ESA- listed salmonids within the CC Chinook salmon ESU, the SONCC coho salmon ESU, and the NC steelhead ESU.

The expiration date of Permit 1413 is June 30, 2003.

Dated: January 8, 2003.

Phil Williams,

Chief, Endangered Species Division, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 03–2412 Filed 1–31–03; 8:45 am]

BILLING CODE 3510–22–S

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[I.D. 010803B]

Permit 1233 Modification

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

ACTION: Issuance of Modification 1 to Permit 1233.

SUMMARY: NMFS has issued a permit 1233 to the State of Idaho Department of Fish and Game (IDFG).

ADDRESSES: Copies of the permit may be obtained from the Hatcheries and Inland Fisheries Branch, Sustainable Fisheries Division, NMFS, 525 N.E. Oregon Street, Suite 510, Portland, OR 97232.

FOR FURTHER INFORMATION CONTACT: Herbert Pollard, Boise, Idaho, at phone number: (208) 378–5614, e-mail: *Herbert.Pollard@noaa.gov.*

SUPPLEMENTARY INFORMATION: The following species and evolutionarily significant units (ESUs) are covered in this notice:

Spring/summer chinook salmon (*Oncorhynchus tshawytscha*): threatened Snake River;

Fall chinook salmon (*Oncorhynchus tshawytscha*): threatened Snake River;

Sockeye salmon (*Oncorhynchus nerka*): endangered Snake River; and

Steelhead (*Oncorhynchus mykiss*): threatened Snake River.

Permits

Permit 1233 was issued to IDFG on May 26, 2000, and Modification 1 to permit 1233 was issued to IDFG on December 6, 2002. Permit 1233 authorizes IDFG annual incidental take of naturally produced and artificially propagated ESA-listed anadromous fish associated with the operation of recreational fisheries that target non-listed, hatchery-origin anadromous fish and resident game fish species. Permit 1233 expires December 31, 2004.

Permit 1233 authorizes IDFG's recreational fishing programs including the following activities: (1) Resident sport-fishing in waters which also support ESA-listed chinook and sockeye salmon under the IDFG General Fishing Regulations, including kokanee and trout fisheries in Redfish, Alturas, and Pettit Lakes; (2) chinook salmon sport-fishing in the Clearwater River, Snake River, lower Salmon River, Little Salmon River, and South Fork Salmon River under the IDFG Anadromous Salmon Fishing Regulations; and (3) summer steelhead fishing during the fall and spring seasons under the IDFG Steelhead Fishing Regulations. The permit constitutes authorization for implementation of the IDFG General Fishing Regulations, the IDFG Anadromous Salmon Fishing Regulations, and the IDFG Steelhead Fishing Regulations. Modification 1 to permit 1233 includes additional authorized locations for conducting the state's recreational chinook salmon

fisheries and authorization of incidental take of steelhead resulting from the authorized recreational fisheries. When permit 1233 was issued on May 26, 2000, no take prohibitions had been established for Snake River steelhead. Anticipating that a 4(d) rule would soon be published, a provision was made to amend the permit when protective rules were published. Protective regulations for threatened Snake River steelhead under Section 4(d) of the ESA were promulgated by NMFS, effective September 8, 2000 (July 10, 2000, 65 FR 42422). Recreational fisheries are monitored in a manner that allows evaluation of the effectiveness of protective regulations and conservation strategies. Take of listed species may occur incidental to otherwise legal fishing activities or illegal actions. Measures are described in the permit to minimize such deleterious effects to the extent possible.

Modification 1 of permit 1233 authorizes take of ESA-listed Snake River Basin steelhead as a result of catch-and-release fisheries, with an associated incidental mortality of 3.2 percent of the natural origin return. The modification further authorizes take of ESA-listed Snake River spring chinook salmon of up to 2.0% of the naturally-produced return to Lower Granite Dam; this take limit applies when the return is greater than 25,000 adults, and decreases on a sliding scale for progressively smaller returns. No additional take of ESA-listed Snake River fall chinook or sockeye salmon is authorized. NMFS has determined that take levels authorized in the modified permit will not jeopardize listed salmon and steelhead nor result in the destruction or adverse modification of critical habitat where described.

NMFS' conditions in the permit will ensure that the take of ESA-listed anadromous fish will not jeopardize the continued existence of the listed species. In issuing the permits, NMFS determined that IDFG's Conservation Plan provides adequate mitigation measures to avoid, minimize, or compensate for take of ESA-listed anadromous fish.

Issuance of this permit, as required by the ESA, was based on a finding that the permit: (1) was applied for in good faith; (2) will not operate to the disadvantage of the listed species which are the subject of the permit; and (3) is consistent with the purposes and policies set forth in section 2 of the ESA. This permit was issued in accordance with, and is subject to, 50 CFR part 222, the NMFS regulations governing listed species permits.

Dated: January 24, 2003.

Phil Williams,

Chief, Endangered Species Division, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 03–2411 Filed 1–31–03; 8:45 am]

BILLING CODE 3510–22–S

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[I.D. 012803A]

Pacific Fishery Management Council; Public Meetings

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

ACTION: Notice of public meeting.

SUMMARY: The Pacific Fishery Management Council's (Council) Ad Hoc Groundfish Habitat Technical Review Committee (Habitat TRC) will hold a working meeting on the methodology and data being considered for an assessment of Pacific Coast groundfish essential fish habitat. The meeting is open to the public.

DATES: The Ad Hoc Groundfish Habitat Technical Review Committee working meeting will take place Wednesday, February 19, 2003, from 9 a.m. until 5 p.m. The meeting will reconvene from 8 a.m. to 5 p.m. Thursday, February 20.

ADDRESSES: The meeting will be held at the U.S. Department of Commerce, NOAA, 7600 Sand Point Way NE, Building 9 (NOAA Auditorium), Seattle, WA 98115–6349; (206) 526–6150. To gain admittance to the complex, visitors should tell the security guard they are attending the Ad Hoc Groundfish Habitat Technical Review Committee meeting sponsored by the Pacific Fishery Management Council.

Council address: Pacific Fishery Management Council, 7700 NE Ambassador Place, Suite 200, Portland, OR 97220–1384.

FOR FURTHER INFORMATION CONTACT: Ms. Jennifer Gilden; (503) 820–2280.

SUPPLEMENTARY INFORMATION: The purpose of this meeting is to guide the ongoing assessment of essential fish habitat for Pacific Coast groundfish. Specifically, the Habitat TRC will review data consolidated thus far and review a proposed analytical framework for assessing the status of groundfish habitat. The data include mapping efforts and literature reviews on fishing impacts, impacts related to non-fishing activities, and fish/habitat associations. The analytical framework for the assessment has been designed to determine if habitat function has been degraded by environmental and anthropogenic inputs. In so doing, it will provide a basis for informed policy discussions. By holding a public meeting, the Habitat TRC will further provide opportunity for public participation in the assessment process. The Habitat TRC will only consider technical and scientific questions related to the assessment and will not engage in policy discussions as part of its mission.

Although nonemergency issues not contained in the meeting agenda may come before the Habitat TRC for discussion, those issues may not be the subject of formal Habitat TRC action during this meeting. Habitat TRC action will be restricted to those issues specifically listed in this document and any issues arising after publication of this document that require emergency action under section 305 (c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the Habitat TRC's intent to take final action to address the emergency.

In our continuing efforts to streamline our meeting notification process, we are building an email notification list. If you would like to be notified of future meetings via email, please contact Ms. Kerry Aden at (503) 820–2409 or *kerry.aden@noaa.gov* to provide your email address.

Special Accommodations

The meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Ms. Diane Marston at (206)526–6383 at least 5 days prior to the meeting date.

Dated: January 28, 2003.

Theophilus R. Brainerd,

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

[FR Doc. 03–2410 Filed 1–31–03; 8:45 am]

BILLING CODE 3510–22–S

CORPORATION FOR NATIONAL AND COMMUNITY SERVICE

Sunshine Act Meeting

The Board of Directors of the Corporation for National and Community Service gives notice of the following meeting:

DATE AND TIME: Tuesday, February 11, 2003, 9:15 a.m.–12 p.m.

PLACE: Corporation for National and Community Service, 1201 New York

Avenue, NW., 8th Floor, Room 8410, Washington, DC 20525.

STATUS: Open.

MATTERS TO BE CONSIDERED:

I. Chair's Opening Remarks.
II. Consideration of Prior Meeting's Minutes.
III. Committee Reports.
IV. Youth and State Service Commissions Panel Presentation.
V. White House Task Force on Disadvantaged Youth.
VI. Martin Luther King, Jr. Day of Service—Philadelphia, PA.
VII. National Association of Service Conservation Corps.

ACCOMMODATIONS: Anyone who needs an interpreter or other accommodation should notify the Corporation's contact person.

CONTACT PERSON FOR MORE INFORMATION: Michele Tennery, Senior Associate, Public Affairs, Corporation for National and Community Service, 8th Floor, Room 8601, 1201 New York Avenue NW., Washington, DC 20525. Phone (202) 606–5000 ext. 125. Fax (202)565–2784. TDD: (202) 565–2799. E-mail: *mtennery@cns.gov.*

Dated: January 30, 2003.

Frank R. Trinity,

General Counsel.

[FR Doc. 03–2518 Filed 1–30–03; 11:43 am]

BILLING CODE 6050–$$–P

DEPARTMENT OF DEFENSE

Office of the Secretary

Proposed Collection; Comment Request

AGENCY: Defense Security Service, Office of the Secretary, DoD.

ACTION: Notice.

In compliance with section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Defense Security Service (DSS) announces the proposed collection affecting cleared DOD contractors and seeks public comments on the provision thereof. Comments are invited on: (a) Whether the proposed collection shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the information to be collected; (c) ways to enhance the quality, utility and clarity of the information to be collected; and (d) ways to minimize the burden of the information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

DATES: Consideration will be given to all comments received by April 4, 2003.

ADDRESSES: Written comments and recommendations on the proposed information collection should be sent to Defense Security Service, Chief, Program Integration Branch, ATTN: Mr. Richard L. Lawhorn, 1340 Braddock Place, Alexandria, VA 22314–1650.

FOR FURTHER INFORMATION CONTACT: To request more information on this proposed data collection or obtain a copy of the proposal and associated collection instrument, please write to the above address, or call Defense Security Service, (703) 325–5327 or (703) 325–6034.

Title and OMB Number: ''Defense Security Industrial Security Review Data'', OMB No. 0704–XXXX and ''Defense Security Service Industrial Security Facility Clearance Survey Data'', OMB No. 0704–XXXX.

Needs and Uses: Executive Order (EO) 12829, ''National Industrial Security Program (NISP)'', dated January 6, 1993, as amended by EO 12885 dated December 14, 1993, established the NISP to safeguard Federal Government classified information. The Department of Defense (DOD) is one of four Cognizant Security Agencies that are signatories to the NISP. EO 12829 stipulates that the Secretary of Defense shall serve as the Executive Agent for inspecting and monitoring the contractors, licensees, and grantees who require or will require access, to or who store or will store classified information; and for determining the eligibility for access to classified information of contractors, licensees, and grantees and their respective employees. The specific requirements necessary to protect classified information released to private industry are set forth in DOD 5220.22M, ''National Industrial Security Program Operating Manual (NISPOM). The Executive agent has the authority to issue, after consultation with affected agencies, standard forms or other standardization that will promote the implementation of the NISP. DOD Contractors are subject to an initial facility clearance survey and periodic government security reviews to determine their eligibility to participate in the NISP and ensure that safeguards employed are adequate for the protection of classified information.

DOD Directive, 5105.42 ''Subject: Defense Security Service'', delineates the mission, functions and responsibilities of DSS. DSS is an Agency of the Department of Defense under the authority, direction, and control of the Assistant Secretary of Defense (Command, Control, Communication and Intelligence) (ASD (C3I)). DSS functions and responsibilities include the administration and implementation of the Defense portion of the NISP pursuant to Executive Order 12829.

DSS is the office of record for the maintenance of information pertaining to contractor facility clearance records and industrial security information regarding cleared contractors under its cognizance. To the extent possible, information required as part of the survey or security review is obtained as a result of observation by the representative of the CSA or its designated Cognizant Security Office. Some of the information may be obtained in conference with Key Management Personnel and/or employees of the company. The information is used to respond to all inquires regarding the facility clearance status and storage capability of cleared contractors. It is also used to assess and/or advise Government Contracting Activities regarding the contractor's continued ability to protect classified information.

Affected Public: Businesses, universities, partnerships or other profit and non-profit organizations participating in the Defense portion of the NISP.

Respondent Burden

Industrial Security Review Data

Total Annual Burden Hours: 38,619.6 hours.
Total Number of Respondents: 11,403.
Possessors of classified: 4,792.
Non-Possessors of classified: 6,611.
Responses per Respondent: 1.
Average Burden Hours per Respondent:
Possessors of classified: 5.3 hours.
Non-Possessors of classified: 2 hours.
Frequency: Periodic (*e.g.* Possessors—Annually, Non-Possessors—18 months, compliance reviews, or when directed.)

Industrial Security Facility Clearance Survey Data:

Total Annual Burden Hours: 3,144 hours.
Number of Respondents: 1,572.
Responses per Respondent: 1.
Average Burden Hours Per Respondent: 2 hours.
Frequency: On occasion (*e.g.* initial eligibility determination and when a significant changed condition, such as change in ownership.)

SUPPLEMENTARY INFORMATION:

Summary of Information Collection

The conduct of an Industrial Security Review and or Industrial Security Facility Clearance Survey assists in determining whether a contractor is eligible to establish its facility security

clearance and/or retain participation in the NISP. It is also the basis for verifying whether contractors are appropriately implementing NISP security requirements. These requirements are necessary in order to preserve and maintain the security of the United States through establishing standards to prevent the improper disclosure of classified information.

In accordance with Department of Defense (DOD), 5220.22–R ''Industrial Security Regulation'', DSS is required to maintain a record of the results of surveys and security reviews. Documentation for each survey and/or security review will be compiled addressing areas applicable to the contractor's security program. Portions of the data collected will be stored in databases. All data collected will be handled and marked, ''For Official Use Only''.

Dated: January 22, 2003.

Patricia L. Toppings,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 03–2281 Filed 1–31–03; 8:45 am]

BILLING CODE 5001–08–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

City of Holyoke Gas & Electric Department Project No. 2004–075–Massachusetts; Notice

January 28, 2003.

The following Commission staff were assigned to help facilitate resolution of environmental and related issues associated with development of a comprehensive settlement agreement for the Holyoke Project. The parties anticipate completing the comprehensive settlement agreement and filing an offer of settlement by May 16, 2003. These ''separated staff'' will take no part in the Commission's review of the offer of settlement and the comprehensive settlement agreement, or deliberations concerning the disposition of the rehearings.

Office of General Counsel: John Katz; Office of Energy Projects: Steve Kartalia, Alan Mitchnick.

Different Commission ''advisory staff'' will be assigned to review the offer of settlement, the comprehensive settlement agreement, and process the requests for rehearing, including providing advice to the Commission with respect to the agreement and rehearings. Separated staff and advisory staff are prohibited from communicating with one another concerning the settlement and rehearings.

Magalie R. Salas,

Secretary.

[FR Doc. 03–2387 Filed 1–31–03; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP03–39–000]

Kinder Morgan Interstate Gas Transmission, LLC; Notice of Application

January 28, 2003.

On January 16, 2003, Kinder Morgan Interstate Gas Transmission, LLC, (KMIGT), located at 370 Van Gordon Street, Lakewood, Colorado, filed an application in the above referenced docket, pursuant to section 7(c) of the Natural Gas Act (NGA), and part 157of the Federal Energy Regulatory Commission's (Commission) Rules and Regulations for a certificate of public convenience and necessity authorizing KMIGT to construct and operate facilities necessary to develop its Cheyenne Market Center Service. To accomplish this, KMIGT proposes to construct (1) Two 3,550 horsepower compressor units and ten injection/withdrawal wells at the Huntsman Storage Field; (2) two 1,680 horsepower compressor units at the Rockport Compressor Station; (3) two 1,151 horsepower compressor units at the Kimball Junction Interconnect in Kimball County, Nebraska; (4) approximately 3,700 feet of 8 and 12-inch pipeline; and (5) certain section 2.55(a) facilities. These new facilities will create incremental storage capacity up to 6,000,000 Dth, with an associated withdrawal deliverability of approximately 62,400 Dth/d. It is estimated the facilities will cost approximately $26,905,570. This filing is available for review at the Commission in the Public Reference Room 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 at *FERCOnlineSupport@ferc.gov* or call toll-free, (866) 208–3676, or for TTY, (202) 502–8659.

Any questions regarding this application should be directed to Skip George, Manager of Certificates, Kinder Morgan Interstate Gas Transmission, LLC, PO Box 281304, Lakewood, Colorado 80228–8304, telephone (303) 914–4969.

There are two ways to become involved in the Commission's review of this project. First, any person wishing to obtain legal status by becoming a party to the proceedings for this project should, on or before the comment date stated below, file with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, a motion to intervene in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 385.214 or 385.211) and the Regulations under the NGA (18 CFR 157.10). A person obtaining party status will be placed on the service list maintained by the Secretary of the Commission and will receive copies of all documents filed by the applicant and by all other parties. A party must submit 14 copies of filings made in the proceeding. with the Commission and must mail a copy to the applicant and to every other party. Only parties to the proceeding can ask for court review of Commission orders in the proceeding.

However, a person does not have to intervene in order to have comments considered. The second way to participate is by filing with the Secretary of the Commission, as soon as possible, an original and two copies of comments in support of or in opposition to this project. The Commission will consider these comments in determining the appropriate action to be taken, but the filing of a comment alone will not serve to make the filer a party to the proceeding. The Commission's rules require that persons filing comments in opposition to the project provide copies of their protests only to the party or parties directly involved in the protest.

Persons who wish to comment only on the environmental review of this project should submit an original and two copies of their comments to the Secretary of the Commission. Environmental commenters will be placed on the Commission's environmental mailing list, will receive copies of the environmental documents, and will be notified of meetings associated with the Commission's environmental review process. Environmental commenters will not be required to serve copies of filed documents on all other parties. However, the non-party commenters will not receive copies of all documents filed by other parties or issued by the Commission (except for the mailing of environmental documents issued by the Commission) and will not have the right

to seek court review of the Commission's final order.

The Commission may issue a preliminary determination on non-environmental issues prior to the completion of its review of the environmental aspects of the project. This preliminary determination typically considers such issues as the need for the project and its economic effect on existing customers of the applicant, on other pipelines in the area, and on landowners and communities. For example, the Commission considers the extent to which the applicant may need to exercise eminent domain to obtain rights-of-way for the proposed project and balances that against the non-environmental benefits to be provided by the project. Therefore, if a person has comments on community and landowner impacts from this proposal, it is important either to file comments or to intervene as early in the process as possible.

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.

If the Commission decides to set the application for a formal hearing before an Administrative Law Judge, the Commission will issue another notice describing that process. At the end of the Commission's review process, a final Commission order approving or denying a certificate will be issued.

Comment Date: February 18, 2003.

Magalie R. Salas,

Secretary.

[FR Doc. 03–2381 Filed 1–31–03; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP03–32–000]

Northwest Pipeline Corporation; Notice of Intent To Prepare an Environmental Assessment for the Proposed White River Replacement Project and Request for Comments on Environmental Issues

January 28, 2003.

The staff of the Federal Energy Regulatory Commission (FERC or Commission) will prepare an environmental assessment (EA) that will discuss the environmental impacts of the White River Replacement Project involving construction and operation of facilities by Northwest Pipeline Corporation (Northwest) on its Ignacio to Sumas mainline in King County, Washington.[1] These facilities consist of approximately 4,400 feet each of parallel 26-inch- and 30-inch-diameter pipelines at the White River crossing located 3.3 miles east of the City of Auburn, Washington. This EA will be used by the Commission in its decision-making process to determine whether the project is in the public convenience and necessity.

If you are a landowner receiving this notice, you may be contacted by a pipeline company representative about the acquisition of an easement to construct, operate, and maintain the proposed facilities. The pipeline company would seek to negotiate a mutually acceptable agreement. However, if the project is approved by the Commission, that approval conveys with it the right of eminent domain. Therefore, if easement negotiations fail to produce an agreement, the pipeline company could initiate condemnation proceedings in accordance with state law.

A fact sheet prepared by the FERC entitled ''An Interstate Natural Gas Facility On My Land? What Do I Need To Know?'' was attached to the project notice Northwestprovided to landowners. This fact sheet addresses a number of typically asked questions, including the use of eminent domain and how to participate in the Commission's proceedings. It is available for viewing on the FERC Internet Web site *(www.ferc.gov).*

Summary of the Proposed Project

The purpose of the proposed project is to provide a more permanent solution for improved pipeline safety and reliability while restoring the natural environment of the White River and its floodplain at this crossing. Recent highwater events have increased the risk of exposure to the parallel 26-inch- and 30-inch-diameter pipelines (existing pipelines) underneath the White River and along its south and north banks. A previously abandoned 26-inch-diameter pipeline has been exposed presenting a hazard to recreational use of the White River. Northwest installed a temporary rip-rap structure on the north riverbank in 1996 to protect its existing pipelines.

Northwest proposes to replace the pipelines at a deeper depth by constructing 4,300 feet of parallel 26-inch- and 30-inch-diameter pipelines (replacement pipelines) using a combination of horizontal directional drill (HDD) and conventional open-trench construction. Northwest proposes to abandon, in place and by removal, 3,200 feet of existing pipelines as well as retain 1,100 feet of existing pipelines. Northwest would also remove the previously abandoned 26-inch-diameter pipeline and the rip-rap structure, and would reconstruct the north riverbank to its surrounding contours (*see* Table 1). Northwest seeks authority to:

- Abandon by removal approximately 2,100 feet of existing pipelines from 3 sections: the south floodplain; the north riverbank; and a private property.
- Abandon in place approximately 1,100 feet of existing pipelines from 3 sections: underneath the White River channel (pipelines filled with grout); the slope above the north riverbank (pipelines filled with nitrogen and capped); and underneath State Highway 164 (pipelines immediately underneath highway filled with grout, remaining pipelines filled with nitrogen and capped).
- Retain approximately 1,100 feet of existing pipelines for continued service to the Enumclaw Meter Station.
- Remove the north riverbank rip-rap structure, 380 feet of sheet piling from the south floodplain, and the 665-foot-long previously abandoned 26-inch-diameter pipeline from the White River channel.
- Install approximately 1,200 feet of replacement pipelines in the south floodplain using conventional construction.

[1] Northwest's application was filed with the Commission under section 7 of the Natural Gas Act and part 157 of the Commission's regulations.

TABLE 1.—CONSTRUCTION AND ABANDONMENT FACILITIES PROPOSED BY NORTHWEST

Project component	Length (feet)	Beginning stationing	Ending stationing
Abandon by Removal 26″ & 30″ Existing Pipelines in the North Bank Structure	325	15388+93	15391+40
Abandon by Removal 26″ Existing Pipeline in the South Floodplain	1360	15370+30	15384+10
Abandon by Removal 30″ Existing Pipeline in the South Floodplain	1420	15370+30	15384+49
Abandon by Removal 26″ & 30″ Existing Pipelines on Private Property	300	15395+23	15397+60
Abandon In Place 26″; Existing Pipeline under the White River	500	15384+10	15388+93
Abandon In Place 30″ Existing Pipeline under the White River	450	15384+49	15388+93
Abandon In Place 26″ & 30″ Existing Pipelines under State Highway 164	340	15397+60	15400+21
Abandon In Place 26″ & 30″ Existing Pipelines on the North Bank Slope	410	15391+40	15395+23
Retain 26″ & 30″ Existing Pipelines for Service Feed to the Enumclaw Meter Station	1,100	15402+00	15413+00
Remove Sheet Piling in the South Floodplain	380	15380+74	15384+23
Remove the North Bank Structure	.....	15388+39	15390+22
Remove the previously abandoned 26″ Pipeline from the White River	665	15383+59	15390+21
Install 26″ Replacement Pipeline by HDD	3120	15378+62	15409+83
Install 30″ Replacement Pipeline by HDD	3260	15377+62	15410+23
Install 26″ Replacement Pipeline in the South Floodplain by conventional trenching	830	15370+30	15378+62
Install 30″ Replacement Pipeline in the South Floodplain by conventional trenching	730	15370+30	15377+62
Tie-in 26″ Replacement Pipeline at north end by conventional trenching	340	15409+83	15413+21
Tie-in 30″ Replacement Pipeline at north end by conventional trenching	300	15410+23	15413+21

• Install approximately 3,200 feet of replacement pipelines with 2 parallel HDDs traversing underneath the floodplain and White River channel, the slope north of the White River, State Route 164, and Cameron Park.

• Install 300–340 feet of replacement pipelines at the north end of the project to tie into the HDD pipelines.

Northwest must construct the replacement pipelines with HDD prior to removing the existing pipelines in order to maintain service though its Ignacio to Sumas Line. In order to limit in-stream construction to the drier summer months, Northwest proposes to break the construction schedule into two parts: (1) construction of the replacement pipelines from June to October 2003, and (2) removal of the existing pipelines and of the previously abandoned 665-foot-long pipeline from April to August 2004. The location of the project facilities is shown in appendix 1, figures1–4.[2]

Land Requirements for Construction

Construction of the proposed facilities would require 35 acres of land. The construction work area is comprised of 5 acres of existing permanent right-of-way and 30 acres of temporary work space. The construction work area is on 16.4 acres of forested riparian land in the floodplain and north slope, 13 acres of cropland/pasture, 4 acres of industrial land in the City of Auburn (for a utility yard), 1.5 acres of commercial property, and 1 acre of residential property. Due to the offsetting of the replacement pipelines 50 to 175 feet to the west, Northwest would require 3 additional acres of new permanent right-of-way but would relinquish 4.2 acres of existing permanent right-of-way.

The EA Process

The National Environmental Policy Act (NEPA) requires the Commission to take into account the environmental impacts that could result from an action whenever it considers the issuance of a Certificate of Public Convenience and Necessity. NEPA also requires us [3] to discover and address concerns the public may have about proposals. This process is referred to as ''scoping''. The main goal of the scoping process is to focus the analysis in the EA on the important environmental issues. By this Notice of Intent, the Commission requests public comments on the scope of the issues it will address in the EA. All comments received are considered during the preparation of the EA. State and local government representatives are encouraged to notify their constituents of this proposed action and encourage them to comment on their areas of concern.

The EA will discuss impacts that could occur as a result of the construction and operation of the proposed project under these general headings:

• geology and soils
• land use
• water resources, fisheries,and wetlands
• cultural resources
• vegetation and wildlife
• air quality and noise
• endangered and threatened species
• hazardous wastes
• public safety
• alternative routes

We will make recommendations on how to lessen or avoid impacts on the various resource areas.

Our independent analysis of the issues will be in the EA. Depending on the comments received during the scoping process, the EA may be published and mailed to Federal, state, and local agencies, public interest groups, interested individuals, affected landowners, newspapers, libraries, and the Commission's official service list for this proceeding. A comment period will be allotted for review if the EA is published. We will consider all comments on the EA before we make our recommendations to the Commission.

To ensure your comments are considered, please carefully follow the instructions in the public participation section below.

Currently Identified Environmental Issues

We have already identified several issues that we think deserve attention based on a preliminary review of the proposed facilities and the environmental information provided by Northwest. This preliminary list of potential impacts may be changed based on your comments and our analysis.

• Federal species of concern which may occur in the project area and could be affected, including the chinook

[2] The appendices referenced in this notice are not being printed in the **Federal Register**. Copies are available on the Commission's Web site at the ''FERRIS'' link or from the Commission's Public Reference and Files Maintenance Branch, 888 First Street, NE., Washington, DC 20426, or call (202) 502–8371. For instructions on connecting to FERRIS refer to the last page of this notice. Copies of the appendices were sent to all those receiving this notice in the mail.

[3] ''We'', ''us'', and ''our'' refer to the environmental staff of the Office of Energy Projects (OEP).

salmon, coho salmon, bull trout, and bald eagle.

• Use of temporary and permanent Right-Of-Way on the Muckleshoot Indian Reservation involving fisheries habitat associated with the White River.

• Permanent removal of the rip-rap structure from the north riverbank of the White River and reconstruction of the north riverbank.

• Residential/commercial area in and around State Road 164 and City of Auburn's Cameron Park.

Public Participation

You can make a difference by providing us with your specific comments or concerns about the project. By becoming a commentor, your concerns will be addressed in the EA and considered by the Commission. You should focus on the potential environmental effects of the proposal and measures to avoid or lessen environmental impact. The more specific your comments, the more useful they will be. Please carefully follow these instructions to ensure that your comments are received in time and properly recorded:

1. Send an original and two copies of your letter to: Magalie R. Salas, Secretary, Federal Energy Regulatory Commission, 888 First St., NE., Room 1A, Washington, DC 20426.

2. Label one copy of the comments for the attention of Gas 2 Branch.

3. Reference Docket No. CP03–32–000.

4. Mail your comments so that they will be received in Washington, DC on or before February 27, 2003

Please note that we are continuing to experience delays in mail deliveries from the U.S. Postal Service. As a result, we will include all comments that we receive within a reasonable time frame in our environmental analysis of this project. However, the Commission strongly encourages electronic filing of any comments or interventions or protests to this proceeding. *See* 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site at *http://www.ferc.gov* under the ''e-Filing'' link and the link to the User's Guide. Before you can file comments you will need to create a free account which can be created by clicking on ''Login to File'' and then ''New User Account.''

We may mail the EA for comment. If you are interested in receiving it, please return the Information Request (appendix 4). If you do not return the Information Request, you will be taken off the mailing list.

Becoming an Intervenor

In addition to involvement in the EA scoping process, you may want to become an official party to the proceeding known as an ''intervenor''. Intervenors play a more formal role in the process. Among other things, intervenors have the right to receive copies of case-related Commission documents and filings by other intervenors. Likewise, each intervenor must provide 14 copies of its filings to the Secretary of the Commission and must send a copy of its filings to all other parties on the Commission's service list for this proceeding. If you want to become an intervenor you must file a motion to intervene according to Rule 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.214) (*see* appendix 2). [4] Only intervenors have the right to seek rehearing of the Commission's decision.

Affected landowners and parties with environmental concerns may be granted intervenor status upon showing good cause by stating that they have a clear and direct interest in this proceeding which would not be adequately represented by any other parties. You do not need intervenor status to have your environmental comments considered.

Environmental Mailing List

This notice is being sent to individuals, organizations, and government entities interested in and/or potentially affected by the proposed project. It is also being sent to all identified potential right-of-way grantors. By this notice we are also asking governmental agencies, especially those in appendix 3, to express their interest in becoming cooperating agencies for the preparation of the EA.

Additional Information

Additional information about the project is available from the Commission's Office of External Affairs, at 1–866–208–FERC or on the FERC Internet Web site (*http://www.ferc.gov*)using the FERRIS link. Click on the FERRIS link, enter the docket number excluding the last three digits in the Docket Number field. Be sure you have selected an appropriate date range. For assistance with FERRIS, the FERRIS helpline can be reached at 1–866–208–3676, TTY (202) 502–8659, or at *FERCOnlineSupport@ferc.gov*. The FERRIS link on the FERC Internet Web site also provides access to the texts of formal documents issued by the Commission, such as orders, notices, and rulemakings.

[4] Interventions may also be filed electronically via the Internet in lieu of paper. *See* the previous discussion on filing comments electronically.

Magalie R. Salas,

Secretary.

[FR Doc. 03–2380 Filed 1–31–03; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Notice of Applications Accepted for Filing and Soliciting Comments, Motions To Intervene, and Protests

January 28, 2003.

Take notice that the following hydroelectric applications have been filed with the Commission and are available for public inspection:

a. *Type of Applications:* Preliminary Permit (Competing).

b. *Project Nos.:* 12341–000, 12370–000, and 12386–000.

c. *Dates filed:* August 21, September 20, and October 7, 2002.

d. *Applicants:* Universal Electric Power Corporation, Nelson Hydroelectric, LLC and Overton Hydro, LLC.

e. *Name and Location of Project:* The proposed project would be located on an existing dam called John H. Overton/Red River L&D No. 2, owned by the U.S. Army Corps of Engineers, located on the Red River in Rapides Parish, Louisiana.

f. *Filed Pursuant to:* Federal Power Act, 16 U.S.C.§§ 791(a)—825(r).

g. *Applicant Contacts:* For Universal: Mr. Raymond Helter, Universal Electric Power Corporation, 1145 Highbrook Street, Akron, OH 44301, (330) 535–7115. For Nelson Hydroelectric LLC: Mr. Robert Larson; Gray, Plant, Mooty, Mooty & Bennett, 33 South Sixth Street, Minneapolis MN 55402, (612) 343–2913.For Overton Hydro, LLC: Mr. Brent L. Smith, Northwest Power Services, Inc., PO Box 535, Rigby, ID 83442, (208) 745–0834.

h. *FERC Contact:* Lynn R. Miles, (202) 502–8763.

i. *Deadline for filing comments, protests, and motions to intervene:* 60 days from the issuance date of this notice.

All documents (original and eight copies) should be filed with: Magalie R. Salas, Secretary, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426. Comments, protests, and interventions may be filed electronically via the Internet in lieu of paper; *see* 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site under the ''e-Filing'' link. The Commission

strongly encourages electronic filings. Please include the noted project numbers (P–12341–000, P–12370–000, and P–12386–000) on any comments or motions filed.

The Commission's Rules of Practice and Procedure require all interveners filing documents with the Commission to serve a copy of that document on each person in the official service list for the project. Further, if an intervener files comments or documents with the Commission relating to the merits of an issue that may affect the responsibilities of a particular resource agency, they must also serve a copy of the document on that resource agency.

j. *Description of Projects:* Universal Electric Power Corp (P–12341–00) and Nelson Hydroelectric, LLC (P–12370–00): The proposed run-of-river projects would utilize the Corps' existing dam and consist of: (1) Five proposed 100-foot-long, 120-inch diameter steel penstocks, (2) a proposed powerhouse containing five generating units having an installed capacity of 23 MW, (3) a proposed 300-foot-long, 14.7 kV transmission line, and (4) appurtenant facilities. Applicant estimates that the average annual generation would be 141 GWh and would be sold to a local utility.

Overton Hydro, LLC (P–12386–000): The proposed run-of river project would consist of modifications to the existing facility by adding: (1) Two 168-inch-diameter, 50-foot-long concrete penstocks, (2) a powerhouse containing two generating units with a total installed capacity of 20 MW, (3) a 25-kv transmission line approximately 1 mile long, and (4) appurtenant facilities. The project would have an annual generation of 165 GWh.

k. These filings are available for review at the Commission in the Public Reference Room 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, call toll-free 1–866–208–3676 or e-mail *ferconlineSupport@ferc.gov*. For TTY, call (202) 502–8659. Copies are also available for inspection and reproduction at the appropriate addresses in item g. above.

l. Competing Preliminary Permit—Anyone desiring to file a competing application for preliminary permit for a proposed project must submit the competing application itself, or a notice of intent to file such an application, to the Commission on or before the specified comment date for the particular application (*see* 18 CFR 4.36). Submission of a timely notice of intent allows an interested person to file the competing preliminary permit application no later than 30 days after the specified comment date for the particular application. A competing preliminary permit application must conform with 18 CFR 4.30(b) and 4.36.

m. Competing Development Application—Any qualified development applicant desiring to file a competing development application must submit to the Commission, on or before a specified comment date for the particular application, either a competing development application or a notice of intent to file such an application. Submission of a timely notice of intent to file a development application allows an interested person to file the competing application no later than 120 days after the specified comment date for the particular application. A competing license application must conform with 18 CFR 4.30(b) and 4.36.

n. Notice of Intent—A notice of intent must specify the exact name, business address, and telephone number of the prospective applicant, and must include an unequivocal statement of intent to submit, if such an application may be filed, either a preliminary permit application or a development application (specify which type of application). A notice of intent must be served on the applicant(s) named in this public notice.

o. Proposed Scope of Studies under Permit—A preliminary permit, if issued, does not authorize construction. The term of the proposed preliminary permit would be 36 months. The work proposed under the preliminary permit would include economic analysis, preparation of preliminary engineering plans, and a study of environmental impacts. Based on the results of these studies, the Applicant would decide whether to proceed with the preparation of a development application to construct and operate the project.

p. Comments, Protests, or Motions to Intervene—Anyone may submit comments, a protest, or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, .211, .214. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or motions to intervene must be received on or before the specified comment date for the particular application.

q. Filing and Service of Responsive Documents—Any filings must bear in all capital letters the title ''COMMENTS'', ''NOTICE OF INTENT TO FILE COMPETING APPLICATION'', ''COMPETING APPLICATION'', ''PROTEST'', or ''MOTION TO INTERVENE'', as applicable, and the Project Number of the particular application to which the filing refers. Any of the above-named documents must be filed by providing the original and the number of copies provided by the Commission's regulations to: The Secretary, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426. An additional copy must be sent to Director, Division of Hydropower Administration and Compliance, Federal Energy Regulatory Commission, at the above-mentioned address. A copy of any notice of intent, competing application or motion to intervene must also be served upon each representative of the Applicant specified in the particular application.

r. Agency Comments—Federal, state, and local agencies are invited to file comments on the described application. A copy of the application may be obtained by agencies directly from the Applicant. If an agency does not file comments within the time specified for filing comments, it will be presumed to have no comments. One copy of an agency's comments must also be sent to the Applicant's representatives.

Magalie R. Salas,

Secretary.

[FR Doc. 03–2382 Filed 1–31–03; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Notice of Application Accepted for Filing and Soliciting Comments, Protests, and Motions To Intervene

January 28, 2003.

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection:

a. *Type of Application:* Preliminary Permit.

b. *Project No.:* 12347–000 .

c. *Date filed:* August 21, 2002.

d. *Applicant:* Universal Electric Power Corporation .

e. *Name and Location of Project:* The Coffeeville L&D Hydroelectric Project would be located on the Tombigbee River in Choctaw County, Alabama. The proposed project would utilize the existing Coffeeville Lock and Dam

administered by the U.S. Army Corps of Engineers.

f. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. 791(a)—825(r).

g. *Applicant contact:* Mr. Raymond Helter, Universal Electric Power Corporation, 1145 Highbrook Street, Akron, OH 44301, (330) 535–7115.

h. *FERC Contact:* Tom Papsidero, (202) 502–6002.

i. *Deadline for filing comments, protests, and motions to intervene:* 60 days from the issuance date of this notice.

All documents (original and eight copies) should be filed with Magalie

r. Salas, Secretary, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426. Comments, protests, and interventions may be filed electronically via the Internet in lieu of paper; *see* 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site under the ''e-Filing'' link. The Commission strongly encourages electronic filings. Please include the project number (P–12347–000) on any comments or motions filed.

The Commission's Rules of Practice and Procedure require all interveners filing documents with the Commission to serve a copy of that document on each person in the official service list for the project. Further, if an intervener files comments or documents with the Commission relating to the merits of an issue that may affect the responsibilities of a particular resource agency, they must also serve a copy of the document on that resource agency.

j. *Description of Project:* The proposed project, using the Corps' existing Coffeeville Lock and Dam and Reservoir, would consist of: (1) Four proposed 328-foot-long, 12.5-foot-diameter steel penstocks, (2) a proposed powerhouse containing eight generating units with a combined installed capacity of 9.5 megawatts, (3) a proposed 25-kv transmission line, and (4) appurtenant facilities. The project would operate in a run-of-river mode and would have an average annual generation of 62 GWh.

k. This filing is available for review at the Commission in the Public Reference Room 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, call toll-free 1–866–208–3678 or e-mail *ferconlineSupport@ferc.gov*. For TTY, call (202) 502–8659. A copy is also available for inspection and reproduction at the applicant's address in item g above.

l. Competing Preliminary Permit—Anyone desiring to file a competing application for preliminary permit for a proposed project must submit the competing application itself, or a notice of intent to file such an application, to the Commission on or before the specified comment date for the particular application (*see* 18 CFR 4.36). Submission of a timely notice of intent allows an interested person to file the competing preliminary permit application no later than 30 days after the specified comment date for the particular application. A competing preliminary permit application must conform with 18 CFR 4.30(b) and 4.36.

m. Competing Development Application—Any qualified development applicant desiring to file a competing development application must submit to the Commission, on or before a specified comment date for the particular application, either a competing development application or a notice of intent to file such an application. Submission of a timely notice of intent to file a development application allows an interested person to file the competing application no later than 120 days after the specified comment date for the particular application. A competing license application must conform with 18 CFR 4.30(b) and 4.36.

n. Notice of Intent—A notice of intent must specify the exact name, business address, and telephone number of the prospective applicant, and must include an unequivocal statement of intent to submit, if such an application may be filed, either a preliminary permit application or a development application (specify which type of application). A notice of intent must be served on the applicant(s) named in this public notice.

o. Proposed Scope of Studies under Permit—A preliminary permit, if issued, does not authorize construction. The term of the proposed preliminary permit would be 36 months. The work proposed under the preliminary permit would include economic analysis, preparation of preliminary engineering plans, and a study of environmental impacts. Based on the results of these studies, the Applicant would decide whether to proceed with the preparation of a development application to construct and operate the project.

p. Comments, Protests, or Motions to Intervene—Anyone may submit comments, a protest, or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, .211, .214. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or motions to intervene must be received on or before the specified comment date for the particular application.

q. Filing and Service of Responsive Documents—Any filings must bear in all capital letters the title ''COMMENTS'', ''NOTICE OF INTENT TO FILE COMPETING APPLICATION'', ''COMPETING APPLICATION'', ''PROTEST'', or ''MOTION TO INTERVENE'', as applicable, and the Project Number of the particular application to which the filing refers. Any of the above-named documents must be filed by providing the original and the number of copies provided by the Commission's regulations to: The Secretary, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426. An additional copy must be sent to Director, Division of Hydropower Administration and Compliance, Federal Energy Regulatory Commission, at the above-mentioned address. A copy of any notice of intent, competing application or motion to intervene must also be served upon each representative of the Applicant specified in the particular application.

r. Agency Comments—Federal, state, and local agencies are invited to file comments on the described application. A copy of the application may be obtained by agencies directly from the Applicant. If an agency does not file comments within the time specified for filing comments, it will be presumed to have no comments. One copy of an agency's comments must also be sent to the Applicant's representatives.

Magalie R. Salas,

Secretary.

[FR Doc. 03–2383 Filed 1–31–03; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Notice of Application Accepted for Filing and Soliciting Comments, Motions To Intervene, and Protests

January 28, 2003.

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection:

a. *Type of Application:* Preliminary Permit.

b. *Project No.:* 12350–000.

c. *Date filed:* August 21, 2002.

d. *Applicant:* Universal Electric Power Corporation.

e. *Name and Location of Project:* The Tom Bevill L&D Hydroelectric Project would be located on the Tombigbee River in Pickens County, Alabama. The project would utilize the U.S. Army Corps of Engineers' existing Tom Bevill Lock and Dam.

f. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. 791(a)—825(r).

g. *Applicant Contact:* Mr. Raymond Helter, Universal Electric Power Corporation, 1145 Highbrook Street, Akron, OH 44301, (330) 535–7115.

h. *FERC Contact:* James Hunter, (202) 502–6086.

i. *Deadline for filing comments, protests, and motions to intervene:* 60 days from the issuance date of this notice.

All documents (original and eight copies) should be filed with: Magalie R. Salas, Secretary, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426. Comments, protests, and interventions may be filed electronically via the Internet in lieu of paper; *see* 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site under the ''e-Filing'' link. The Commission strongly encourages electronic filings. Please include the project number (P–12350–000) on any comments or motions filed.

The Commission's Rules of Practice and Procedure require all interveners filing documents with the Commission to serve a copy of that document on each person in the official service list for the project. Further, if an intervener files comments or documents with the Commission relating to the merits of an issue that may affect the responsibilities of a particular resource agency, they must also serve a copy of the document on that resource agency.

j. *Description of Project:* The proposed project, using the existing Tom Bevill Lock and Dam, would consist of: (1) Penstocks connecting to the powerhouse, (2) a powerhouse containing five generating units with a total installed capacity of 3.66 megawatts, (3) a 12.7 or 14.7-kilovolt transmission line connecting to an existing power line, and (4) appurtenant facilities. The project would have an average annual generation of 24 gigawatthours.

k. This filing is available for review at the Commission in the Public Reference Room 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, call toll-free 1–866–208–3676 or e-mail *ferconlineSupport@ferc.gov* . For TTY, call (202) 502–8659. A copy is also available for inspection and reproduction at the address in item g. above.

l. Competing Preliminary Permit—Anyone desiring to file a competing application for preliminary permit for a proposed project must submit the competing application itself, or a notice of intent to file such an application, to the Commission on or before the specified comment date for the particular application (*see* 18 CFR 4.36). Submission of a timely notice of intent allows an interested person to file the competing preliminary permit application no later than 30 days after the specified comment date for the particular application. A competing preliminary permit application must conform with 18 CFR 4.30(b) and 4.36.

m. Competing Development Application—Any qualified development applicant desiring to file a competing development application must submit to the Commission, on or before a specified comment date for the particular application, either a competing development application or a notice of intent to file such an application. Submission of a timely notice of intent to file a development application allows an interested person to file the competing application no later than 120 days after the specified comment date for the particular application. A competing license application must conform with 18 CFR 4.30(b) and 4.36.

n. Notice of Intent—A notice of intent must specify the exact name, business address, and telephone number of the prospective applicant, and must include an unequivocal statement of intent to submit, if such an application may be filed, either a preliminary permit application or a development application (specify which type of application). A notice of intent must be served on the applicant(s) named in this public notice.

o. Proposed Scope of Studies under Permit—A preliminary permit, if issued, does not authorize construction. The term of the proposed preliminary permit would be 36 months. The work proposed under the preliminary permit would include economic analysis, preparation of preliminary engineering plans, and a study of environmental impacts. Based on the results of these studies, the Applicant would decide whether to proceed with the preparation of a development application to construct and operate the project.

p. Comments, Protests, or Motions to Intervene—Anyone may submit comments, a protest, or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, .211, .214. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or motions to intervene must be received on or before the specified comment date for the particular application.

q. Filing and Service of Responsive Documents—Any filings must bear in all capital letters the title ''COMMENTS'', ''NOTICE OF INTENT TO FILE COMPETING APPLICATION'', ''COMPETING APPLICATION'', ''PROTEST'', or ''MOTION TO INTERVENE'', as applicable, and the Project Number of the particular application to which the filing refers. Any of the above-named documents must be filed by providing the original and the number of copies provided by the Commission's regulations to: The Secretary, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426. An additional copy must be sent to Director, Division of Hydropower Administration and Compliance, Federal Energy Regulatory Commission, at the above-mentioned address. A copy of any notice of intent, competing application or motion to intervene must also be served upon each representative of the Applicant specified in the particular application.

r. Agency Comments—Federal, state, and local agencies are invited to file comments on the described application. A copy of the application may be obtained by agencies directly from the Applicant. If an agency does not file comments within the time specified for filing comments, it will be presumed to have no comments. One copy of an agency's comments must also be sent to the Applicant's representatives.

Magalie R. Salas,

Secretary.

[FR Doc. 03–2384 Filed 1–31–03; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Notice of Application Accepted for Filing and Soliciting Comments, Motions To Intervene, and Protests

January 28, 2003.

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection:

a. *Type of Application:* Preliminary Permit.

b. *Project No.:* 12430–000.

c. *Date filed:* December 27, 2002.

d. *Applicant:* Alternative Light & Hydro Associates.

e. *Name and Location of Project:* The Russell Falls Hydroelectric Project would be located at an existing dam owned by Indian River Power Supply, LLC on the Westfield River in Hampden County, Massachusetts.

f. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. 791(a)—825(r).

g. *Applicant Contact:* Mr. Paul V. Nolan, 5515 North 17th Street, Arlington, VA 22205, (703) 534–5509.

h. *FERC Contact:* James Hunter, (202) 502–6086.

i. *Deadline for filing comments, protests, and motions to intervene:* 60 days from the issuance date of this notice.

All documents (original and eight copies) should be filed with: Magalie R. Salas, Secretary, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426. Comments, protests, and interventions may be filed electronically via the Internet in lieu of paper; *see* 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site under the ''e-Filing'' link. The Commission strongly encourages electronic filings. Please include the project number (P–12430–000) on any comments or motions filed.

The Commission's Rules of Practice and Procedure require all interveners filing documents with the Commission to serve a copy of that document on each person in the official service list for the project. Further, if an intervener files comments or documents with the Commission relating to the merits of an issue that may affect the responsibilities of a particular resource agency, they must also serve a copy of the document on that resource agency.

j. *Description of Project:* The proposed project would consist of: (1) The existing 3-foot-high, 365-foot-long concrete weir creating a small impoundment that would have a normal water surface elevation of 275.5 feet, with the addition of one-foot flashboards, (2) two existing 60-foot-long, 84-inch-diameter steel penstocks and a proposed 50-foot-long, 60-inch-diameter steel penstock, (3) an existing powerhouse containing two generating units with a total installed capacity of 700 kilowatts and a proposed powerhouse containing one generating unit with a maximum installed capacity of 300 kilowatts, (4) a proposed 500-foot-long transmission line connecting to an existing distribution system, and (5) appurtenant facilities. The project would have an average annual generation of 4 gigawatthours.

k. This filing is available for review at the Commission in the Public Reference Room 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, call toll-free 1–866–208–3676 or e-mail *ferconlineSupport@ferc.gov* . For TTY, call (202) 502–8659. A copy is also available for inspection and reproduction at the address in item g. above.

l. Competing Preliminary Permit—Anyone desiring to file a competing application for preliminary permit for a proposed project must submit the competing application itself, or a notice of intent to file such an application, to the Commission on or before the specified comment date for the particular application (*see* 18 CFR 4.36). Submission of a timely notice of intent allows an interested person to file the competing preliminary permit application no later than 30 days after the specified comment date for the particular application. A competing preliminary permit application must conform with 18 CFR 4.30(b) and 4.36.

m. Competing Development Application— Any qualified development applicant desiring to file a competing development application must submit to the Commission, on or before a specified comment date for the particular application, either a competing development application or a notice of intent to file such an application. Submission of a timely notice of intent to file a development application allows an interested person to file the competing application no later than 120 days after the specified comment date for the particular application. A competing license application must conform with 18 CFR 4.30(b) and 4.36.

n. Notice of Intent—A notice of intent must specify the exact name, business address, and telephone number of the prospective applicant, and must include an unequivocal statement of intent to submit, if such an application may be filed, either a preliminary permit application or a development application (specify which type of application). A notice of intent must be served on the applicant(s) named in this public notice.

o. Proposed Scope of Studies under Permit—A preliminary permit, if issued, does not authorize construction. The term of the proposed preliminary permit would be 36 months. The work proposed under the preliminary permit would include economic analysis, preparation of preliminary engineering plans, and a study of environmental impacts. Based on the results of these studies, the Applicant would decide whether to proceed with the preparation of a development application to construct and operate the project.

p. Comments, Protests, or Motions to Intervene—Anyone may submit comments, a protest, or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, .211, .214. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or motions to intervene must be received on or before the specified comment date for the particular application.

q. Filing and Service of Responsive Documents—Any filings must bear in all capital letters the title ''COMMENTS'', ''NOTICE OF INTENT TO FILE COMPETING APPLICATION'', ''COMPETING APPLICATION'', ''PROTEST'', or ''MOTION TO INTERVENE'', as applicable, and the Project Number of the particular application to which the filing refers. Any of the above-named documents must be filed by providing the original and the number of copies provided by the Commission's regulations to: The Secretary, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426. An additional copy must be sent to Director, Division of Hydropower Administration and Compliance, Federal Energy Regulatory Commission, at the above-mentioned address. A copy of any notice of intent, competing application or motion to intervene must also be served upon each representative of the Applicant specified in the particular application.

r. Agency Comments—Federal, state, and local agencies are invited to file

comments on the described application. A copy of the application may be obtained by agencies directly from the Applicant. If an agency does not file comments within the time specified for filing comments, it will be presumed to have no comments. One copy of an agency's comments must also be sent to the Applicant's representatives.

Magalie R. Salas,

Secretary.

[FR Doc. 03–2385 Filed 1–31–03; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Notice of Transfer of License and Soliciting Comments, Motions to Intervene, and Protests

January 28, 2003.

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection:

a. *Application Type:* Transfer of License.

b. *Project No.:* 1651–024.

c. *Date Filed:* November 29, 2002.

d. *Applicants:* Swift Creek Power Company, Inc. (Transferor) and the Town of Afton, Wyoming (Transferee).

e. *Name of Project:* Swift Creek.

f. *Location:* Located partially within the Bridger-Teton National Forest, on Swift Creek, in Lincoln County, Wyoming.

g. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. 791(a)–825(r).

h. *Applicants Contacts:* Mr. E. Farley Eskelson, Swift Creek Power Company, Inc., 5864 South Green Street, Murray, UT 84123, (801) 713–3000 (Transferor); Mr. Scott Darrington, City Manager, 416 Washington Street, Afton, WY 83110, (307) 885–9831 (Transferee).

i. *FERC Contact:* Regina Saizan, (202) 502–8765.

j. *Deadline for filing comments and or motions:* February 28, 2003.

All documents (original and eight copies) should be filed with: Magalie R. Salas, Secretary, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426. Comments, protests, and interventions may be filed electronically via the Internet in lieu of paper; *see* 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site under the ''e-Filing'' link. The Commission strongly encourages electronic filings. Please include the project number (P–1651–024) on any comments or motions filed.

The Commission's rules of practice and procedure require all interveners filing a document with the Commission to serve a copy of that document on each person in the official service list for the project. Further, if an intervener files comments or documents with the Commission relating to the merits of an issue that may affect the responsibilities of a particular resource agency, they must also serve a copy of the document on that resource agency.

k. *Description of Transfer:* The applicants seek Commission approval to transfer the license for the Swift Creek Project from Swift Creek Power Company, Inc. to the Town of Afton, Wyoming, which has the resources to develop the project.

l. This filing is available for review at the Commission in the Public Reference Room 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, call toll-free 1–866–208–3676 or e-mail *ferconlineSupport@ferc.gov*. For TTY, call (202) 502–8659. A copy is also available for inspection and reproduction at the addresses in item h.

m. Individuals desiring to be included on the Commission's mailing list should so indicate by writing to the Secretary of the Commission.

n. Comments, Protests, or Motions to Intervene—-Anyone may submit comments, a protest, or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, .211, .214. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or motions to intervene must be received on or before the specified comment date for the particular application.

o. Filing and Service of Responsive Documents—-Any filings must bear in all capital letters the title ''COMMENTS'', ''RECOMMENDATIONS FOR TERMS AND CONDITIONS'', ''PROTEST'', OR ''MOTION TO INTERVENE'', as applicable, and the Project Number of the particular application to which the filing refers. A copy of any motion to intervene must also be served upon each representative of the Applicant specified in the particular application.

p. Agency Comments—-Federal, state, and local agencies are invited to file comments on the described application. A copy of the application may be obtained by agencies directly from the Applicant. If an agency does not file comments within the time specified for filing comments, it will be presumed to have no comments. One copy of an agency's comments must also be sent to the Applicant's representatives.

Magalie R. Salas,

Secretary.

[FR Doc. 03–2386 Filed 1–31–03; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Notice of Application for Amendment of License and Soliciting Comments, Motions To Intervene, and Protests

January 28, 2003.

Take notice that the following application has been filed with the Commission and is available for public inspection:

a. *Applicant Type:* Amendment of License to Change Project Boundary.

b. *Project No:* 2192–010.

c. *Date Filed:* July 30, 2002.

d. *Applicant:* Consolidated Water Power Company.

e. *Name of Project:* Biron Hydroelectric Project.

f. *Location:* The Biron Hydroelectric Project is located on the Wisconsin River, in Wood and Portage Counties, Wisconsin.

g. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. 791(a)-825 (r) and ** 799 and 801.

h. *Applicant Contact:* Mark E. Anderson, Resources Coordinator, Consolidated Water Power Company, General Offices, P.O. Box 8050, Wisconsin Rapids, WI 54495–8050, (715) 422–3927, or e-mail *mark.anderson@storaenso.com*.

i. *FERC Contact:* Any questions on this notice should be addressed to Etta Foster at (202) 502–8769, or e-mail address: *etta.foster@ferc.gov*.

j. *Deadline for filing comments and/or motions:* February 28, 2003.

All documents (original and eight copies) should be filed with: Magalie R. Salas, Secretary, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426. Please include the project number (P–2192–010) on any comments or motions filed.

k. *Description of Request:* Consolidated Water Power Company (CWPCo) is proposing a land swap with a local resident, Joe Berry. The affected

parcels are located within Section 26, T23N, R6E, Town of Rudolph, Wood County, Wisconsin. Lot 1 contains 19.28 acres owned by CWPCo, and Lot 2 contains 9.18 acres owned by Joe Berry. The exchange would provide CWPCo with additional land to provide pedestrian access to the project and also provide additional land to buffer the existing wetlands. CWPCo requests that the project boundary be changed to include the 9.18 acres, and to remove the 19.28 acres conveyed to Mr. Berry from the project.

l. *Location of the Application:* A copy of the application is available for inspection and reproduction at the Commission's Public Reference Room, located at 888 First Street, NE., Room 2A, Washington, DC 20426, or by calling (202) 502–8371. This filing may also be viewed on the Commission's Web site at *http://www.ferc.gov* using the ''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. A copy is also available for inspection and reproduction at the address in item (h) above.

m. Individuals desiring to be included on the Commission's mailing list should so indicate by writing to the Secretary of the Commission.

n. Comments, Protests, or Motions to Intervene-Anyone may submit comments, a protest, or a motion to intervene in accordance with the requirements of rules of practice and procedure, 18 CFR 385.210, .211, .214. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a motion to intervene in accordance with the Commission's rules may become a party to the proceeding. Any comments, protests, or motions to intervene must be received on or before the specified comment date for the particular application.

o. Filing and Service of Responsive Documents-Any filings must bear in all capital letters the title ''COMMENTS'', ''PROTEST'', OR ''MOTION TO INTERVENE'', as applicable, and the Project Number of the particular application to which the filing refers. A copy of any motion to intervene must also be served upon each representative of the Applicant specified in the particular application.

p. Agency Comments-Federal, state, and local agencies are invited to file comments on the described application. A copy of the application may be obtained by agencies directly from the Applicant. If an agency does not file comments within the time specified for filing comments, it will be presumed to have no comments. One copy of an agency's comments must also be sent to the Applicant's representatives. q. Comments, protests and interventions may be filed electronically via the Internet in lieu of paper. *See* 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site at *http://www.ferc.gov* under the ''e-filing'' link.

Magalie R. Salas,

Secretary.

[FR Doc. 03–2388 Filed 1–31–03; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Notice of Amendment of License and Soliciting Comments, Motions To Intervene, and Protests

January 28, 2003.

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection:

a. *Application Type*: Amendment of License.

b. *Project No.:* 516–374.

c. *Date Filed:* January 10, 2003.

d. *Applicant:* South Carolina Electric & Gas Company (SCE&G).

e. *Name of Project:* Saluda.

f. *Location:* On the Saluda River in Lexington, Newberry, Richland, and Saluda Counties, South Carolina. The project does not utilize federal or tribal lands.

g. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. 791(a)–825(r).

h. *Applicant Contact:* Thomas G. Eppink, SCANA Corporation, 1426 Main Street, Columbia, SC 29218–0001, (803) 217–9448; Brian J. McManus, Jones Day, 51 Louisiana Avenue, NW., Washington, DC 20001–2113, (202) 879–3939.

i. *FERC Contact:* Regina Saizan, (202) 502–8765.

j. *Deadline for filing comments and or motions:* February 28, 2003.

All documents (original and eight copies) should be filed with: Magalie R. Salas, Secretary, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426. Comments, protests, and interventions may be filed electronically via the Internet in lieu of paper; *see* 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site under the ''e-Filing'' link. The Commission strongly encourages electronic filings. Please include the project number (P–516–374) on any comments or motions filed.

The Commission's rules of practice and procedure require all interveners filing a document with the Commission to serve a copy of that document on each person in the official service list for the project. Further, if an intervener files comments or documents with the Commission relating to the merits of an issue that may affect the responsibilities of a particular resource agency, they must also serve a copy of the document on that resource agency.

k. *Description of Amendment:* SCE&G requests that its license be amended to extend the termination date by 5 years (from August 31, 2007 to August 31, 2012) to provide the time necessary to conduct, under normal operating conditions, the studies that will be requested or required under the relicensing procedures for the Saluda Project. The Commission has ordered a remediation of the project's dam that will necessitate a drawdown of Lake Murray for several years. The dam remediation project will create conditions that are not representative of the conditions under which the project normally operates and render meaningless any relicensing studies pursued under such conditions. SCE&G filed a notice of intent to relicense the project on August 30, 2002.

l. This filing is available for review at the Commission in the Public Reference Room 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, call toll-free 1–866–208–3676 or e-mail *ferconlineSupport@ferc.gov*. For TTY, call (202) 502–8659. Copies are also available for inspection and reproduction at the addresses in item h.

m. Individuals desiring to be included on the Commission's mailing list should so indicate by writing to the Secretary of the Commission.

n. Comments, Protests, or Motions to Intervene—Anyone may submit comments, a protest, or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, .211, .214. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments,

protests, or motions to intervene must be received on or before the specified comment date for the particular application.

o. Filing and Service of Responsive Documents—Any filings must bear in all capital letters the title ''COMMENTS'', ''RECOMMENDATIONS FOR TERMS AND CONDITIONS'', ''PROTEST'', OR ''MOTION TO INTERVENE'', as applicable, and the Project Number of the particular application to which the filing refers. A copy of any motion to intervene must also be served upon each representative of the Applicant specified in the particular application.

p. Agency Comments—Federal, state, and local agencies are invited to file comments on the described application. A copy of the application may be obtained by agencies directly from the Applicant. If an agency does not file comments within the time specified for filing comments, it will be presumed to have no comments. One copy of an agency's comments must also be sent to the Applicant's representatives.

Magalie R. Salas,

Secretary.

[FR Doc. 03–2389 Filed 1–31–03; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–7446–7]

Agency Information Collection Activities OMB Responses

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notices.

SUMMARY: This document announces the Office of Management and Budget's (OMB) responses to Agency clearance requests, in compliance with the Paperwork Reduction Act (44 U.S.C. 3501 *et. seq.*). 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 and 48 CFR chapter 15.

FOR FURTHER INFORMATION CONTACT: Susan Auby at (202) 566–1672, or email at *auby.susan@epa.gov*. and please refer to the appropriate EPA Information Collection Request (ICR) Number.

SUPPLEMENTARY INFORMATION:

OMB Responses to Agency Clearance Requests

OMB Approvals

EPA ICR No. 2085.01; 2003 Drinking Water Infrastructure Needs Survey; was approved 11/27/2002; OMB No. 2040–0251; expires 11/30/2005.

EPA ICR No. 1426.06; EPA Worker Protection Standard for Hazardous Waste Operations and Emergency Response in 40 CFR 311.1 and 311.2; was approved 12/20/2002; OMB No. 2050–0105; expires 12/31/2005.

EPA ICR No. 1131.07; NSPS for Glass Manufacturing Plants in 40 CFR part 60, subpart CC, was approved 12/30/2002; OMB No. 2060–0054; expires 12/31/2005.

EPA ICR No. 1031.07; Recordkeeping and Reporting Requirements for Allegations of Significant Adverse Reactions to Human Health or the Environment (TSCA section 8(c)) in 40 CFR part 717; was approved 12/30/2002; OMB No. 2070–0017; expires 12/31/2005.

EPA ICR No. 0938.09; General Administrative Requirements for Assistance Programs in 40 CFR parts 30 and 31; was approved 12/30/2002; OMB No. 2030–0020; expires 12/31/2005.

EPA ICR No. 0746.05; NSPS for Calciners and Dryers in Mineral Industries in 40 CFR part 60, subpart UUU; was approved 12/30/2002; OMB No. 2060–0251; expires 12/31/2005.

EPA ICR No. 1910.02; Synopses of Proposed Contract Actions and Market Research Activity; was approved 12/30/2002; OMB No. 2030–0039; expires 12/31/2005.

EPA ICR No. 1884.02; TSCA Inventory Update Rule Amendment in 40 CFR part 710; was approved 12/31/2002; OMB No. 2070–0162; expires 12/31/2005.

EPA ICR No. 0660.08; NSPS for Metal Coil Surface Coating in 40 CFR part 60, subpart TT; was approved 12/30/2002; OMB No. 2060–0107; expires 12/31/2005.

EPA ICR No. 1867.02; Voluntary Aluminum Industrial Partnership (VAIP); was approved 12/30/2002; OMB No. 2060–0411; expires 12/31/2005.

EPA ICR No. 0983.07; NSPS Equipment Leaks of VOC in Petroleum Refineries in 40 CFR part 60, subpart GGG; was approved 12/30/2002; OMB No. 2060–0067; expires 12/31/2005.

EPA ICR No. 1557.05; NSPS for Municipal Solid Waste Landfills; in 40 CFR part 60, subpart WWW; was approved 12/30/2002; OMB No. 2060–0220; expires 12/31/2005.

EPA ICR No. 0664.07; NSPS Bulk Gasoline Terminals in 40 CFR part 60, subpart XX; was approved 12/30/2002; OMB No. 2060–0006; expires 12/31/2005.

EPA ICR No. 1188.07; TSCA section 5(a)(2) Significant New Use Rules for Existing Chemicals in 40 CFR part 721; was approved on 01/13/2003; OMB No. 2070–0038; expires on 01/31/2006.

Short Term Extensions

EPA ICR No. 1838.01; Industry Detailed Questionnaire: Phase II Cooling Water Intake Structures; OMB No. 2040–0213; on 12/17/2002 OMB extended the expiration date through 03/31/2003.

EPA ICR No. 1912.01; Information Collection Request: National Primary Drinking Water Regulation for Lead and Copper (Final Rule); OMB No. 2040–0210; on 12/19/2002 OMB extended the expiration date through 03/31/2003.

EPA ICR No. 0794.09; Notification of Substantial Risk of Injury to Health and the Environment under TSCA section 8(e); OMB No. 2070–0046; on 01/06/2003 OMB extended the expiration date through 04/30/2003.

EPA ICR No. 0795.10; Notification of Chemical Exports—TSCA Section 12(b); OMB No. 2070–0030; on 01/06/2003 OMB extended the expiration date through 04/30/2003.

Comments Filed

EPA ICR No. 2080.01; Motor Vehicle and Engine Compliance Program Fees (Proposed Rule); on 12/30/2002 OMB filed a comment.

EPA ICR No. 2079.01; NESHAP: Metal Can Surface Coating (Proposed Rule); on 01/06/2003 OMB filed a comment.

EPA ICR No. 2050.01; NESHAP for Taconite Iron Ore Processing Industry (Proposed Rule); on 01/06/2003 OMB filed a comment.

Dated: January 23, 2003.

Oscar Morales,

Director, Collection Strategies Division.

[FR Doc. 03–2430 Filed 1–31–03; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[OW–2002–0041; FRL–7446–8]

Agency Information Collection Activities; Proposed Collection; Comment Request; (OMB Control No. 2040–0095, EPA ICR No. 0909.07)

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 the following Information Collection Request (ICR) has been forwarded to the Office of Management and Budget (OMB) for review and approval: Construction Grants Delegation to States. The ICR, which describes the nature of the information collection and its estimated burden and cost.

DATES: Additional comments may be submitted on or before March 5, 2003.

ADDRESSES: Follow the detailed instructions in **SUPPLEMENTARY INFORMATION.**

FOR FURTHER INFORMATION CONTACT: Gajindar Singh, Office of Wastewater Management, Mail Code 4204M, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (202) 564–0634 , fax number: (202) 501–2396, e-mail: *singh.gajindar@epa.gov.*

SUPPLEMENTARY INFORMATION: EPA has submitted the following ICR to OMB for review and approval according to the procedures prescribed in 5 CFR 1320.12. On July 5, 2002, EPA sought comments on this ICR (67 FR 44829) pursuant to 5 CFR 1320.8(d). EPA received no comments.

EPA has established a public docket for this ICR under Docket ID No. OW–2002–0041, which is available for public viewing at the Water Docket in the EPA Docket Center (EPA/DC), EPA West, Room B102, 1301 Constitution Ave., NW., Washington, DC. 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 Water Docket is (202) 566–2426. An electronic version of the public docket is available through EPA Dockets (EDOCKET) at *http://www.epa.gov/edocket.* Use EDOCKET to 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 and OMB within 30 days of this notice, and according to the following detailed instructions: (1) Submit your comments to EPA online using EDOCKET (our preferred method), by e-mail to *OW-Docket@epa.gov,* or by mail to: EPA Docket Center, Environmental Protection Agency, Mailcode: 4204M, 1200 Pennsylvania Ave., NW., Washington, DC 20460, and (2) Mail your comments to OMB at: Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), Attention: Desk Officer for EPA, 725 17th Street, NW., Washington, DC 20503.

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, Confidential Business Information (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 copyrighted 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.*

Title: Construction Grants Delegation to States (OMB Control No. 2040–0095, EPA ICR Number 0909.07). This is a request to renew an existing approved collection that is scheduled to expire on 03/31/2003. Under the OMB regulations, the Agency may continue to conduct or sponsor the collection of information while this submission is pending at OMB.

Abstract: The purpose of this ICR is to revise and extend the current clearance for the collection of information under the Construction Grants Program Delegation to States, 40 CFR part 35, subpart J, and Title II of the Clean Water Act (CWA). While the Construction Grants Program is being phased out and replaced by the State Revolving Loan Fund (SRF) program, collection activities for the Construction Grants Program must continue until program completion in all the States and territories. The program includes reporting, monitoring and program requirements for municipalities and delegated States.

The information collection activities described in this ICR are authorized under section 205(g) of the Clean Water Act as amended, 33 U.S.C. 1251 *et seq.*, and under 40 CFR part 35, subpart J. The requested information provides the minimum data necessary for the Federal government to maintain appropriate fiscal accountability for use of section 205(g) construction grant funds. The information is also needed to assure an adequate management overview of those State project review activities that are most important to fiscal and project integrity, design performance, Federal budget control, and attainment of national goals.

Managers at the State and Federal levels both rely on the information described in this ICR. State managers rely on the information for their own program and project administration. Federal managers rely on this information to assess, control, and predict the impacts of the construction grants program on the Federal Treasury and future budget requirements. Federal managers also use this information to respond to OMB and Congressional requests and to maintain fiscal accountability. In addition, builders of wastewater treatment plants use the information discussed in this ICR.

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 and 48 CFR chapter 15, and are identified on the form and/or instrument, if applicable.

Burden Statement: The annual public reporting and recordkeeping burden for this collection of information is estimated to average about 55 hours per response. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information.

Respondents/Affected Entities: States and municipalities.

Estimated Number of Respondents: 15.

Frequency of Response: On occasion and annually.

Estimated Total Annual Hour Burden: 2,071 hours.

Estimated Total Annual Cost: $69,399, includes $0 in annual startup and O&M costs.

Changes in the Estimates: There is a decrease of 3,945 hours in the total estimated burden currently identified in the OMB Inventory of Approved ICR Burdens. This decrease is a result of EPA phasing out the Title II Construction Grants Program, and State Delegation of this program, due to the establishment of a State Revolving Loan Fund program.

Dated: January 23, 2003.

Oscar Morales,

Director, Collection Strategies Division.

[FR Doc. 03–2429 Filed 1–31–03; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–7446–9]

Notice of Open Meeting; Environmental Financial Advisory Board, March 4–5, 2003

The Environmental Protection Agency's (EPA) Environmental Financial Advisory Board (EFAB) will hold an open meeting of the full Board in Washington, DC on March 4–5, 2003. The meeting will be held at the National Press Club, 13th Floor in the Holeman Lounge, 14th and F Street, NW., Washington, DC. The Tuesday, March 4 session will run from 8:30 a.m. to 5 p.m. and the Wednesday, March 5 session will begin at 8 a.m. and end at approximately 11 a.m.

EFAB is chartered with providing analysis and advice to the EPA Administrator and program offices on environmental finance. The purpose of this meeting is to hear from informed speakers on environmental finance issues, proposed legislation and Agency priorities and to discuss progress with work products under EFAB's current strategic action agenda. Environmental financing topics expected to be discussed include: State environmental funding, financial assurance at industrial sites; water infrastructure gap, cost-effective environmental management and other public finance projects.

The meeting is open to the public, but seating is limited. To confirm your participation or get further information, please contact Vanessa Bowie, EFAB Coordinator, U.S. EPA on (202) 564–5186.

Dated: January 24, 2003.

Joseph Dillon,

Comptroller.

[FR Doc. 03–2432 Filed 1–31–03; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

Public Information Collection Approved by Office of Management and Budget

January 27, 2003.

The Federal Communications Commission (FCC) has received Office of Management and Budget (OMB) approval for the following public information collections pursuant to the Paperwork Reduction Act of 1995, Public Law 104–13. For further information contact Judith Boley Herman, Federal Communications Commission, (202) 418–0214.

Federal Communications Commission

OMB Control No.: 3060–1031.
Expiration Date: 07/31/2003.
Title: Revision of the Commission's Rules to Ensure Compatibility with Enhanced 911.
Emergency Calling Systems: Petition of City of Richardson, Texas: Order on Reconsideration II.
Form No.: N/A.
Respondents: Business or other for-profit; public safety agencies.
Responses: 1,358.
Estimated Time Per Response: 2–40 hours.
Estimated Total Annual Burden: 13,960 hours.
Total Annual Cost: 0.
Description: The information and coordination burdens are needed to ensure the appropriate application of the Commission's E911 rules and to facilitate speedy E911 implementation.

Federal Communications Commission.

Marlene H. Dortch,

Secretary.

[FR Doc. 03–2370 Filed 1–31–03; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

Public Information Collection Approved by Office of Management and Budget

January 27, 2003.

The Federal Communications Commission (FCC) has received Office of Management and Budget (OMB) approval for the following public information collections pursuant to the Paperwork Reduction Act of 1995, Public Law 104–13. An agency may not conduct or sponsor a collection of information unless it displays a currently valid control number. For further information contact Judith Boley Herman, Federal Communications Commission, (202) 418–0214.

Federal Communications Commission

OMB Control No.: 3060–0954.
Expiration Date: 07/31/05.
Title: Implementation of the 911 Act.
Form No.: N/A.
Respondents: Business or other for-profit, not for profit institutions, state, local, or tribal governments.
Responses: 800.
Estimated Time Per Response: 4.5 hours.
Estimated Total Annual Burden: 3,100 hours.
Total Annual Cost: 0.
Description: The reporting requirement is a two time burden. All of the burdens contained in the submission are needed to ensure prompt and smooth transition to universal 911 emergency calling services.
OMB Control No.: 3060–0900.
Expiration Date: 12/31/05.
Title: Compatibility of Wireless Services with Enhanced 911; Second Report and Order in CC Docket No. 94–102.
Form No.: N/A.
Respondents: Individuals or households, business or other for-profit, state, local, or tribal governments, not for profit institutions.
Responses: 140.
Estimated Time Per Response: 20 hours.
Estimated Total Annual Burden: 2,190 hours.
Total Annual Cost: 0.
Description: The information submitted by manufacturers or carriers wishing to incorporate new or modified E911 call processing modes will be used to keep the Commission informed of technological developments and thus to ensure that the Commission's regulations are kept current and reflect the preferences of the industry in complying with E911 call completion regulations. The voluntary education program will enable consumers to use wireless analog sets to make E911 calls in an informative manner, ensuring a fast, reliable response.
OMB Control No.: 3060–0813.
Expiration Date: 6/30//05.
Title: Revision of the Commission's Rules to Ensure Compatibility with Enhanced 911 Emergency Calling Services.
Form No.: N/A.
Respondents: Business or other for-profit, state, local, or tribal governments.
Responses: 47,031.
Estimated Time Per Response: 1 to 5 hours.
Estimated Total Annual Burden: .198,200 hours.
Total Annual Cost: 0.
Description: The notification burden on Public Safety Answering Points

(PSAPs) will be used by the carriers to verify that wireless E911 calls are referred to PSAPs who have the technical capability to use the data to the caller's benefit. TTU and dispatch notification requirements will be used to avoid consumer confusion as to the capabilities of their handsets in reaching help in emergency situations, thus minimizing the possibility of critical delays in response time. The annual TTY reports will be used to monitor the progress of TTY technology and thus compatibility. Consultations on the specific meaning assigned to pseudo-ANI are appropriate to ensure that all parties are working with the same information. Coordination between carriers and State and local entities to determine the appropriate PSAPs to receive and respond to E911 calls is necessary because of the difficulty in assigning PSAPs based on the location of the wireless caller. The deployment schedule that must be submitted by carriers seeking a waiver of Phase I or Phase II deployment schedule will be used by the Commission to guarantee that the rules adopted in this proceeding are enforced in as timely a manner as possible within technological constraints.

Federal Communications Commission.

Marlene H. Dortch,

Secretary.

[FR Doc. 03–2371 Filed 1–31–03; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

Notice of Public Information Collection(s) Being Submitted to OMB for Review and Approval

January 24, 2003.

SUMMARY: The Federal Communications Commissions, as part of its continuing effort to reduce paperwork burden invites the general public and other Federal agencies to take this opportunity to comment on the following information collection, as required by the Paperwork Reduction Act of 1995, Public Law 104–13. An agency may not conduct or sponsor a collection of information unless it displays a currently valid control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the Paperwork Reduction Act (PRA) that does not display a valid control number. Comments are requested concerning (a) whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; (b) the accuracy of the Commission's burden estimate; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology.

DATES: Written comments should be submitted on or before March 5, 2003. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contact listed below as soon as possible.

ADDRESSES: Direct all comments to Les Smith, Federal Communications Commission, Room 1–A804, 445 12th Street, SW., Washington, DC 20554 or via the Internet to *lesmith@fcc.gov.*

FOR FURTHER INFORMATION CONTACT: For additional information or copies of the information collections contact Les Smith at (202) 418–0217 or via the Internet at *lesmith@fcc.gov.*

SUPPLEMENTARY INFORMATION:

OMB Control Number: 3060–0960.

Title: Application of Network Non-Duplication, Syndicated Exclusivity, and Sports Blackout Rules to Satellite Retransmissions of Broadcast Signals.

Form Number: N/A.

Type of Review: Revision of a currently approved collection.

Respondents: Businesses or other for-profit entities.

Number of Respondents: 1,407.

Estimated Time per Response: 0.5 to 1.0 hours.

Frequency of Response: On occasion reporting requirements; Third party disclosure.

Total Annual Burden: 63,992 hours.

Total Annual Costs: None.

Needs and Uses: In response to the FCC's Report and Order in *Implementation of the Satellite Home Viewer Improvement Act of 1999: Application of Network Non-duplication, Syndicated Exclusivity and Sports Blackout Rules to Satellite Retransmission of Broadcast Signals,* CS Docket No. 00–2, FCC 00–38 (rel. November 2, 2000), parties filed petitions to reconsider certain aspects of the satellite program exclusivity rules adopted therein. In its Order on Reconsideration in the same docket, FCC 02–287 (rel. October 17, 2002), the Commission denied petitions to extend the phase-in period for implementation of the rules, and also maintained the application of the sports blackout rule to satellite carriage of network stations. The Commission revised section 76.122(c)(2), pertaining to identification of information about programming to be deleted, so that the satellite rule conforms to the cable rules. In addition, the Commission clarified and amended section 76.127(c), pertaining to notifications of deletions for sports broadcasts, to permit sports rights holders with a discernable season to submit blackout notifications for an entire season, but also to establish a date certain by when those notifications must be received by satellite carriers.

Federal Communications Commission.

Marlene H. Dortch,

Secretary.

[FR Doc. 03–2372 Filed 1–31–03; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

[Report No. AUC–02–47–D (Auction No. 47); DA 02–3602]

Closed Auction Of Licenses For Cellular Unserved Service Areas Cancelled

AGENCY: Federal Communications Commission.

ACTION: Notice.

SUMMARY: This document announces the cancellation of the auction of seven licenses to provide cellular service in unserved areas scheduled for February 12, 2003.

DATES: Auction No. 47 that was scheduled for February 12, 2003 is cancelled.

FOR FURTHER INFORMATION CONTACT: Kenneth Burnley, Attorney, Auctions and Industry Analysis Division, at (202) 418–0660 or Lisa Stover, Project Manager, Auctions and Industry Analysis Division, at (717) 338–2888.

SUPPLEMENTARY INFORMATION: This is a summary of the *Auction No. 47 Cancellation PN* released on December 26, 2002. The complete text of the *Auction No. 47 Cancellation PN* is available for public inspection and copying during regular business hours at the FCC Reference Information Center, Portals II, 445 12th Street, SW., Room CY–A257, Washington, DC, 20554. The *Auction No. 47 Cancellation PN* may also be purchased from the Commission's duplicating contractor, Qualex International, Portals II, 445 12th Street, SW., Room CY–B402, Washington, DC, 20554, telephone 202–863–2893, facsimile 202–863–2898, or via e-mail *qualexint@aol.com.*

The Wireless Telecommunications Bureau announces the cancellation of

the auction of seven licenses to provide cellular service in unserved areas (''Auction No. 47'') scheduled for February 12, 2003. On December 23, 2002, the Policy and Rules Branch of the Commercial Wireless Division (the ''Division''), Wireless Telecommunications Bureau, approved the Joint Motion for Dismissal and Approval of Settlement (''Settlement Agreement'') filed by WWC License L.L.C. and WWC Holding Co, Inc., both wholly-owned subsidiaries of Western Wireless Corporation, and N.E. Colorado Cellular, Inc (DA 02–3573). The Division concluded that the Settlement Agreement resolved the mutual exclusivity of the applications that were filed, thus eliminating the need to conduct this auction.

Federal Communications Commission.

Margaret Wiener,

Chief, Auctions and Industry Analysis Division, WTB.

[FR Doc. 03–2373 Filed 1–31–03; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR Part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The applications listed below, as well as other related filings required by the Board, are available for immediate inspection at the Federal Reserve Bank indicated. The application also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)). If the proposal also involves the acquisition of a nonbanking company, the review also includes whether the acquisition of the nonbanking company complies with the standards in section 4 of the BHC Act (12 U.S.C. 1843). Unless otherwise noted, nonbanking activities will be conducted throughout the United States. Additional information on all bank holding companies may be obtained from the National Information Center website at *www.ffiec.gov/nic/*.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than February 28, 2003.

A. Federal Reserve Bank of Atlanta (Sue Costello, Vice President) 1000 Peachtree Street, N.E., Atlanta, Georgia 30303:

1. Georgia Commerce Bancshares, Inc., Atlanta, Georgia; to become a bank holding company by acquiring 100 percent of the voting shares of Georgia Commerce Bank, Atlanta, Georgia (in organization).

B. Federal Reserve Bank of Kansas City (Susan Zubradt, Assistant Vice President) 925 Grand Avenue, Kansas City, Missouri 64198-0001:

1. ABM Holding Company, Miltonvale, Kansas; to become a bank holding company by acquiring 100 percent of the voting shares of The Citizens State Bank, Miltonvale, Kansas.

C. Federal Reserve Bank of San Francisco (Maria Villanueva, Consumer Regulation Group) 101 Market Street, San Francisco, California 94105-1579:

1. Five Star Bancorp , Rocklin, California; to become a bank holding company by acquiring 100 percent of the voting shares of Five Star Bank, Rocklin, California.

Board of Governors of the Federal Reserve System, January 28, 2003.

Robert deV. Frierson,

Deputy Secretary of the Board.

[FR Doc. 03–2360 Filed 1–31–03; 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 March 3, 2003.

A. Federal Reserve Bank of Richmond (A. Linwood Gill, III, Vice President) 701 East Byrd Street, Richmond, Virginia 23261–4528:

1. Surrey Bancorp, Mount Airy, North Carolina; to become a bank holding company by acquiring 100 percent of the voting shares of Surrey Bank and Trust, Mount Airy, North Carolina.

B. Federal Reserve Bank of St. Louis (Randall C. Sumner, Vice President) 411 Locust Street, St. Louis, Missouri 63166–2034:

1. Bank of Mulberry Employee Stock Ownership Trust, Mulberry, Arkansas; and its subsidiary, ACME Holding Company, Inc., Mulberry, Arkansas, to acquire 81.65 percent of Madison Corporation, Little Rock, Arkansas, and thereby indirectly acquire Madison Bank and Trust, Kingston, Arkansas.

2. Reliance Bancshares, Inc., Des Peres, Missouri; to acquire 100 percent of the voting shares of The Bank of Godfrey, Godfrey, Illinois.

C. Federal Reserve Bank of San Francisco (Maria Villanueva, Consumer Regulation Group) 101 Market Street, San Francisco, California 94105–1579:

1. Gaslight Leasing, Inc., Fremont, California; to become a bank holding company by acquiring 100 percent of Fremont Bancorporation, and thereby indirectly acquire Fremont Bank, all of Fremont, California.

Board of Governors of the Federal Reserve System, January 29, 2003.

Robert deV. Frierson,

Deputy Secretary of the Board.

[FR Doc. 03–2445 Filed 1–31–03; 8:45 am]

BILLING CODE 6210–01–S

FEDERAL RESERVE SYSTEM

Sunshine Meeting Notice

TIME AND DATE: 11 a.m., Thursday, February 6, 2003.

PLACE: Marriner S. Eccles Federal Reserve Board Building, 20th and C Streets, NW., Washington DC 20551.

STATUS: Closed.

MATTERS TO BE CONSIDERED:

1. Personnel actions (appointments, promotions, assignments, reassignments, and salary actions) involving individual Federal Reserve System employees.

2. Any items carried forward from a previously announced meeting.

FOR MORE INFORMATION PLEASE CONTACT: Michelle A. Smith, Assistant to the Board; 202–452–2955.

SUPPLEMENTARY INFORMATION: You may call 202–452–3206 beginning at approximately 5 p.m. two business days before the meeting for a recorded announcement of bank and bank holding company applications scheduled for the meeting; or you may contact the Board's Web site at *http://www.federalreserve.gov* for an electronic announcement that not only lists applications, but also indicates procedural and other information about the meeting.

Dated: January 30, 2003.

Jennifer J. Johnson,

Secretary of the Board.

[FR Doc. 03–2596 Filed 1–30–03; 2:22 pm]

BILLING CODE 6210–01–P

GENERAL SERVICES ADMINISTRATION

[OMB Control No. 3090–0278]

National Contact Center; Customer Evaluation Survey

AGENCY: Citizen Services and Communications, Federal Citizen Information Center, (GSA).

ACTION: Notice of a new one-time collection.

SUMMARY: Under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the General Services Administration, Office of Citizen Services and Communications (OSCS), Federal Citizen Information Center, National Contact Center (NCC) will submit to the Office of Management and Budget (OMB) a request to review and approve a new information collection requirement. This information collection will be used to assess the public's satisfaction with the NCC service, to assist in increasing the efficiency in responding to the public's need for Federal information, and to assess the effectiveness of marketing efforts. The respondents include users of the NCC.

Public comments are particularly invited on: Whether this collection of information is necessary for the proper performance of the functions of the agency including 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, including through the use of automated collection techniques or other forms of information technology.

DATES: Submit comments on or before: April 4, 2003.

FOR FURTHER INFORMATION CONTACT: Tonya Beres, Office of Citizen Services and Communications, at (202) 501–1803.

ADDRESSES: Submit comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to the Regulatory and Federal Assistance Publications Division, General Services Administration (MVA), Room 4035, 1800 F Street, NW., Washington, DC 20405.

SUPPLEMENTARY INFORMATION:

A. Purpose

This information collection will be used to assess the public's satisfaction with the NCC service, to assist in increasing the efficiency in responding to the public's need for Federal information, and to assess the effectiveness of marketing efforts.

B. Annual Reporting Burden

Respondents: 2,250.

Responses Per Respondent: 1.

Total Responses: 2,250.

Hours Per Response: .05 (3 minutes).

Total Burden Hours: 112.5.

Obtaining Copies of Proposals: Requesters may obtain a copy of the information collection documents from the General Services Administration, Regulatory and Federal Assistance Publications Division (MVA), 1800 F Street, NW., Room 4035, Washington, DC 20405, telephone (202) 208–7312, or by faxing your request to (202) 501–4067. Please cite 3090–0278, National Contact Center Customer Evaluation Survey in all correspondence.

Dated: January 2, 2003.

Michael W. Carleton,

Chief Information Officer (I).

[FR Doc. 03–2450 Filed 1–31–03; 8:45 am]

BILLING CODE 6820–CX–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Prospective Grant of Exclusive License: Nucleic Acid Vaccines for Prevention of Flavivirus Infection

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: This is a notice in accordance with 35 U.S.C. 209(e) and 37 CFR 404.7(a)(1)(i) that the Centers for Disease Control and Prevention (CDC), Technology Transfer Office, Department of Health and Human Services (DHHS), is contemplating the grant of a worldwide exclusive license to practice the inventions embodied in the patents and patent applications referred to below to Fort Dodge Animal Health, a Division of Wyeth, located in Overland Park, Kansas. The patent rights in these inventions have been assigned to the government of the United States of America. The patents and patent applications to be licensed are:

Title:

U.S. Patent Application SN 60/087,908 entitled ''Nucleic Acid Vaccines for Prevention of Flavivirus Infection,'' filed 5.13.1999. And related applications: PCT/US99/12298, filed 6.3.1999; U.S. Patent Application SN 09/701,536; and all foreign applications listed in Appendix A. CDC reference No. I–008–97

U.S. Patent application SN 09/826,115 entitled ''Nucleic Acid Vaccines for Prevention of Flavivirus Infection,'' filed 4.4.2001. And related application PCT/US02/10764 filed 4.4.2002. CDC reference No. I–001–01

The prospective exclusive license will be royalty-bearing and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR 404.7.

This invention covers a recombinant DNA vaccine candidate for the prevention of flavivirus. Licensee will further develop this vaccine candidate for use as an animal vaccine.

ADDRESSES: Requests for a copy of the patent applications, inquiries, comments, and other materials relating

to the contemplated license should be directed to Andrew Watkins, Director, Technology Transfer Office, Centers for Disease Control and Prevention (CDC), 4770 Buford Highway, Mailstop K–79, Atlanta, GA 30341, telephone: (770) 488–8600; facsimile: (770) 488–8615. Applications for a license filed in response to this notice will be treated as objections to the grant of the contemplated license. Only written comments and/or applications for a license which are received by CDC within sixty days of this notice will be considered. Comments and objections submitted in response to this notice will not be made available for public inspection, and, to the extent permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C. 552. A signed Confidential Disclosure Agreement will be required to receive a copy of any pending patent application.

Dated: January 27, 2003.

Joseph R. Carter,

Associate Director for Management and Operations, Centers for Disease Control and Prevention (CDC).

[FR Doc. 03–2393 Filed 1–31–03; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02N–0454]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Notice of a Claim for Generally Recognized as Safe Exemption Based on a Generally Recognized as Safe Determination

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: Submit written comments on the collection of information by March 5, 2003.

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Stuart Shapiro, Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Peggy Robbins, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

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.

Notice of a Claim for GRAS Exemption Based on a GRAS Determination (OMB Control Number 0910–0342)—Extension

Description: Section 409 of the act (21 U.S.C. 348) establishes a premarket approval requirement for ''food additives;'' section 201(s) of the act (21 U.S.C. 321) provides an exemption from the definition of ''food additive'' and thus from the premarket approval requirement, for uses of substances that are generally recognized as safe (GRAS) by qualified experts. FDA is proposing a voluntary procedure whereby members of the food industry who determine that use of a substance satisfies the statutory exemption may notify FDA of that determination. The notice would include a detailed summary of the data and information that support the GRAS determination, and the notifier would maintain a record of such data and information. FDA would make the information describing the GRAS claim, and the agency's response to the notice, available in a publicly accessible file; the entire GRAS notice would be publicly available consistent with the Freedom of Information Act and other Federal disclosure statutes.

Description of Respondents: Manufacturers of Substances Used in Food and Feed.

In the **Federal Register** of October 31, 2002 (67 FR 66404), the agency requested comments on the proposed collection of information. No comments were received that pertained to this collection of information.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
170.36	50	1	50	150	7,500
570.36	10	1	10	150	1,500
Total					9,000

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency of Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
170.36(c)(v)	50	1	50	15	750
570.36(c)(v)	10	1	10	15	150
Total					900

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

The reporting requirement is for a proposed rule (62 FR 18937, April 17, 1997) that has not yet been issued as a final rule. In developing the proposed rule, FDA solicited input from representatives of the food industry on the reporting requirements, but could not fully discuss with those representatives the details of the proposed notification procedure. FDA received no comments on the agency's estimate of the hourly reporting requirements, and thus has no basis to revise that estimate at this time. During 1998, FDA received 12 notices that were submitted under the terms of the proposed rule. FDA received 23 notices in 1999, 30 notices in 2000, and 28 notices in 2001. To date, the number of annual notices is less than FDA's estimate; however, the number of annual notices could increase when the proposed rule becomes final.

Dated: January 28, 2003.

Margaret M. Dotzel,

Assistant Commissioner for Policy.

[FR Doc. 03–2458 Filed 1–31–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 03N–0015]

International Drug Scheduling; Convention on Psychotropic Substances; Single Convention on Narcotic Drugs; World Health Organization Scheduling Recommendation for Amineptine (7-[(10,11–dihydro–5*H*-dibenzo[*a,d*]cyclohepten–5–yl)amino]heptanoic acid)

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is providing interested persons with the opportunity to submit written comments concerning a recommendation by the World Health Organization (WHO) to impose international manufacturing and distribution restrictions, under international treaties, on a drug substance. The comments received in response to this notice will be considered in preparing the U.S. position on this proposal for a meeting of the United Nations Commission on Narcotic Drugs (CND) in Vienna, Austria, April 8 to 17, 2003. This notice is issued under the Controlled Substances Act.

DATES: Submit written or electronic comments by March 1, 2003.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. To ensure expeditious review of written comments, send a copy by facsimile or e-mail to: James R. Hunter (see following address).

FOR FURTHER INFORMATION CONTACT: James R. Hunter, Controlled Substances Staff (HFD–9) Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–2098, FAX: 301–443–9222, e-mail: *hunterj@cder.fda.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

The United States is a party to the 1971 Convention on Psychotropic Substances (the Convention). Section 201(d)(2)(B) of the Controlled Substances Act (the CSA) (21 U.S.C. 811(d)(2)(B)) provides that when the United States is notified under Article 2 of the Convention that CND proposes to decide whether to add a drug or other substance to one of the schedules of the Convention, transfer a drug or substance from one schedule to another, or delete it from the schedules, the Secretary of State must transmit notice of such information to the Secretary of Health and Human Services (HHS). The Secretary of HHS must then publish a summary of such information in the **Federal Register** and provide opportunity for interested persons to submit comments. The Secretary of HHS must then evaluate the proposal and furnish a recommendation to the Secretary of State that shall be binding on the representative of the United States in discussions and negotiations relating to the proposal.

As detailed in the following paragraphs, the Secretary of State has received notification from the Secretary-General of the United Nations (the Secretary-General) regarding a substance to be considered for control under the Convention. This notification reflects the recommendation from the 33d WHO Expert Committee for Drug Dependence (ECDD), which met September 14 to 16, 2002. In the **Federal Register** of April 9, 2002 (67 FR 17074), FDA announced the WHO ECDD review and invited interested persons to submit information for WHO's consideration.

The full text of the notification from the Secretary-General is provided in section II of this document. Section 201(d)(2)(B) of the CSA requires the Secretary of HHS, after receiving a notification proposing scheduling, to publish a notice in the **Federal Register** to provide the opportunity for interested persons to submit information and comments on the proposed scheduling action.

II. United Nations Notification

The formal United Nations notification that identifies the drug substance and explains the basis for the recommendation is reproduced below.

Notification on amineptine:

Reference: NAR/CL.12/2002 CS18/02 CU 2002/262.

The Secretary-General of the United Nations presents his compliments to the Secretary of State of the United States of America and has the honour to inform the Government that the World Health Organization (WHO), pursuant to article 2, paragraphs 1 and 4 of the Convention on Psychotropic Substances, 1971, has notified him that it is of the opinion that amineptine should be placed in Schedule II of that Convention.

Article 2, paragraphs 1 and 4, of the Convention read:''

1. If a Party or the World Health Organization has information relating to a substance not yet under international control which in its opinion may require the addition of that substance to any of the Schedules of this Convention, it shall notify the Secretary-General and furnish him with the information in support of that notification. The foregoing procedure shall also apply when a Party or the World Health Organization has information justifying the transfer of a substance from one Schedule to another among those Schedules, or the deletion of a substance from the Schedules.''

''4. If the World Health Organization finds: (a) That the substance has the capacity to produce (i)(1) a state of dependence, and (2) central nervous system stimulation or depression, resulting in hallucinations or disturbances in motor function or thinking or behaviour or perception or mood, or (ii) similar abuse and similar ill effects as a substance in Schedule I, II, III or IV, and (b) That there is sufficient evidence that the substance is being or is likely to be abused so as to constitute a public health and social problem warranting the placing of the substance under international control, the World Health Organization shall communicate to the Commission an assessment of the substance, including the extent or likelihood of abuse, the degree of seriousness of the public health and social problem and the degree of usefulness of the substance in medical therapy, together with recommendations on control measures, if any, that would be appropriate in the light of its assessment.''

In accordance with the provisions of article 2, paragraph 2, of the 1971 Convention, the Secretary-General hereby transmits the text of that notification as an annex to the present note. The notification together with the assessments and recommendations from WHO as well as any data received from governments on that substance, will also be brought to the attention of the Commission

on Narcotic Drugs at its forty-sixth session in April 2003.

Any decision taken by the Commission with respect to that notification, pursuant to article 2, paragraph 5 of the Convention, will be notified to States Parties in due course.

Article 2, paragraph 5, of the Convention reads:

''The Commission, taking into account the communication from the World Health Organization, whose assessments shall be determinative as to medical and scientific matters, and bearing in mind the economic, social, legal, administrative and other factors it may consider relevant, may add the substance to Schedule I, II, III or IV. The Commission may seek further information from the World Health Organization or from other appropriate sources.''

The Secretary-General would appreciate it if the Government would submit data on seizures of amineptine or on the existence of clandestine laboratories manufacturing it, as well as any economic, social, administrative or other factors the Government may consider relevant to the question of the possible scheduling of amineptine by the Commission.

The Secretary-General would also appreciate it if the requested information could be communicated by 30 January 2003 to the Secretary, Commission on Narcotic Drugs, P.O. Box 500, A–1400 Vienna, Austria, fax: +43–1–26060–5885.

20 December 2002

NAR/CL.12/2002

Annex—Note Addressed to the United Nations by the World Health Organization

The World Health Organization presents its compliments to the United Nations and has the honour to submit, in accordance with article 2, paragraphs 1 and 4 of the Convention on Psychotropic Substances, 1971, assessments and recommendations of the World Health Organization, as set forth in the annex hereto, concerning the proposed placement of amineptine in Schedule II of the 1971 Convention.

The World Health Organization avails itself of this opportunity to present to the United Nations the assurance of its highest consideration.

AMINEPTINE (INN)

Substance identification

Amineptine (7-[(10,11–dihydro–5*H*-dibenzo[*a,d*]cyclohepten–5–yl)amino]heptanoic acid) is available as either the free base (CAS 57574–09–1) or as the hydrochloride salt (CAS 30272–08–3). There are no chiral carbon atoms; therefore, no stereoisomers or racemates are possible.

Similarity to known substances and effects on the central nervous system

Amineptine is a synthetic, atypical tricyclic antidepressant with central nervous system stimulating effects. It is an indirect dopamine agonist, selectively inhibiting dopamine uptake and inducing dopamine release, with additional stimulation of the adrenergic system. Its antidepressant effects are similar to other tricyclic antidepressant drugs but it has a more rapid action, is better tolerated and has little cardiovascular, analgesic or anorectic effects. It produces a similar spectrum of pharmacological effects to psychomotor stimulants in Schedule II of the 1971 Convention on Psychotropic Substances.

Dependence potential

There have been few animal studies regarding the dependence or abuse potential of amineptine. However, some clinical studies indicated that amineptine has both dependence and abuse potential, particularly in patients with a previous history of substance abuse. Clinical observations of significant abuse and dependence are reported in patients treated with amineptine in France. Its dependence potential appeared to be associated with its psychomotor stimulant effect. Withdrawal has been clinically manifested by anxiety, insomnia, psychomotor agitation or bulimia. Instances of dependence have been reported in Europe and Asia.

Actual abuse and/or evidence of likelihood of abuse

Amineptine abuse has mainly been reported in Europe and Asia. It has been withdrawn from the market in France, where the drug was developed a few decades ago, for reasons of considerable hepatotoxicity and abuse. Despite this measure, medical use in developing countries, as well as abuse still continues. The abuse-related adverse drug reaction reports for amineptine collected by the international drug monitoring programme indicate a larger number of case reports of abuse and dependence than anorectic stimulants currently placed in Schedule IV of the 1971 Convention on Psychotropic Substances, such as amfepramone. Response of governments to the WHO questionnaire also indicated limited diversion and abuse of the drug. Some reported hospital admissions due to adverse consequences of amineptine abuse.

Therapeutic usefulness

The therapeutic usefulness of amineptine is low because of hepatotoxicity, secondary features such as acne eruption and anxiety and the availability of safer antidepressants. Of the 103 countries that responded to the WHO questionnaire, only 17 indicated amineptine use.

III. Discussion

Although WHO has made specific scheduling recommendations for amineptine, the CND is not obliged to follow the WHO recommendations. Options available to the CND for substances considered for control under the Psychotropic Convention include: (1) Acceptance of the WHO recommendations; (2) acceptance of the recommendations to control, but control the drug substance in a schedule other than that recommended; or (3) rejection of the recommendations entirely. Amineptine is not approved for marketing in the United States and is not a controlled substance in the United States. Therefore, current controls in the United States on amineptine do not appear to meet the requirements of the recommended Schedule II of the Psychotropic Convention.

IV. Comments

Interested persons may, submit to the Dockets Management Branch (see **ADDRESSES**) written comments regarding this notice. 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 Dockets Management Branch (see **ADDRESSES**) between 9 a.m. and 4 p.m., Monday through Friday.

Dated: January 28, 2003.

Margaret M. Dotzel,

Assistant Commissioner for Policy.

[FR Doc. 03–2456 Filed 1–31–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Biological Response Modifiers Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). At least one portion of the meeting will be closed to the public.

Name of Committee: Biological Response Modifiers Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on February 27, 2003, from 8 a.m. to 6 p.m., and on February 28, 2003, from 8 a.m. to 4:30 p.m.

Location: Holiday Inn, 8777 Georgia Ave., Silver Spring, MD.

Contact Person: Gail Dapolito or Rosanna L. Harvey, Center for Biologics Evaluation and Research (HFM–71), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–0314, or FDA Advisory Committee Information Line, 1–800–741–8138 301–443–0572 in the Washington, DC area), code 12389. Please call the Information Line for up-to-date information on this meeting.

Agenda: On February 27, 2003, from 8 a.m. to approximately 3:45 p.m., the committee will discuss efficacy data for the use of minimally manipulated hematopoietic stem cells from placental/umbilical cord blood for hematopoietic reconstitution for particular age groups. From approximately 3:45 p.m. to 5:30 p.m., the committee will receive updates of

research programs in the Division of Monoclonal Antibodies, Center for Biologics Evaluation and Research (CBER). On February 28, 2003, from 8 a.m. to approximately 4:30 p.m., the committee will discuss safety issues related to the use of retrovirus vectors in gene therapy clinical trials.

Procedure: On February 27, 2003, from 8 a.m. to 5:30 p.m., the meeting is open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by February 20, 2003. On February 27, oral presentations from the public will be scheduled between approximately 11:30 a.m. and 12:30 p.m. On February 28, oral presentations from the public will be scheduled between approximately 11 a.m. and 12 noon. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before February 20, 2003, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Closed Committee Deliberations: On February 27, 2003, from approximately 5:30 p.m. to 6 p.m., the meeting will be closed to permit discussion where disclosure would constitute a clearly unwarranted invasion of personal privacy (5 U.S.C. 552b(c)(6)). The committee will discuss reports of a review of individual research programs in CBER.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Gail Dapolito or Rosanna L. Harvey at least 7 days in advance of the meeting.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: January 24, 2003.

William K. Hubbard,

Associate Commissioner for Policy and Planning.

[FR Doc. 03–2374 Filed 1–31–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Food Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Food Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on Monday, February 24, 2003, from 8:30 a.m. to 5 p.m., and Tuesday, February 25, 2003, from 8:30 a.m. to 5 p.m.

Location: Sheraton College Park Hotel, Salons A, B, and C, 4095 Powder Mill Rd., Beltsville, MD 20705, 301–937–4422.

Contact Person: Sylvia M. Smith, Center for Food Safety and Applied Nutrition (HFS–006), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–2397, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 10564. Please call the Information Line for up-to-date information on this meeting.

Agenda: On February 24 and 25, 2003, the committee will meet to discuss FDA's action plan for addressing the issue of acrylamide in food and to discuss the findings and recommendations from the Contaminants and Natural Toxicants Subcommittee of the Food Advisory Committee.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by February 10, 2003. Oral presentations from the public will be scheduled between approximately 4 p.m. and 5 p.m. on February 24, 2003. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person on or before February 10, 2003, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Sylvia Smith at least 7 days in advance of the meeting.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: January 24, 2003.

William K. Hubbard,

Associate Commissioner for Policy and Planning.

[FR Doc. 03–2457 Filed 1–31–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Advisory Committee for Pharmaceutical Science; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Advisory Committee for Pharmaceutical Science.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on March 12, 2003, from 8:30 a.m. to 5 p.m. and March 13, 2003, from 8:30 a.m. to 5 p.m.

Location: Center for Drug Evaluation and Research Advisory Committee Conference Room, rm. 1066, 5630 Fishers Lane, Rockville, MD.

Contact Person: Kathleen Reedy or Carolyn Jones, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, rm. 1093), Rockville, MD 20857, 301–827–7001, or e-mail: *REEDYK@cder.fda.gov*, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the

Washington, DC area), code 12539. Please call the Information Line for up-to-date information on this meeting.

Agenda: On March 12, 2003, the committee will: (1) Receive a final report from the Process Analytical Technology Subcommittee and provide direction to the Manufacturing Subcommittee; (2) receive an update on sterile products produced by aseptic processing; (3) discuss and provide direction for future subcommittees: Biopharmaceutics Subcommittee and Microbiology Subcommittee; (4) discuss and provide comments on topical dermatological drug product nomenclature; and (5) discuss and provide comments on topical dermatological bioequivalence, methods development. On March 13, 2003, the committee will: (1) Discuss and provide direction for future subcommittee: Pharmacology/Toxicology Subcommittee; (2) receive an update on the Office of Pharmaceutical Science research projects; (3) discuss and provide comments on dose content uniformity, parametric interval test for aerosol products; (4) discuss and provide comments on levothyroxine bioequivalence; and (5) discuss and provide comments on comparability protocols.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by March 3, 2003. Oral presentations from the public will be scheduled between approximately 1:30 p.m. to 2 p.m. on March 12, 2003, and 11:30 a.m. to 12 noon on March 13, 2003. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before March 3, 2003, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Carolyn Jones at least 7 days in advance of the meeting.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: January 27, 2003.

William K. Hubbard,

Associate Commissioner for Policy and Planning.

[FR Doc. 03–2459 Filed 1–31–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D–2212]

Medical Devices; Final Guidance on Quality System Information for Certain Premarket Application Reviews; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a final guidance entitled ''Quality System Information for Certain Premarket Application Reviews.'' This guidance has been prepared by the Center for Devices and Radiological Health (CDRH), in coordination with the Center for Biologics Evaluation and Research (CBER), to assist medical device manufacturers in preparing and maintaining the quality system (QS) information required in certain premarket submissions.

DATES: Submit written or electronic comments on the guidance at any time. General comments on agency guidance documents are welcome at any time.

ADDRESSES: See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for single copies on a 3.5″ diskette of the final guidance document entitled ''Quality System Information for Certain Premarket Application Reviews'' to the Division of Small Manufacturers, International and Consumer Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301–443–8818.

FOR FURTHER INFORMATION CONTACT: Kimberly A. Trautman, Center for Devices and Radiological Health (HFZ–340), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 301–594–4648, or Leonard Wilson, Center for Biologics Evaluation and Research (HFM–25), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–0373.

SUPPLEMENTARY INFORMATION:

I. Background

This level 1 guidance entitled ''Quality System Information for Certain Premarket Application Reviews'' provides guidance to manufacturers who prepare and maintain QS information that should be included in premarket approval applications (PMA), PMA supplements, product development protocols (PDP), humanitarian device exemptions (HDE), and modular review submissions. This QS information guidance is meant to assist applicants in providing the information in a clear format for efficient review and timely decisions.

CDRH first published a guidance document entitled ''Guidance for Preparation of PMA Manufacturing Information'' on March 22, 1991, that was modified in 1992. The 1992 document was incorporated into the ''Regulatory Requirements for Medical Devices: A Workshop Manual.'' Feedback from industry and FDA reviewers, as well as revisions to the regulation in 1996, prompted this revision to the guidance.

This guidance entitled ''Quality System Information for Certain Premarket Application Reviews'' replaces the 1991 and 1992 guidance documents concerning the kind of good manufacturing practice (GMP) information that should be submitted in premarket submissions before an inspection is conducted as part of the premarket approval process. The document should be used for PMA, PMA supplements, PDP, HDE, and modular review applications. The information identified in this guidance addresses the current GMP requirements found in the quality system regulation (see 21 CFR part 820).

Applicants who use this guidance should be able to focus their submissions on the information CDRH and CBER need to review. Based on their review, CDRH and CBER will provide to FDA field staff inspectional guidance to plan the premarket approval inspection. This should reduce the amount of time the investigator will need to conduct the onsite inspection.

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices (GGPs) regulation (21 CFR 10.115). The guidance represents the agency's current thinking on QS

information for certain premarket application reviews. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations. This guidance document is issued as a level 1 guidance consistent with GGPs.

This guidance, when used in conjunction with the QS regulation, illustrates an approach for complying with the content requirements for premarket submissions found in section 515(c) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360e(c)) and 21 CFR part 814. A manufacturer who chooses to meet application requirements for the QS information in an alternative way may wish to consult with the appropriate office prior to the submission. The FDA staff can help identify areas that might raise particular concerns for CDRH and CBER reviewers or investigators.

III. Comments from the Draft Guidance

In the **Federal Register** of August 3, 1999 (64 FR 42137), ''Medical Devices, Draft Guidance on Quality System Regulation Information for Various Premarket Submissions; Availability'' was published as a draft level 1 guidance document for comment under GGPs. Six individuals or organizations filed comments on the draft guidance.

Most of the comments requested a better understanding of how FDA used the information previously submitted under the GMP manufacturing section and how the information requested in this guidance would be used. The introduction of the final guidance document explains that CDRH's Office of Compliance (OC) will review the QS information submitted in the premarket application at the same time the Office of Device Evaluation (ODE) reviews the other portions of the application. The appropriate offices in CBER will review the QS information submitted in CBER-regulated premarket submissions. Applicants who use this guidance should be able to focus their submissions on the information CDRH/CBER will need for review. Based on their review, CDRH/CBER will provide inspectional guidance to FDA field staff. Submission of this information can help focus the preapproval inspection process and limit the amount of time field staff will need to spend in the facility.

A few comments questioned the recommendation that manufacturers have design control information available, upon request, for devices subject to 510(k) clearance because it suggested that such documentation could be requested as part of the determination of substantial equivalence. FDA agrees with the comments and, therefore, has limited the applicability of this guidance document to exclude 510(k) submissions.

A few comments questioned whether the draft guidance document exceeded requirements in the QS regulation. The introduction to the final guidance document explains that the guidance document requests copies of written procedures or lists of items related to the QS regulation. In most cases, these procedures or lists are explicitly required under provisions of the QS regulation. In a few cases, the explanations or lists will facilitate FDA's review of your QS information. In the cases where the information is not explicitly required under statute or regulation (e.g., production flow diagram, list of any standards used, process validation master plan), FDA believes the information is the type you are likely to create and maintain as part of your QS. FDA believes submission of such information as part of your application will reduce or eliminate the need for us to request additional information during our review and preapproval inspection. However, because this is a guidance document, compliance with the recommendation is not required.

The final guidance also incorporates many editorial comments and wording suggestions that were submitted by comments.

IV. Electronic Access

In order to receive the guidance document ''Quality System Information for Certain Premarket Application Reviews '' via your fax machine, call the CDRH Facts-On-Demand (FOD) system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. At the first voice prompt press 1 to access DSMA Facts, at the second voice prompt press 2, and then enter the document number (1140) followed by the pound sign (#). Then follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the document may also do so by using the Internet. CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with access to the Internet. Updated on a regular basis, the CDRH home page includes the ''Quality System Information for Certain Premarket Application Reviews,'' device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturers' assistance, information on video conferencing and electronic submissions, mammography matters, and other device-oriented information. The CDRH home page may be accessed at http://www.fda.gov/cdrh. The guidance entitled ''Quality System Information for Certain Premarket Application Reviews'' will be available at http://www.fda.gov/cdrh/comp/guidance/1140.pdf.

V. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520) . The collections of information addressed in the guidance document have been approved by OMB in accordance with the PRA under the regulations governing premarket approval applications (21 CFR part 814, OMB control number 0910–0231) and the regulations governing quality systems (21 CFR part 820, OMB control number 0910–0073).

VI. Comments

Interested parties may submit to Dockets Management Branch (see **ADDRESSES**) written or electronic comments regarding this guidance. Submit two copies of any mailed comments, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guidance document and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: January 10, 2003.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. 03–2375 Filed 1–31–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98N–1109]

Mercury Compounds in Drugs and Food; List

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for information.

SUMMARY: The Food and Drug Administration (FDA) is announcing a

request for information to update a list of drug and biologic products that contain intentionally introduced mercury compounds, e.g., phenylmercuric acetate, phenylmercuric nitrate, and thimerosal. This request is part of the implementation of the Food and Drug Administration Modernization Act of 1997 (FDAMA).

DATES: Submit written and electronic comments and information by April 4, 2003.

ADDRESSES: Submit written comments to the Dockets Management Branch (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: Gerald M. Rachanow, 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

FDAMA (Public Law 105–115) was enacted on November 21, 1997. Section 413 of FDAMA entitled ''Food and Drug Administration Study of Mercury Compounds in Drugs and Food'' required FDA to: (1) Compile a list of drugs and foods that contain intentionally introduced mercury compounds, and (2) provide a quantitative and qualitative analysis of the mercury compounds in this list. The statute did not differentiate whether the mercury compound was present in the products as an active or an inactive ingredient and required FDA to compile the list and provide the analysis within 2 years after the date of its enactment. FDA prepared this list and announced its availability in the **Federal Register** of November 19, 1999 (64 FR 63323).

II. Request for Information

The agency is aware that some manufacturers or distributors with products on the list have reformulated their products since 1999. Accordingly, the agency would like to update the list to delete any products that no longer contain mercury ingredients. The agency is requesting any affected manufacturer or distributor with a product(s) on the list that no longer contains mercury to send an acknowledgement to the agency [to Docket No. 98N–1109] stating that the product(s) has been reformulated to no longer contain mercury. The agency will compile this information and announce the availability of an updated list in a future issue of the **Federal Register**.

The agency wishes to assure that it has a copy of the revised labeling for any product that has been reformulated. Part 207 (21 CFR part 207) entitled ''Registration of Producers of Drugs and Listing of Drugs in Commercial Distribution'' provides that owners or operators of drug establishments that engage in the manufacture, preparation, propagation, compounding, or processing of a drug or drugs register and submit a list of every drug in commercial distribution (§ 207.20(a)). Owners or operators of establishments that distribute under their own label or trade name a drug manufactured or processed by a registered establishment may submit listing information directly to FDA and obtain a labeler code (§ 207.20(b)). Registrants are required to provide a copy of all current labeling for each new drug (§ 207.25(b)(2)) and human prescription drug that is not a new drug (§ 207.25(b)(4)), and a copy of the label for each human over-the-counter drug listed that is not a new drug (§ 207.25(b)(5)). Information about inactive ingredients in the product is requested but not required (§ 207.31(b)).

Owners and operators of all registered establishments are required to update their drug listing information every June and December (§ 207.21(b)). The updated information includes listing each drug for which commercial distribution has been discontinued or for which any material change has occurred in any information previously submitted (e.g., reformulation) (§ 207.30(a)(2) and (a)(4), respectively). The agency is requesting that any manufacturers or distributors who have reformulated their products to remove the mercury ingredients update their labeling in accordance with part 207. These submissions should be highlighted with the words ''Mercury List'' on the envelope. The submission of information to FDA under part 207 is an approved collection of information under the Office of Management and Budget (OMB) control number 0910–0045 entitled ''Registration of Producers of Drugs and Listing of Drugs in Commercial Distribution,'' which expires July 31, 2004.

Affected manufacturers or distributors should submit the acknowledgement information to the Dockets Management Branch (see **ADDRESSES**). Two copies of all written information are to be submitted. Anyone submitting information electronically may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. A copy of the list and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

The list is entitled ''Mercury in Drug and Biologic Products'' and is available on the Internet at *http://www.fda.gov/cder/fdama/mercury300.htm.*

Dated: January 15, 2003.

Margaret M. Dotzel,

Assistant Commissioner for Policy.

[FR Doc. 03–2378 Filed 1–31–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–0834]

Draft Guidance for Industry on Labeling for Noncontraceptive Estrogen Drug Products for the Treatment of Vasomotor Symptoms and Vulvar and Vaginal Atrophy Symptoms—Prescribing Information for Health Care Providers and Patient Labeling; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Labeling Guidance for Noncontraceptive Estrogen Drug Products for the Treatment of Vasomotor Symptoms and Vulvar and Vaginal Atrophy Symptoms—Prescribing Information for Health Care Providers and Patient Labeling.'' The draft guidance is intended to assist applicants in developing labeling for new drug applications for such drug products. This is the second draft of the guidance, which initially issued in September 1999.

DATES: Submit written or electronic comments on the draft guidance by April 4, 2003. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm.

1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments.* See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Margaret Kober, Center for Drug Evaluation and Research (HFD–580), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4243.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Labeling Guidance for Noncontraceptive Estrogen Drug Products for the Treatment of Vasomotor Symptoms and Vulvar and Vaginal Atrophy Symptoms—Prescribing Information for Health Care Providers and Patient Labeling.'' The draft guidance describes the recommended labeling for health care providers and patient instructions for inclusion in new drug applications (NDAs). A draft of this guidance was first issued in September 1999 (64 FR 52100). However, on September 10, 2002, the agency withdrew the draft guidance (67 FR 57432), pending consideration of the results from the National Institutes of Health (NIH) Women's Health Initiative (WHI).[1] This second draft reflects the agency's thinking after considering the results of the WHI substudy.

In the WHI substudy, postmenopausal women who took conjugated estrogen 0.625 milligram (mg) combined with medroxyprogesterone acetate 2.5 mg had higher risks of several serious adverse events relative to those women who took placebo. Conjugated estrogens alone also increased the rates of cardiovascular disease compared to placebo. Other doses of conjugated estrogens and medroxyprogesterone acetate and other combinations of estrogens and progestins were not studied in the WHI. However, in the absence of comparable data, the risks of serious adverse events should be assumed to be similar because other studies show that estrogens and progestins are associated with these types of events.

This second draft of the guidance reflects several changes. For example, the draft guidance provides specific labeling recommendations for two indications (moderate to severe vasomotor symptoms and moderate to severe symptoms of vulvar and vaginal atrophy). It refers sponsors to the appropriate review divisions for guidance on labeling products to treat other indications. In addition, the guidance recommends that the following additions be made to the labeling for noncontraceptive estrogen drug products for the treatment of vasomotor symptoms and symptoms of vulvar and vaginal atrophy:

- New information to the boxed warning;
- Information from the WHI, including a statement that, although only a single dose and type of estrogen and progestin were studied in the WHI, risks for serious adverse events should be assumed to be similar for other estrogens and progestins until data show otherwise;
- A statement recommending that use of estrogens should be at the lowest doses and for the shortest duration in hopes of minimizing risks;
- A revised indication for the treatment of vulvar and vaginal atrophy in women who have moderate to severe symptoms so that benefits from drug therapy may outweigh risks; and
- Information from the WHI on cardiovascular and cancer risks as well as other information from the WHI and other studies.

Finally, the new draft updates other information in the label based on current scientific studies.

This level 1 draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance represents the agency's current thinking on labeling for noncontraceptive estrogen drug products for the treatment of vasomotor symptoms and vulvar and vaginal atrophy symptoms. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Dockets Management Branch (see **ADDRESSES**) written or electronic comments regarding the draft guidance. Submit a single copy of electronic comments to http://www.fda.gov/dockets/ecomments or two hard copies of any written comments, except that individuals may submit one hard copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/cder/guidance/index.htm* or *http://www.fda.gov/ohrms/dockets/default.htm.*

Dated: January 23, 2003.

Margaret M. Dotzel,

Assistant Commissioner for Policy.

[FR Doc. 03–2377 Filed 1–31–03; 8:45 am]

BILLING CODE 4160–01–S

[1] The results of the NIH Women's Health Initiative trial were reported in the *Journal of the American Medical Association*, 288: 321–333, 2002.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 03D–0001]

Draft Guidance for Industry on Nonclinical Safety Evaluation of Pediatric Drug Products; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Nonclinical Safety Evaluation of Pediatric Drug Products.'' The draft guidance provides recommendations on the role and timing of animal studies in the safety evaluation of therapeutics intended for the treatment of pediatric patients.

DATES: Submit written or electronic comments on the draft guidance by May 5, 2003. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments.* See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Karen Davis Bruno, Center for Drug Evaluation and Research (HFD–580), Food and Drug Administration, 5600

Fishers Lane, Rockville, MD 20857, 301–827–6430.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Nonclinical Safety Evaluation of Pediatric Drug Products.'' Many therapeutics marketed in the United States and used in pediatric patients lack adequate information in the labeling for use in that population. In most cases to date, safety data from clinical studies in adults, supported by nonclinical studies in adult animals, have been used to support the use of a drug in pediatric patients. These studies may not always assess possible drug effects on developmental processes specific to pediatric age groups. Some drug effects also may be difficult to detect in clinical trial or during routine postmarketing surveillance.

The draft guidance provides recommendations on the role and timing of animal studies in the safety evaluation of therapeutics intended for the treatment of pediatric patients. It describes how juvenile animal studies can be useful in monitoring, timing, and phasing of trials for initial enrollment in pediatric clinical studies. The draft guidance is intended to serve as a resource for general considerations in animal testing and to provide recommendations based on the available science and pragmatic considerations. The scope of animal studies is limited to safety effects that cannot be reasonably, ethically, and safely assessed in pediatric clinical trials.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance represents the agency's current thinking on ''Nonclinical Safety Evaluation of Pediatric Drug Products.'' It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Dockets Management Branch (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 hard copies of any written comments, except that individuals may submit one hard copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance and received comments may be seen in the Dockets Managment Branch between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document at either http://www.fda.gov/cder/guidance/index.htm or http://www.fda.gov/ohrms/dockets/default.htm.

Dated: January 21, 2003.

Margaret M. Dotzel,

Assistant Commissioner for Policy.

[FR Doc. 03–2376 Filed 1–31–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 concerning opportunity for public comment on proposed collections of information, the Substance Abuse and Mental Health Services Administration will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the information collection plans, call the SAMHSA Reports Clearance Officer on (301) 443–7978.

Comments are invited on: (a) Whether the proposed collections of information are necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: SAMHSA/HRSA Collaboration to Link Health Care for the Homeless Programs and Community Mental Health Agencies—(New)—The Substance Abuse and Mental Health Services Administration (SAMHSA), Center for Mental Health Services (CMHS); the Health Resources and Services Administration (HRSA), Bureau of Primary Health Care (BPHC); and the Office of the Assistant Secretary for Planning and Evaluation (ASPE) propose to conduct a longitudinal, multi-site evaluation assessing their initiative to foster collaborations between Health Care for the Homeless programs (HCH) and community mental health agencies (CMHA). In 12 designated communities, an HCH site and a CMHA site will collaborate to increase the availability of mental health and primary care services for persons with serious mental illness and co-occurring substance use disorders who are homeless. The evaluation of these collaborative efforts will advance knowledge on elements of the implementation process associated with establishment of a successful collaboration, such as partnering mechanisms, success of referral links, intensity of services, the effects of collaboration on client outcomes, and plans for sustainability.

Data collection will be conducted over a 30-month period. In each community, both a process and an outcome evaluation will be conducted to address the following questions: How is the project being implemented? What are the identified collaboration mechanisms? What are the service/agency level outcomes? What are the system-level outcomes? What are the client-level outcomes? To what extent do the various collaboration strategies predict outcomes?

To reduce burden and increase uniformity across the study sites, a common case study protocol will be used to guide the evaluation. Information for the service/agency and system level evaluations will be collected by staff from the central Evaluation Center (EC) during annual site visits and through activity logs. Common site visit protocols will dictate what data collection methods will be used. Site visitors will rely on focus groups and interviews to obtain information from project directors, local evaluators, project staff, and clients. Activity logs monitoring each community's efforts to implement collaboration strategies, will be completed by program administrators and submitted to the EC quarterly. Key outcomes to be examined at the service/agency level through these data collection methods include increased availability of mental health, substance abuse, specialty care, housing and services; increased access to primary care, mental health, and substance abuse services; more comprehensive assessment of and services for individual needs; increased integrated delivery of services; and increased engagement and retention in services. System-level outcomes to be examined include increased cross-agency activity;

increased mental health capacity at Hch sites; less redundancy in data collection; and enhanced screening for multi-dimensional issues.

The estimated response burden for this project is as follows:

Instrument	Number of responses	Responses/ respondent	Burden/response (Hrs.)	Total burden hours
Administrative Interviews	24	3	1.5	108
Evaluator Interviews	12	3	1.0	36
Line Staff Interviews	48	3	1.0	144
Consumer Focus Groups	84	3	1.0	252
Other Key Informants	48	3	1.0	144
Activity Logs	12	10	2.0	240
Total	228	.....	.....	924
3-yr. Annual Average	228	.....	.....	308

A total of approximately 6,500 program participants are expected to be recruited from the 12 sites. Each site will collect GPRA data on these participants using the CMHS GPRA Core Client Outcome measures approved by the Office of Management and Budget under control number 0930–0208, which cover such domains as drug and alcohol use, family and living conditions, education, employment, and income, crime and criminal justice status, and mental and physical health problems and treatment. To obtain information on client-level outcomes the central Evaluation Center will work with each site to develop methods for obtaining relevant material from the GPRA data. It is expected that client-level data will be submitted to the Evaluation Center via electronic means. The Evaluation Center will provide training and technical assistance to all sites on data submission procedures.

Send comments to Nancy Pearce, SAMHSA Reports Clearance Officer, Room 16–105, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received within 60 days of this notice.

Dated: January 27, 2003.

Richard Kopanda,

Executive Officer, Substance Abuse and Mental Health Services Administration.

[FR Doc. 03–2392 Filed 1–31–03; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Current List of Laboratories Which Meet Minimum Standards To Engage in Urine Drug Testing for Federal Agencies

AGENCY: Substance Abuse and Mental Health Services Administration, HHS.

ACTION: Notice.

SUMMARY: The Department of Health and Human Services notifies Federal agencies of the laboratories currently certified to meet standards of Subpart C of Mandatory Guidelines for Federal Workplace Drug Testing Programs (59 FR 29916, 29925). A notice listing all currently certified laboratories is published in the **Federal Register** during the first week of each month. If any laboratory's certification is suspended or revoked, the laboratory will be omitted from subsequent lists until such time as it is restored to full certification under the Guidelines.

If any laboratory has withdrawn from the National Laboratory Certification Program during the past month, it will be listed at the end, and will be omitted from the monthly listing thereafter.

This notice is also available on the internet at the following websites: *http://workplace.samhsa.gov* and *http://www.drugfreeworkplace.gov.*

FOR FURTHER INFORMATION CONTACT: Mrs. Giselle Hersh or Dr. Walter Vogl, Division of Workplace Programs, 5600 Fishers Lane, Rockwall 2 Building, Room 815, Rockville, Maryland 20857; Tel.: (301) 443–6014, Fax: (301) 443–3031.

SUPPLEMENTARY INFORMATION:

Mandatory Guidelines for Federal Workplace Drug Testing were developed in accordance with Executive Order 12564 and section 503 of Public Law 100–71. Subpart C of the Guidelines, ''Certification of Laboratories Engaged in Urine Drug Testing for Federal Agencies,'' sets strict standards which laboratories must meet in order to conduct urine drug testing for Federal agencies. To become certified an applicant laboratory must undergo three rounds of performance testing plus an on-site inspection.

To maintain that certification a laboratory must participate in a quarterly performance testing program plus periodic, on-site inspections.

Laboratories which claim to be in the applicant stage of certification are not to be considered as meeting the minimum requirements expressed in the HHS Guidelines. A laboratory must have its letter of certification from SAMHSA, HHS (formerly: HHS/NIDA) which attests that it has met minimum standards.

In accordance with Subpart C of the Guidelines, the following laboratories meet the minimum standards set forth in the Guidelines:

ACL Laboratories, 8901 W. Lincoln Ave., West Allis, WI 53227, 414–328–7840/800–877–7016 (Formerly: Bayshore Clinical Laboratory).

ACM Medical Laboratory, Inc., 160 Elmgrove Park, Rochester, NY 14624, 585–429–2264.

Advanced Toxicology Network, 3560 Air Center Cove, Suite 101, Memphis, TN 38118, 901–794–5770/888–290–1150.

Aegis Analytical Laboratories, Inc., 345 Hill Ave., Nashville, TN 37210, 615–255–2400.

Alliance Laboratory Services, 3200 Burnet Ave., Cincinnati, OH 45229, 513–585–6870, (Formerly: Jewish Hospital of Cincinnati, Inc.).

Associated Pathologists Laboratories, Inc., 4230 South Burnham Ave., Suite 250, Las Vegas, NV 89119–5412, 702–733–7866 / 800–433–2750.

Baptist Medical Center—Toxicology Laboratory, 9601 I–630, Exit 7, Little Rock, AR 72205–7299, 501–202–2783, (Formerly: Forensic Toxicology Laboratory Baptist Medical Center).

Clinical Reference Lab, 8433 Quivira Rd., Lenexa, KS 66215–2802, 800–445–6917.

Cox Health Systems, Department of Toxicology, 1423 North Jefferson Ave., Springfield, MO 65802, 800–876–3652 / 417–269–3093, (Formerly: Cox Medical Centers).

Diagnostic Services Inc., dba DSI, 12700 Westlinks Drive, Fort Myers, FL 33913, 239–561–8200 / 800–735–5416.

Doctors Laboratory, Inc., P.O. Box 2658, 2906 Julia Dr., Valdosta, GA 31602, 912–244–4468.

DrugProof, Divison of Dynacare, 543 South Hull St., Montgomery, AL 36103, 888–777–9497 / 334–241–0522, (Formerly: Alabama Reference Laboratories, Inc.).

DrugProof, Division of Dynacare/ Laboratory of Pathology, LLC, 1229 Madison St., Suite 500, Nordstrom Medical Tower, Seattle, WA 98104, 206–386–2661 / 800–898–0180, (Formerly: Laboratory of Pathology of Seattle, Inc., DrugProof, Division of Laboratory of Pathology of Seattle, Inc.).

DrugScan, Inc., P.O. Box 2969, 1119 Mearns Rd., Warminster, PA 18974, 215–674–9310.

Dynacare Kasper Medical Laboratories *, 10150–102 Street, Suite 200, Edmonton, Alberta, Canada TJ5 5E2, 780–451–3702 / 800–661–9876.

ElSohly Laboratories, Inc., 5 Industrial Park Dr., Oxford, MS 38655, 662–236–2609.

Express Analytical Labs, 3405 7th Avenue, Suite 106, Marion, IA 52302, 319–377–0500.

Gamma-Dynacare Medical Laboratories *, A Division of the Gamma-Dynacare Laboratory Partnership, 245 Pall Mall St., London, ONT, Canada N6A 1P4, 519–679–1630.

General Medical Laboratories, 36 South Brooks St., Madison, WI 53715, 608–267–6225.

Kroll Laboratory Specialists, Inc., 1111 Newton St., Gretna, LA 70053, 504–361–8989 / 800–433–3823 (Formerly: Laboratory Specialists, Inc.).

LabOne, Inc., 10101 Renner Blvd., Lenexa, KS 66219, 913–888–3927 / 800–873–8845 (Formerly: Center for Laboratory Services, a Division of LabOne, Inc.).

Laboratory Corporation of America Holdings, 7207 N. Gessner Road, Houston, TX 77040, 713–856–8288 / 800–800–2387.

Laboratory Corporation of America Holdings, 69 First Ave., Raritan, NJ 08869, 908–526–2400 / 800–437–4986 (Formerly: Roche Biomedical Laboratories, Inc.).

Laboratory Corporation of America Holdings, 1904 Alexander Drive, Research Triangle Park, NC 27709, 919–572–6900 / 800–833–3984 (Formerly: LabCorp Occupational Testing Services, Inc., CompuChem Laboratories, Inc.; CompuChem Laboratories, Inc., A Subsidiary of Roche Biomedical Laboratory; Roche CompuChem Laboratories, Inc., A Member of the Roche Group).

Laboratory Corporation of America Holdings, 10788 Roselle Street, San Diego, CA 92121, 800–882–7272 (Formerly: Poisonlab, Inc.).

Laboratory Corporation of America Holdings, 1120 Stateline Road West, Southaven, MS 38671, 866–827–8042 / 800–233–6339 (Formerly: LabCorp Occupational Testing Services, Inc., MedExpress/National Laboratory Center).

Marshfield Laboratories, Forensic Toxicology Laboratory, 1000 North Oak Ave., Marshfield, WI 54449, 715–389–3734 / 800–331–3734.

MAXXAM Analytics Inc.*, 5540 McAdam Rd., Mississauga, ON, Canada L4Z 1P1, 905–890–2555 (Formerly: NOVAMANN (Ontario) Inc.).

Medical College Hospitals Toxicology Laboratory, Department of Pathology, 3000 Arlington Ave., Toledo, OH 43699, 419–383–5213.

MedTox Laboratories, Inc., 402 W. County Rd. D, St. Paul, MN 55112, 651–636–7466 / 800–832–3244.

MetroLab-Legacy Laboratory Services, 1225 NE 2nd Ave., Portland, OR 97232, 503–413–5295 / 800–950–5295.

Minneapolis Veterans Affairs Medical Center, Forensic Toxicology Laboratory, 1 Veterans Drive, Minneapolis, Minnesota 55417, 612–725–2088.

National Toxicology Laboratories, Inc., 1100 California Ave., Bakersfield, CA 93304, 661–322–4250 / 800–350–3515.

Northwest Drug Testing, a division of NWT Inc., 1141 E. 3900 South, Salt Lake City, UT 84124, 801–293–2300 / 800–322–3361 (Formerly: NWT Drug Testing, NorthWest Toxicology, Inc.).

One Source Toxicology Laboratory, Inc., 1705 Center Street, Deer Park, TX 77536, 713–920–2559 (Formerly: University of Texas Medical Branch, Clinical Chemistry Division; UTMB Pathology-Toxicology Laboratory).

Oregon Medical Laboratories, P.O. Box 972, 722 East 11th Ave., Eugene, OR 97440–0972, 541–687–2134.

Pacific Toxicology Laboratories, 6160 Variel Ave., Woodland Hills, CA 91367, 818–598–3110 / 800–328–6942 (Formerly: Centinela Hospital Airport Toxicology Laboratory).

Pathology Associates Medical Laboratories, 110 West Cliff Drive, Spokane, WA 99204, 509–755–8991 / 800–541–7891x8991.

PharmChem Laboratories, Inc., 4600 N. Beach, Haltom City, TX 76137, 817–605–5300 (Formerly: PharmChem Laboratories, Inc., Texas Division; Harris Medical Laboratory).

Physicians Reference Laboratory, 7800 West 110th St., Overland Park, KS 66210, 913–339–0372 / 800–821–3627.

Quest Diagnostics Incorporated, 3175 Presidential Dr., Atlanta, GA 30340, 770–452–1590/800–729–6432 (Formerly: SmithKline Beecham Clinical Laboratories, SmithKline Bio-Science Laboratories).

Quest Diagnostics Incorporated, 4770 Regent Blvd., Irving, TX 75063, 800–824–6152 (Moved from the Dallas location on 03/31/01; Formerly: SmithKline Beecham Clinical Laboratories, SmithKline Bio-Science Laboratories).

Quest Diagnostics Incorporated, 400 Egypt Rd., Norristown, PA 19403, 610–631–4600 / 877–642–2216 (Formerly: SmithKline Beecham Clinical Laboratories, SmithKline Bio-Science Laboratories).

Quest Diagnostics Incorporated, 506 E. State Pkwy., Schaumburg, IL 60173, 800–669–6995 / 847–885–2010 (Formerly: SmithKline Beecham Clinical Laboratories, International Toxicology Laboratories).

Quest Diagnostics Incorporated, 7600 Tyrone Ave., Van Nuys, CA 91405, 818–989–2520 / 800–877–2520 (Formerly: SmithKline Beecham Clinical Laboratories).

Scientific Testing Laboratories, Inc., 450 Southlake Blvd., Richmond, VA 23236, 804–378–9130.

S.E.D. Medical Laboratories, 5601 Office Blvd., Albuquerque, NM 87109, 505–727–6300 / 800–999–5227.

South Bend Medical Foundation, Inc., 530 N. Lafayette Blvd., South Bend, IN 46601, 574–234–4176x276.

Southwest Laboratories, 2727 W. Baseline Rd., Tempe, AZ 85283, 602–438–8507 / 800–279–0027.

Sparrow Health System, Toxicology Testing Center, St. Lawrence Campus, 1210 W. Saginaw, Lansing, MI 48915, 517–377–0520 (Formerly: St. Lawrence Hospital & Healthcare System).

St. Anthony Hospital Toxicology Laboratory, 1000 N. Lee St., Oklahoma City, OK 73101, 405–272–7052.

Sure-Test Laboratories, Inc., 2900 Broad Avenue, Memphis, Tennessee 38112, 901–474–6028.

Toxicology & Drug Monitoring Laboratory, University of Missouri Hospital & Clinics, 2703 Clark Lane, Suite B, Lower Level, Columbia, MO 65202, 573–882–1273.

Toxicology Testing Service, Inc., 5426 N.W. 79th Ave., Miami, FL 33166, 305–593–2260.

US Army Forensic Toxicology Drug Testing Laboratory, 2490 Wilson Street, Fort George G. Meade, MD 20755–5235, 301–677–3714.

The following laboratory will be voluntarily withdrawing from the National Laboratory Certification Program (NLCP) effective January 31, 2003:

American Medical Laboratories, Inc., 14225 Newbrook Dr., Chantilly, VA 20151, 703–802–6900.

*The Standards Council of Canada (SCC) voted to end its Laboratory Accreditation Program for Substance Abuse (LAPSA) effective May 12, 1998. Laboratories certified through that program were accredited to conduct forensic urine drug testing as required by U.S. Department of Transportation (DOT) regulations. As of that date, the certification of those accredited Canadian laboratories will continue under DOT authority. The responsibility for conducting quarterly performance testing plus periodic on-site inspections of those LAPSA-accredited laboratories was transferred to the U.S. DHHS, with the DHHS' National Laboratory Certification Program (NLCP) contractor continuing to have an active role in the performance testing and laboratory inspection processes. Other Canadian laboratories wishing to be considered for the NLCP may apply directly to the NLCP contractor just as U.S. laboratories do.

Upon finding a Canadian laboratory to be qualified, the DHHS will recommend that DOT certify the laboratory (**Federal Register**, 16 July 1996) as meeting the minimum standards of the ''Mandatory Guidelines for Workplace Drug Testing'' (59 **Federal Register**, 9 June 1994, Pages 29908–29931). After receiving the DOT certification, the laboratory will be included in the monthly list of DHHS certified laboratories and participate in the NLCP certification maintenance program.

Richard Kopanda,

Executive Officer, SAMHSA.

[FR Doc. 03–2490 Filed 1–31–03; 8:45 am]

BILLING CODE 4160–20–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

2003 Migratory Bird Hunting and Conservation Stamp (Federal Duck Stamp) Contest

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice.

SUMMARY: The Fish and Wildlife Service announces the dates and locations of the 2003 Federal Duck Stamp contest; the public is invited to enter and to attend.

DATES: 1. The official date to begin submission of entries to the 2003 contest is July 1, 2003. All entries must be postmarked no later than midnight, Monday, September 15, 2003.

2. The public may view the 2003 Federal Duck Stamp Contest entries on Monday, November 3, 2003, from 10 a.m. to 2 p.m.

3. Judging will be held on Tuesday, November 4, 2003, from 10:30 a.m. to 5 p.m. and Wednesday, November 5, 2003, from 9 a.m. to 2 p.m.

ADDRESSES: Requests for complete copies of the regulations, reproduction rights agreement, and display and participation agreement may be requested by calling 1–703–358–2000, or requests may be addressed to: Federal Duck Stamp Contest, U.S. Fish and Wildlife Service, Department of the Interior, 4401 North Fairfax Drive, Mail Stop MBSP–4070, Arlington, VA 22203–1610. You may also download the information from the Federal Duck Stamp Web site at *http://duckstamps.fws.gov.*

FOR FURTHER INFORMATION CONTACT: Ms. Terry Bell, telephone (703) 358–2002, E-mail *terry_bell@fws.gov* or fax: (703) 358–2009.

SUPPLEMENTARY INFORMATION:

Background

On March 16, 1934, Congress passed and President Franklin Roosevelt signed the Migratory Bird Hunting Stamp Act. Popularly known as the Duck Stamp Act, it required all waterfowl hunters 16 years or older to buy a stamp annually. The revenue generated was originally earmarked for the Department of Agriculture, but 5 years later was transferred to the Department of the Interior and the Fish and Wildlife Service to buy or lease waterfowl sanctuaries.

In the years since its enactment, the Federal Duck Stamp Program has become one of the most popular and successful conservation programs ever initiated. Today, some 1.6 million stamps are sold each year, and, as of 2002, Federal Duck Stamps have generated more than $600 million for the preservation of more than 5 million acres of waterfowl habitat in the United States. Numerous other birds, mammals, fish, reptiles and amphibians have similarly prospered because of habitat protection made possible by the program. An estimated one-third of the Nation's endangered and threatened species find food or shelter in refuges preserved by Duck Stamp funds. Moreover, the protected wetlands help dissipate storms, purify water supplies, store flood water, and nourish fish hatchlings important for sport and commercial fishermen.

The Contest

The first Federal Duck Stamp was designed, at President Franklin Roosevelt's request, by Jay N. ''Ding'' Darling, a nationally known political cartoonist for the *Des Moines Register* and a noted hunter and wildlife conservationist. In subsequent years, noted wildlife artists were asked to submit designs. The first contest was opened in 1949 to any U.S. artist who wished to enter, and 65 artists submitted a total of 88 design entries in the only art competition of its kind sponsored by the U.S. Government. To select each year's design, a panel of noted art, waterfowl, and philatelic authorities are appointed by the Secretary of the Interior. Winners receive no compensation for the work, except a pane of their stamps, but winners may sell prints of their designs, which are sought by hunters, conservationists, and art collectors.

The public may view the 2003 Federal Duck Stamp Contest entries on Monday, November 3, 2003, from 10 a.m. to 2 p.m. in the Department of the Interior Auditorium (''C'' Street entrance), 1849 C Street, NW., Washington, DC. This year's judging will be held Tuesday, November 4, 2003, beginning at 10:30 a.m. and continuing at 9 a.m. on Wednesday, November 5, 2003.

Dated: January 26, 2003.

Steve Williams,

Director.

[FR Doc. 03–2379 Filed 1–31–03; 8:45 am]

BILLING CODE 4310–55–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[ID–070–1020–PG]

Notice of Public Meeting, Upper Snake River Resource Advisory Council Meeting

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of public meeting.

SUMMARY: In accordance with the Federal Land Policy and Management Act (FLPMA) and the Federal Advisory Committee Act of 1972 (FACA), the U.S. Department of the Interior, Bureau of Land Management (BLM) Upper Snake River Resource Advisory Council (RAC), will meet as indicated below.

DATES: The meeting will be held February 26 and 27 at the BLM's Fire Warehouse Conference Room, 3630 Overland Avenue, in Burley, Idaho. The meeting will start February 26 at 2 p.m., with the public comment period beginning at approximately 2:10 p.m. The meeting will adjourn on February 27 at noon.

SUPPLEMENTARY INFORMATION: The 15-member Council advises the Secretary of the Interior, through the Bureau of

Land Management, on a variety of planning and management issues associated with public land management in the BLM Upper Snake River District (USRD), which covers south-central and southeast Idaho. At this meeting, topics we plan to discuss include:

Updates on major planning projects in the USRD
Review feedback and action items from National RAC videoconference
Planning for RAC Allotment tours in 2003
Introduction to RAC of BLM Idaho State Director
Other items of interest raised by the Council

All meetings are open to the public. The public may present written comments to the Council. Each formal Council meeting will also have time allocated for hearing public comments. Depending on the number of persons wishing to comment and time available, the time for individual oral comments may be limited. Individuals who plan to attend and need special assistance, such as sign language interpretation, tour transportation or other reasonable accommodations, should contact the BLM as provided below.

Other USRD RAC meetings for 2003 have been planned for June, July and November 2003, and will be announced in a future **Federal Register** Notice and through local media.

FOR FURTHER INFORMATION CONTACT: David Howell, RAC Coordinator, Upper Snake River District, 1405 Hollipark Dr., Idaho Falls, ID 83401. Telephone (208) 524–7559.

Dated: January 28, 2003.

David O. Howell,

Public Affairs Specialist.

[FR Doc. 03–2394 Filed 1–31–03; 8:45 am]

BILLING CODE 4310–GG–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[ID–090–1610–PG; DBG–0200001]

Notice of Public Meeting: Resource Advisory Council to the Lower Snake River District, Bureau of Land Management, U.S. Department of the Interior

AGENCY: Bureau of Land Management, U.S. Department of the Interior.

ACTION: Notice of public meeting.

SUMMARY: In accordance with the Federal Land Policy and Management Act (FLPMA) and the Federal Advisory Committee Act of 1972 (FACA), the U.S. Department of the Interior, Bureau of Land Management (BLM) Lower Snake River District Resource Advisory Council (RAC), will meet as indicated below.

DATES: The meeting will be held February 18, 2003 at the Lower Snake River District Offices, located at 3948 Development Avenue, Boise, Idaho, beginning at 9 a.m. The public comment periods will be held after each topic on the agenda. The meeting is expected to adjourn at 4 p.m.

FOR FURTHER INFORMATION CONTACT: MJ Byrne, Public Affairs Officer and RAC Coordinator, Lower Snake River District, 3948 Development Ave., Boise, ID 83705, Telephone (208) 384–3393.

SUPPLEMENTARY INFORMATION: The 15-member Council advises the Secretary of the Interior, through the Bureau of Land Management, on a variety of planning and management issues associated with public land management in southwestern Idaho. At this meeting, the following topics will be discussed:

- Subgroup reports on Sage Grouse Habitat Management, OHV and Transportation Management, River Recreation and Resource Management Plans, and Fire and Fuels Management;
- RAC Members will discuss and prioritize the issues and focus of the Council for 2003, finalize membership on the subcommittees, and plan for hosting a meeting with the other two BLM District RACs;
- A presentation on drought conditions in the Lower Snake River District, across Idaho and the region.
- An update will be given on the two Resource Management Plans under development in the District, and
- Each of the Field Office Managers will provide an update on current activities and issues in each of their field office areas.

All meetings are open to the public. The public may present written comments to the Council. Each formal Council meeting will also have time allocated for hearing public comments. Depending on the number of persons wishing to comment and time available, the time for individual oral comments may be limited. Individuals who plan to attend and need special assistance, such as sign language interpretation, tour transportation or other reasonable accommodations, should contact the BLM as provided below. Expedited publication is requested to give the public adequate notice. The urgency of having the meeting on the identified date is due to the emergency conditions of public lands caused by the drought.

Dated: January 29, 2003.

Howard Hedrick,

Acting District Manager.

[FR Doc. 03–2493 Filed 1–31–03; 8:45 am]

BILLING CODE 4310–GG–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[UT–020–03–2640–HO–UTZA]

Notice

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of availability.

SUMMARY: Notice is hereby given that an administrative settlement agreement under the Comprehensive Environmental Response Compensation and Liability Act is available for public comment.

SUPPLEMENTARY INFORMATION: Under section 122(i) of the Comprehensive Environmental Response, Compensation, and Liability Act (''CERCLA''), 42 U.S.C. 9622(i), notice is hereby given that on October 30, 2002, the Bureau of Land Management (''BLM''), by and through the Department of the Interior and with the concurrence of the Department of Justice, signed a proposed administrative settlement agreement (''Agreement'') concerning the Manning Canyon Mill Site (''Site'') located near Fairfield, Utah.

The Site comprises public land managed by the BLM and private land owned by Leo Ault, Howard Ault, Louis O. Ault, Leonard Ault, and Virginia A. Coleman (collectively hereinafter the ''Ault family''). A milling facility located at the Site produced approximately 720,000 cubic yards of tailings and other mine wastes between 1890 and 1937. These tailings were disposed of in tailings impoundments behind earthen dams that subsequently breached, allowing tailings to migrate down gradient from the Site. BLM and the U.S. Environmental Protection Agency conducted a preliminary assessment of the tailings impoundments on-Site as well as downstream areas to which tailings had migrated. BLM completed a site inspection in September, 1999. Sampling results revealed elevated levels of lead, mercury, arsenic and other hazardous substances in the tailings. BLM performed an engineering evaluation/cost analysis (''EE/CA'') of response alternatives and, by action memorandum dated May 8, 2001, selected a non-time-critical removal action from among the alternatives

analyzed. BLM is currently implementing this removal action by which an engineered tailings repository will be built on-Site to consolidate tailings in order to prevent future migration of or exposure to hazardous substances. BLM expects that this removal action will fully protect human health and the environment from risks associated with hazardous substances at the Site.

Through the proposed Agreement the United States and the Ault family would resolve the alleged liability of the Ault family under section 107 of CERCLA, 42 U.S.C. 9607. The Ault family would provide resources and materials needed to implement the removal action. In addition, the proposed Agreement would authorize BLM to construct a portion of the tailings repository on Ault family property. The BLM estimates that the proposed Agreement with the Ault family will reduce the total response costs incurred to clean up the Manning Canyon Mill Site by approximately $4.5 million.

The BLM will receive comments on the proposed Agreement for a period of 30 days from the date of this publication. Comments should refer to the Manning Canyon Mill Site. The proposed Agreement may be examined at the BLM Salt Lake Field Office. A copy of the proposed Agreement may also be obtained from the BLM Salt Lake Field Office upon request. Comments or requests to obtain a copy of the proposed Agreement should be addressed to: Tim Ingwell, BLM Salt Lake Field Office, 2370 South 2300 West, Salt Lake City, UT 84119, (801) 977–4353.

Dated: December 5, 2002.

Glenn A. Carpenter,

Field Office Manager.

[FR Doc. 03–2368 Filed 1–31–03; 8:45 am]

BILLING CODE 4310–$$–P

DEPARTMENT OF THE INTERIOR

Bureau of Reclamation

Kit Fox Mitigation Area Closure

AGENCY: Bureau of Reclamation, Interior.

ACTION: Notice of closure of public lands to public access.

SUMMARY: The Bureau of Reclamation is temporarily closing 171 acres of Federal land to public access. The closure will protect a mitigation area for the San Joaquin kit fox. The closure includes all lands, waters, and facilities within the fence enclosure west and east of the San Luis Canal and adjacent to the San Luis Canal Right of Way in Merced County, California.

EFFECTIVE DATES: This closure is effective from February 3, 2003 until November 1, 2007.

ADDRESSES: A map of the closed area is available for inspection at the Bureau of Reclamation's South Central California Office, located at 1243 N Street, Fresno, California 93721. The map may be viewed between the hours of 8 a.m. and 4 p.m., Monday through Friday. To have a map mailed to your address, call Mr. Dan Holsapple at 559–487–5409.

FOR FURTHER INFORMATION CONTACT: Mr. Dan Holsapple, Bureau of Reclamation, telephone: 559–487–5409.

SUPPLEMENTARY INFORMATION: Following is the closure order:

By virtue of the authority vested in the authorized officer of this notice, under the regulations of the Secretary of the Interior, 43 CFR part 423, public access to the following facilities, lands, or waters is closed until November 1, 2007:

Kit Fox Mitigation Area—The closure area includes all lands, waters, and facilities within the fence enclosure west and east of the San Luis Canal and adjacent to the San Luis Canal Right of Way in Merced County. Property consists of approximately 171 acres.

The following acts are prohibited on the facilities, lands, and waters in the closure area:

1. Trespassing, entering, or remaining in or upon the closure areas described above. Exceptions: Operations and Maintenance personnel that have express authorization from Reclamation, law enforcement officers and Reclamation employees acting within the scope of their employment, and any others who have received express written authorization from Reclamation to enter the closure areas.

2. Tampering or attempting to tamper with the facilities, structures, or other property located within the closure areas or moving, manipulating, or setting in motion any of the parts thereof. Exceptions: see 1 above.

3. Vandalism or destroying, injuring, defacing, or damaging property or real property that is not under one's lawful control or possession.

4. Depositing or abandoning any refuse, agricultural wastes, hazardous materials/waste, vehicles, tires, or any other items not expressly authorized by Reclamation.

5. Grazing of sheep, cattle or any other livestock within the closure area without written permit from Reclamation or their managing agent.

6. Surface occupancy unless specifically authorized and permitted by Reclamation.

This order is posted in accordance with 43 CFR 423.3(b). Violations of this prohibition or any prohibition listed in 43 CFR part 423 are punishable by fine, or imprisonment for not more than 6 months, or both.

Dated: October 17, 2002.

Frank Michny,

Regional Environmental Officer, Mid-Pacific Region.

[FR Doc. 03–2391 Filed 1–31–03; 8:45 am]

BILLING CODE 4310–MN–P

DEPARTMENT OF THE INTERIOR

Bureau of Reclamation

Millerton Lake Resource Management Plan and General Plan, Fresno and Madera Counties, CA

AGENCY: Bureau of Reclamation, Interior.

ACTION: Notice of intent to prepare a programmatic environmental impact statement/environmental impact report for a resource management plan and general plan.

SUMMARY: Pursuant to Section 102(2)(c) of the National Environmental Policy Act (NEPA), Reclamation proposes to prepare a Programmatic Environmental Impact Statement/Environmental Impact Report (PEIS/EIR) for the Millerton Lake Resource Management Plan (RMP) and General Plan, which will be issued concurrent with the PEIS/EIR. A scoping meeting will be conducted to elicit comments on the scope and issues to be addressed in the PEIS/EIR. The date and time for this meeting is noted below. The draft RMP/General Plan and draft PEIS/EIR are expected to be issued in early 2003.

DATES: The scoping meeting will be held on February 12, 2003, at 6:30 p.m. in Friant, California. Written comments should be sent to Reclamation at the address below by March 5, 2003.

ADDRESSES: The meeting location is at the Millerton Courthouse, Millerton State Recreation Area, 5290 Millerton Road, Friant, California 93626.

Written comments on the scope of the alternatives and impacts should be sent to Mr. Dan Holsapple, Bureau of Reclamation, South-Central California Area Office, 1243 N Street, Fresno, CA 93721–1813; or faxed to 559–487–5130 (TDD 559–487–5933).

FOR FURTHER INFORMATION CONTACT: Mr. Dan Holsapple, Bureau of Reclamation, at the above address, telephone: 559–487–5409.

SUPPLEMENTARY INFORMATION: Millerton Lake is located in the southern portion of California's Central Valley in Fresno and Madera counties. The lake lies in the upper San Joaquin River Watershed. The San Joaquin River has an average annual inflow of 1,860,000 acre-feet upstream of Friant Dam. Millerton Lake was created in 1942 by the construction of Friant Dam, approximately 25 miles northeast of Fresno. The dam is a concrete gravity structure, 319 feet high and 3,488 feet wide at its crest. Millerton Lake has a total storage capacity of 520,500 acre-feet and supplies water to the Central Valley Project water users. The lake and the majority of adjacent lands are owned by Reclamation. Land within the project area is managed by Reclamation and the California Department of Parks and Recreation.

Millerton Lake is a multi-purpose facility, supplying agricultural irrigation water, flood control, and recreational functions such as boating, fishing, camping, and swimming. The lake receives approximately 600,000 visitor days per year. Operation of the reservoir requires evacuation of a large portion of the storage space prior to the rainy season. Due to its small capacity compared to the potential runoff from the watershed, it is necessary to draw down water levels annually to its minimum pool in order to make effective use of available storage space. Thus, there is little opportunity to carry over water from one season to another.

Reclamation is preparing an RMP and General Plan for the Millerton Lake area. The RMP will specifically address the Millerton Lake State Recreation Area, including the entire lake and all Reclamation land surrounding the lake. The objectives of the joint plan are to establish management objectives, guidelines, and actions to be implemented by Reclamation directly, or through its recreation contract with the California Department of Parks and Recreation, that will protect the water supply and water quality functions of Millerton Lake; protect and enhance natural and cultural resources in the Recreation Area, consistent with Federal law and Reclamation policies; and provide recreational opportunities and facilities consistent with the Central Valley Project purposes, and Reclamation policies. In addition, the General Plan is the primary management guideline for defining a framework for resource stewardship, interpretation, facilities, visitor use, and services. General plans define an ultimate purpose, vision, and intent for management through goal statements, guidelines, and broad objectives, but stop short of defining specific objectives, methodologies, and designs on how to accomplish these goals.

The development of the RMP and General Plan will be performed within the authorities provided by the Congress through the Reclamation Act, Federal Water Project Recreation Act, Reclamation Recreation Management Act, and applicable agency and Department of the Interior policies and the California Public Resources Code Division 5.

The RMP and General Plan shall be a long-term plan (with an approximate 20-year planning horizon) that will guide specific actions in the Millerton Lake State Recreation Area and on Reclamation lands surrounding the lake. The RMP and General Plan will be developed based on a comprehensive inventory of environmental resources and Project facilities. It will include an analysis of resources in the area, identification of land use suitability and capability, and development of management policies, objectives, responsibilities, guidelines, and plans. Resource areas to be addressed in the RMP and General Plan include: Soils and geology, biology, cultural resources, water resources, hydrology, groundwater and water quality, land use, transportation/traffic, rangeland, fire/fuels management, hazardous materials, recreation, and park administration. Data from these resource areas will be included in a GIS database, as available.

The RMP and General Plan will enable managers to make land use and resource decisions that are consistent with the overall management objectives of Reclamation land and water areas, while meeting the needs of the public. The RMP and General Plan will assist Reclamation in its efforts to minimize conflicts among the competing interests and types of use at Millerton Lake.

The RMP and General Plan will be developed through a cooperative effort between the Federal and State agencies and the public in an effort to manage the similar resources in the area as one. The plan will be developed with input from other Federal agencies such as U.S. Fish and Wildlife Service, the U.S. Forest Service, and the Bureau of Land Management; involved state agencies such as the California Department of Fish and Game and the California Department of Forestry and Fire Protection; and local involved agencies such as Friant Water Users Authority and the Chowchilla Madera Water and Power Authority; and the general public.

The environmental impacts of the RMP and General Plan and associated alternatives will be assessed in a PEIS/EIR that will be prepared concurrent with the RMP and General Plan. The environmental review will focus on the potential for management actions to cause adverse environmental impacts to natural and cultural resources such as water quality, endangered species, public safety, and historic resources. It will include an analysis of alternative land, recreation, and natural resource management approaches. The joint document will be programmatic in nature in that it will be used as a planning tool to guide future resource management. Specific projects will tier off this programmatic document and will have their own environmental process and report.

It is Reclamation's practice to make comments, including names and home addresses of respondents, available for public review. Individual respondents may request that we withhold their home address from public disclosure, which we will honor to the extent allowable by law. There may also be circumstances in which we would withhold a respondent's identity from public disclosure, 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. 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 disclosure in their entirety.

Dated: December 4, 2002.

Frank Michny,

Regional Environmental Officer, Mid-Pacific Region.

[FR Doc. 03–2390 Filed 1–31–03; 8:45 am]

BILLING CODE 4310–MN–P

DEPARTMENT OF LABOR

Mine Safety and Health Administration

Proposed Information Collection Request Submitted for Public Comment and Recommendations; Qualification and Certification Program

ACTION: Notice.

SUMMARY: The Department of Labor, 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 (PRA95) [44 U.S.C. 3506 (c)(2)(A)]. This

program helps to ensure that requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements on respondents can be properly assessed.

Currently, the Mine Safety and Health Administration (MSHA) is soliciting comments concerning the extension of the information collection related to the 30 CFR Sections 75.100—Certified Person; 75.155—Qualified hoisting engineer; qualifications; 77.100—Certified Person; and 77.105—Qualified hoist-man; slope or shaft sinking operation; qualifications.

DATES: Submit comments on or before April 4, 2003.

ADDRESSES: Send comments to Jane Tarr, Management Analyst, Administration and Management 1100 Wilson Boulevard, Room 2171, Arlington, VA 22209–3939. Commenters are encouraged to send their comments on computer disk, or via Internet E-mail to *Tarr-Jane@Msha.Gov.* Ms. Tarr can be reached at (202) 693–9824 (voice), or (202) 693–9801 (facsimile).

FOR FURTHER INFORMATION CONTACT: Jane Tarr, Management Analyst, Records Management Group, U.S. Department of Labor, Mine Safety and Health Administration, Room 2171, 1100 Wilson Boulevard, Arlington, VA 22209–3939. Ms. Tarr can be reached at *Tarr-Jane@Msha.Gov* (Internet E-mail), (202) 693–9824 (voice), or (202) 693–9801 (facsimile).

SUPPLEMENTARY INFORMATION:

I. Background

Persons performing tasks and certain required examinations at coal mines which are related to miner safety and health, and which required specialized experience, are required to be either ''certified'' or ''qualified''. The regulations recognize State certification and qualification programs. However, where state programs are not available, under the Mine Act and MSHA standards, the Secretary may certify and qualify persons for as long as they continue to safisfy the requirements needed to obtain the certification or qualification, fulfill any applicable retraining requirements, and remain employed at the same mine or by the same independent contractor. Applications for Secretarial certification must be submitted to the MSHA Qualification and Certification Unit in Denver, Colorado. MSHA Forms 5000–4 and 5000–7 provide the coal mining industry with a standardized reporting format that expedites the certification process while ensuring compliance with the regulations. The information provided on the forms enables the Secretary of Labor's delegate—MSHA, Qualification and Certification Unit—to determine if the applicants satisfy the requirements to obtain the certification or qualification. Persons must meet certain minimum experience requirements depending on the type of certification or qualification applied for.

MSHA is presently in the process of streamlining its Forms. Forms 5000–4 and 5000–7 will be combined into one form 5000–41 for future use by coal mine operators. MSHA is requesting approval of this form.

II. Desired Focus of Comments

MSHA is particularly interested in comments which:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submissions of responses.

A copy of the proposed information collection request can be obtained by contacting the employee listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice, or viewed on the Internet by accessing the MSHA home page (*http://www.msha.gov*) and then choosing ''Statutory and Regulatory Information'' and ''Federal Register Documents.''

III. Current Actions

This request for collection of information contains provisions whereby persons may be temporarily qualified or certified to perform tests and examinations; requiring specialized expertise; related to miner safety and health at coal mines.

Type of Review: Extension.

Agency: Mine Safety and Health Administration.

Title: Qualification and Certification Program.

OMB Number: 1219–0069.

Recordkeeping: The information collection requires respondents to submit only the original MSHA form to the Agency. The information collection does not require the maintenance of records. However, 30 CFR 75.159 and 77.106 require mine operators to maintain lists of all certified and qualified persons. This recordkeeping requirement has been approved by OMB under control number 1219–0127.

Frequency: On Occasion.

Affected Public: Business or other for-profit.

Respondents: 684.

Estimated Time Per Respondent: .28 hours.

Total Burden Hours: 192 hours.

Total Burden Cost (capital/startup): $0.

Total Burden Cost (operating/maintaining): $0.

Comments submitted in response to this notice will be summarized and/or included in the request for Office of Management and Budget approval of the information collection request; they will also become a matter of public record.

Dated at Arlington, Virginia, this 28th day of January, 2003.

David L. Meyer,

Director, Office of Administration and Management.

[FR Doc. 03–2354 Filed 1–31–03; 8:45 am]

BILLING CODE 4510–43–M

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Notice (03–007)]

NASA Advisory Council, Aerospace Technology Advisory Committee, Revolutionize Aviation Subcommittee; Meeting

AGENCY: National Aeronautics and Space Administration (NASA).

ACTION: Notice of meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, Public Law 92–463, as amended, the National Aeronautics and Space Administration announces a forthcoming meeting of the NASA Advisory Council, Aerospace Technology Advisory Committee (ATAC), Revolutionize Aviation Subcommittee (RAS).

DATES: Tuesday, February 25, 2003, 8 a.m. to 4:30 p.m.

ADDRESSES: National Aeronautics and Space Administration, Room 7H46, 300 E Street, SW., Washington, DC 20546.

FOR FURTHER INFORMATION CONTACT: Ms. Bernice E. Lynch, Office of Aerospace Technology, National Aeronautics and

Space Administration, Washington, DC 20546 (202) 358–4594.

SUPPLEMENTARY INFORMATION: The meeting will be open to the public up to the seating capacity of the room. The agenda for the meeting is as follows:

—Welcome/Review Actions
—Working Group Reports
—Aeronautics Technology Update
—Discussion on Integrated Results of Working Groups
—SATS Update & ASRS Subcommittee Briefings
—Next Steps/Action Summary

It is imperative that the meeting be held on these dates to accommodate the scheduling priorities of the key participants. Due to the increased security at NASA facilities, any members of the public who wish to attend the Revolutionize Aviation Subcommittee meeting must provide their name, date and place of birth, citizenship, social security number, passport or visa information (number, country of issuance and expiration), business address, and phone number. This information is to be provided at least 72 hours prior to the date of the public meeting (5 p.m. EDT on February 19, 2003). Identification information is to be provided to Bernice E. Lynch, 202/358–4594, *blynch@hq.nasa.gov.* Failure to timely provide such information may result in denial of attendance. Photo identification may be required for entry into the building. Persons with disabilities who require assistance should indicate this in their message. Due to limited availability of seating, members of the public will be admitted on a first-come, first-serve basis. News media wishing to attend the meeting should follow standard accreditation procedures. Members of the press who have questions about these procedures should contact the NASA Headquarters newsroom (202) 358–1600.

June W. Edwards,

Advisory Committee Management Officer, National Aeronautics and Space Administration.

[FR Doc. 03–2451 Filed 1–31–03; 8:45 am]

BILLING CODE 7510–10–P

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Notice (03–008)]

NASA Advisory Council, Aerospace Technology Advisory Committee; Meeting

AGENCY: National Aeronautics and Space Administration.

ACTION: Notice of meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, Public Law 92–463, as amended, the National Aeronautics and Space Administration announces a meeting of the NASA Advisory Council, Aerospace Technology Advisory Committee (ATAC).

DATES: Wednesday, February 26, 2003, 8:30 a.m. to 5 p.m.; and Thursday, February 27, 2003, 8:30 a.m. to 12 Noon.

ADDRESSES: National Aeronautics and Space Administration, 300 E Street, SW., Room 7H46 (MIC 7), Washington, DC 20546.

FOR FURTHER INFORMATION CONTACT: Mrs. Mary-Ellen McGrath, Code RG, National Aeronautics and Space Administration, Washington, DC 20546 (202) 358–4729.

SUPPLEMENTARY INFORMATION: The meeting will be open to the public up to the seating capacity of the room. The agenda for the meeting is as follows:

—Opening Remarks
—Aerospace Technology Enterprise Overview
—Subcommittee Reports
—Enterprise Plans for FY 2004
—Closing Comments

It is imperative that the meeting be held on this date to accommodate the scheduling priorities of the key participants. Visitors will be requested to sign a visitor's register. Due to the increased security at NASA facilities, any members of the public who wish to attend this meeting of the Aerospace Technology Advisory Committee must provide their name, date and place of birth, citizenship, social security number, or passport and visa information (number, country of issuance and expiration), business address and phone number, if any. This information is to be provided at least 72 hours (5 PM EDT on February 20, 2003) prior to the date of the public meeting. Identification information is to be provided to Mary-Ellen McGrath, (202) 358–4729, *mmcgrath@hq.nasa.gov.* Failure to timely provide such information may result in denial of attendance. Photo identification may be required for entry into the building. Persons with disabilities who require assistance should indicate this in their message. Due to limited availability of seating, members of the public will be admitted on a first-come, first-serve basis. NASA may provide for simulcast in an overflow facility. News media wishing to attend the meeting should follow standard accreditation procedures. Members of the press who have questions about these procedures should contact the NASA Headquarters Newsroom (202) 358–1600.

June W. Edwards,

Advisory Committee Management Officer, National Aeronautics and Space Administration.

[FR Doc. 03–2452 Filed 1–31–03; 8:45 am]

BILLING CODE 7510–01–P

NATIONAL SCIENCE FOUNDATION

Sunshine Act Meeting

AGENCY HOLDING MEETING: National Science Foundation, National Science Board and its Subdivisions.

DATE AND TIME: *February 5, 2003:* 8 a.m.–5:30 p.m.—Open Session.

Concurrent Session: February 5, 2003: 2:20 p.m.–3 p.m.—Closed Session.

February 6, 2003: 8 a.m.–4:30 p.m.—Open Session.

Concurrent Session: February 6, 2003: 8 a.m.–8:40 a.m.—Closed Session.

February 6, 2003: 12:30 p.m.–1 p.m.—Closed Session.

February 7, 2003: 8:30 a.m.–3 p.m.—Open Session.

PLACE: *February 5, 6, 2003:* The National Science Foundation, Room 1235, 4201 Wilson Boulevard, Arlington, VA 22230, *www.nsf.gov/nsb.*

February 7, 2003: Fairmont Hotel, Sulgrave Room, 2401 M Street NW., Washington, DC.

CONTACT FOR INFORMATION: NSF Information Center (703) 292–5111.

STATUS: Part of this meeting will be closed to the public.

Part of this meeting will be open to the public.

MATTERS TO BE CONSIDERED:

Wednesday, February 5, 2003

Open

Task Force on National Workforce Policy for S&E (8 a.m.–10 a.m.), Room 1295:

• Working session on draft NWP report.

Task Force on S&E Infrastructure (8:30 a.m.–10 a.m.), Room 1235:

• Analysis of comments received in response to the INF draft report.
• INF response to comments/suggested revisions.
• Plans for completing the report.

Committee on Strategy & Budget (10 a.m.–12 Noon), Room 1235:

• Future Role of CSB.
• Major Research Equipment & Facilities.
• NSF Strategic Plan Update.
• Strategies for Follow-up on NSB Studies.
• Update on Support of Environmental Sciences.

Subcommittee on S&E Indicators (1 p.m.–2 p.m.), Room 1295:
- S&E Indicators 2004.
- Assigning Chapter Reviewers.
- 2004 Companion Piece.

Executive Committee (2 p.m.–2:20 p.m.), Room 1295:
- Discussion of New Quorum Requirements.

Subcommittee on Polar Issues (2 p.m.–3 p.m.), Room 1235:
- OPP Director's Update.
- Study of Environmental Arctic Change (SEARCH).
- International Trans-Antarctic Science Expedition (ITASE).
- *Aircraft Safety:* Antarctica.

Committee on Education & Human Resources (3 p.m.–5:30 p.m.), Room 1235:
- Report from the Subcommittee on S&EI.
- Report from the EHR AD.
- Report from the Task Force on NWP.
- *Focus on the Future:* Virtual Laboratories.
- Report on Education & Diversity Activities in the CISE Directorate.
- The EHR Budget for FY 03 and Prospects for FY 04.
- Information Item: NSF Partnership with DoD for the Funding of REU Sites.

Closed

Executive Committee (2:20 p.m.–3 p.m.), Room 1295:
- Specific Personnel Matters.
- Future NSF Budgets.

Thursday, February 6, 2003

Closed

Committee on Programs & Plans (8 a.m.–8:40 a.m.), Room 1235:
- NSM Action Item: Elementary Particle Physics Program, Division of Physics, Mathematical and Physical Sciences Directorate.
- National Facilities & Instrumentation Program Award, Division of Materials Research, Mathematical and Physical Sciences Directorate.

Plenary Session of the Board (12:30 p.m.–1 p.m.):
- Awards & Agreements.
- Executive Officer Search.

Open

Committee on Audit & Oversight (8 a.m.–10 a.m.), Room 1295:
- Performance and Accountability Report Overview.
- FY 2002 Financial Statement Audit Process & Results.
- Responses to Audit Findings and Follow-up Activities.
- Security Considerations—CIO.

Committee on Programs & Plans (8:40 a.m.–10:15 a.m.), Room 1235:
- Infrastructure Task Force Report.
- CPP Issues.
- *NSB Information Item:* Status of George E. Brown Network for Earthquake Engineering Simulation.
- *NSB Information Item:* Science of Learning Centers.
- Polar Issues Subcommittee Report.

Plenary Session of the Board (10:30 a.m.–11:30 a.m.), Room 1235:
- Office of Polar Programs Science Update.

Plenary Session of the Board (1 p.m.–4:30 p.m.), Room 1235:
- Minutes.
- Closed Session Items for March 2003.
- Chairman's Report.
- Director's Report.
- Committee Reports.

Friday, February 7, 2003

Open

National Science Board Retreat, Sulgrave Room, Fairmont Hotel, 3401 M Street NW., Washington, DC.
- Review and Discussion of May, 2002 Retreat Issues.
- Director's Perspective on Next Steps and Challenges.
- Presentation and Discussion of White Paper on NSB Policy Voice.
- *Budget:* How to Give Input to Budget Priorities.
- Vision of Future Directions/ Challenges—Standing Committees.
- NSB/NSBO Operational Issues and Challenges.
- *Discussion:* Is the Board Organized Optimally To Do Its Work?
- General Discussion of Next Steps/ Other Business.

Gerard Glaser,

Executive Officer, NSB.

[FR Doc. 03–2516 Filed 1–30–03; 1:10 pm]

BILLING CODE 7555–01–M

NUCLEAR REGULATORY COMMISSION

[Docket No. 030–28641]

Notice of Consideration of Amendment Request for Department of the Air Force, Eglin Air Force Base, Florida, and Opportunity for Providing Comments and Requesting a Hearing

I. Introduction

The U.S. Nuclear Regulatory Commission (NRC) is considering issuance of a license amendment to Materials License 42–23539–01AF issued to the Department of the Air Force (the licensee), to authorize decommissioning of its Test Area C–74L at Eglin Air Force Base in Florida.

The licensee currently possesses radioactive material under a master materials license of broad scope. The licensee uses radioactive material for a variety of reasons. On May 24, 2002, the Air Force submitted a Decommissioning Plan (DP) to the NRC and requested approval to begin decommissioning of a site previously used by the Air Force for depleted uranium munitions testing between 1974–1978. The area is known as Test Area C–74L and is located at Eglin Air Force Base, Florida. The licensee previously conducted limited decommissioning at the site and desires to conduct additional decommissioning with the goal of free-releasing the property for unrestricted use.

The DP was submitted to the NRC by letter dated May 24, 2002. Supplemental information was submitted by letter dated November 1, 2002. An NRC administrative review, documented in a letter to the licensee dated November 25, 2002, found the DP acceptable to begin a technical review.

If the NRC approves the DP, the approval will be documented in an amendment to NRC License 42–23539–01AF. However, before approving the proposed amendment, the NRC will need to make the findings required by the Atomic Energy Act of 1954, as amended, and NRC's regulations. These findings will be documented in a Safety Evaluation Report and an Environmental Assessment.

II. Opportunity To Provide Comments

In accordance with 10 CFR 20.1405, the NRC is providing notice to individuals in the vicinity of the site that the NRC is in receipt of a DP, and will accept comments concerning this decommissioning proposal and its associated environmental impacts. Comments with respect to this action should be provided in writing within 30 days of this notice and addressed to D. Blair Spitzberg, Ph.D., Chief, Fuel Cycle and Decommissioning Branch, Division of Nuclear Materials Safety, Region IV, U.S. Nuclear Regulatory Commission, 611 Ryan Plaza Drive, Suite 400, Arlington, Texas, 76011–4005. Telephone: (817) 860–8191, fax number (817) 860–8188, e-mail: *dbs@nrc.gov.* Comments received after 30 days will be considered if practicable to do so, but only those comments received on or before the due date can be assured consideration.

III. Opportunity To Request a Hearing

NRC also provides notice that this is a proceeding on an application for an amendment of a license falling within the scope of Subpart L, ''Informal Hearing Procedures for Adjudications in

Materials and Operator License Proceedings,'' of NRC's rules and practice for domestic licensing proceedings in 10 CFR Part 2. Whether or not a person has or intends to provide comments as set out in Section II above, pursuant to § 2.1205(a), any person (other than an applicant) whose interest may be affected by this proceeding may file a request for a hearing in accordance with § 2.1205(d). A request for a hearing must be filed within thirty (30) days of the date of publication of this **Federal Register** notice.

The request for a hearing must be filed with the Office of the Secretary either:

1. By delivery to Secretary, U.S. Nuclear Regulatory Commission, One White Flint North, 11555 Rockville Pike, Rockville, MD 20852–2738; between 7:45 a.m. and 4:15 p.m., Federal workdays; or

2. By mail, telegram, or facsimile (301–415–1101) addressed to the Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001. Attention: Rulemakings and Adjudications Staff.

In accordance with 10 CFR § 2.1205(f), each request for a hearing must also be served, by delivering it personally or by mail, to:

1. The applicant; Lt. Col. Kali K. Mather, Chief, AFMOA/SGZR, 110 Luke Avenue, Room 405, Bolling Air Force Base, Department of the Air Force, Washington, D.C. 20332–7050; and

2. The NRC staff; by delivery to the General Counsel, U.S. Nuclear Regulatory Commission, One White Flint North, 11555 Rockville Pike, Rockville, MD 20852–2738, between 7:45 a.m. and 4:15 p.m., Federal workdays, or by mail, addressed to General Counsel, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

In addition to meeting other applicable requirements of 10 CFR Part 2 of the NRC's regulations, a request for a hearing filed by a person other than an applicant must describe in detail:

1. The interest of the requestor in the proceeding;

2. How that interest may be affected by the results of the proceeding, including the reasons why the requestor should be permitted a hearing, with particular reference to the factors set out in § 2.1205(h);

3. The requester's areas of concern about the licensing activity that is the subject matter of the proceeding; and

4. The circumstances establishing that the request for a hearing is timely in accordance with § 2.1205(d).

IV. Public Meeting

There are no public meetings scheduled for this proceeding.

V. Further Information

The application for the license amendment and supporting documentation are available for inspection at NRC's Public Electronic Reading Room at *http://www.nrc.gov/NRC/ADAMS/index.html.* The DP can be found in ADAMS at Accession Numbers ML021970666 and ML021970654, while supporting documentation can be found at ML023370482. The acceptance letter can be found at ML023290265. Any questions with respect to this action should be referred to D. Blair Spitzberg, Ph.D., Chief, Fuel Cycle and Decommissioning Branch, Division of Nuclear Materials Safety, Region IV, U.S. Nuclear Regulatory Commission, 611 Ryan Plaza Drive, Suite 400, Arlington, Texas, 76011–4005. Telephone: (817) 860–8191, fax number (817) 860–8188.

Dated at Arlington, Texas, this 27th day of January 2003.

For the Nuclear Regulatory Commission.

D. Blair Spitzberg,

Chief, Fuel Cycle Decommissioning Branch, Division of Nuclear Materials Safety, Region IV.

[FR Doc. 03–2414 Filed 1–31–03; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

Draft Revision 9 of NUREG–1021, ''Operator Licensing Examination Standards for Power Reactors''; Notice of Availability

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice of Availability for comment and voluntary, trial use.

SUMMARY: The Nuclear Regulatory Commission (NRC) has issued for public comment and voluntary use, on a trial basis, Draft Revision 9 of NUREG–1021, ''Operator Licensing Examination Standards for Power Reactors.'' The Commission uses NUREG–1021 to provide policy and guidance for the development, administration, and grading of written examinations and operating tests used to determine the qualifications of individuals who apply for reactor operator (RO) and senior reactor operator (SRO) licenses at nuclear power plants pursuant to the Commission's regulations in 10 CFR Part 55, ''Operators' Licenses.'' NUREG–1021 also provides guidance for verifying the continued qualifications of licensed operators when the staff determines that NRC requalification examinations are necessary.

The draft revision includes a number of changes that the NRC staff believes will reduce the regulatory burden on facility licensees and improve efficiency, while maintaining operational safety and public confidence: Notably, the RO written examination has been shortened from 100 to 75 questions, the design of the 100-question SRO written examination has been clarified and simplified, the administrative and systems portions of the walk-through operating test have been combined and reapportioned, and the grading criteria for the simulator operating test have been clarified to enhance consistency. A number of additional changes have been made to address questions raised since Revision 8, Supplement 1, was issued in April 2001 and to conform with other regulatory activities. The changes are outlined in the Executive Summary of the draft revision and are identified with highlights and strikeouts for ease of review.

The draft revision is available for review via the NRC's Public Electronic Reading Room (*http://www.nrc.gov/public-involve/doc-comment.html*), on the NRC's Operator Licensing Web site (*http://www.nrc.gov/reactors/operator-licensing.html*), and in the NRC's Public Document Room located at 11555 Rockville Pike, Rockville, Maryland. If you do not have electronic access to NRC documents, you may request a single copy of the draft revision by writing to the Office of the Chief Information Officer, Reproduction and Distribution Services Branch, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001 (Facsimile: 301–512–2289). Telephone requests cannot be accommodated. NUREG documents are not copyrighted, and Commission approval is not required to reproduce them.

Draft Revision 9 is being immediately implemented on a voluntary, trial basis. The NRC will evaluate any comments and recommendations that are received and any lessons that are learned during the trial period, incorporate any additional changes, as appropriate, and, thereafter, publish final Revision 9 for general use. Minor changes and clarifications that may become necessary during the trial period will be promulgated, without formal notice, via the NRC's Operator Licensing Web site (*http://www.nrc.gov/reactors/operator-licensing.html*).

DATES: The comment period ends December 31, 2003. Comments received after this date will be considered if it is practical to do so, but the staff is able to assure consideration only for comments received on or before this date.

ADDRESSES: Written comments may be submitted to the Rules and Directives Branch, Division of Administrative Services, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001. You may also provide comments via the NRC's Operator Licensing Web site (*http://www.nrc.gov/reactors/operator-licensing.html*) or the NRC's Public Electronic Reading Room (*http://www.nrc.gov/reading-rm/doc-collections/nuregs/ #comments*). Copies of comments received may be examined at the NRC's Public Document Room, 11555 Rockville Pike, Rockville, Maryland.

FOR FURTHER INFORMATION CONTACT: Mr. S. Guenther by telephone at (301) 415–1056, or by e-mail at sxg@nrc.gov.

Dated at Rockville, Maryland, this 23rd day of January 2003.

For the Nuclear Regulatory Commission.

Theodore R. Quay,

Chief, Equipment and Human Performance Branch, Division of Inspection Program Management, Office of Nuclear Reactor Regulation.

[FR Doc. 03–2413 Filed 1–31–03; 8:45 am]

BILLING CODE 7590–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–47274; File No. 4–429]

Joint Industry Plan; Order Approving Joint Amendment No. 5 to the Options Intermarket Linkage Plan To Provide a Process for Potential New Options Exchanges To Have Interim Access to Linkage Information

January 29, 2003.

I. Introduction

On November 8, 2002, November 14, 2002, November 15, 2002, November 26, 2002, and December 6, 2002, the Philadelphia Stock Exchange, Inc. (''Phlx''), International Securities Exchange, Inc. (''ISE''), Chicago Board Options Exchange, Inc. (''CBOE''), American Stock Exchange LLC (''Amex''), and Pacific Exchange, Inc. (''PCX'') (collectively the ''Participants'') respectively submitted to the Securities and Exchange Commission (''SEC'' or ''Commission'') in accordance with section 11A of the Securities Exchange Act of 1934 (''Act'')[1] and rule 11Aa3–2 thereunder,[2] a proposed amendment to the Options Intermarket Linkage Plan (the ''Plan'').[3] The amendment proposes to provide a process for potential new options exchanges to have interim access to Linkage information to help such exchanges prepare to join the Plan.

The proposed amendment to the Plan was published in the **Federal Register** on December 26, 2002.[4] No comments were received on the proposed amendment. This order approves the proposed amendment to the Plan.

II. Description of the Proposed Amendment

Currently, the Plan allows a new exchange to join the Linkage by executing the Plan, filing an amendment to the Plan including themselves as a participant, and paying the then-applicable participation fee if that exchange is already a participant in The Options Clearing Corporation and is a party to the Plan for Reporting of Consolidated Options Last Sale Reports and Quotation Information (''OPRA Plan'').[5] Proposed Amendment No. 5 will provide conditional interim access to Linkage information by permitting an applicant to have access to Linkage documentation, testing and other necessary Linkage facilities once the Commission has published for comment the applicant's proposed rules governing the trading of standardized options.

Proposed Amendment No. 5 also requires that the applicant affirm that it is seriously pursuing the establishment of an options market and pay a refundable deposit towards the participation fee. Once an applicant is granted interim access, such access will remain in effect for one year. If the applicant has not yet joined the Linkage after this time period, it can request an additional period of access, and the Linkage participants will not unreasonably deny such a request.

III. Discussion

After careful consideration, the Commission finds that the proposed amendment to the Plan is consistent with the requirements of the Act and the rules and regulations thereunder. Specifically, the Commission finds that the proposed amendment to the Plan is consistent with section 11A of the Act[6] and rule 11Aa3–2 thereunder,[7] in that it is appropriate in the public interest, for the protection of investors and the maintenance of fair and orderly markets.

The current provisions of the Plan effectively require that an applicant exchange have rules for the trading of options approved by the Commission before it can become a participant in the Linkage. While the Commission believes that this is a reasonable requirement for full participation in the Linkage, this structure does not recognize that an entity proposing to develop an options market reasonably needs access to Linkage information, particularly technical information, in order to build its market and prepare for Linkage participation. The proposed Amendment will provide an applicant with conditional interim access to Linkage information before it is able to meet the requirements for full participation.

The Commission recognizes, however, that new entrants to the Linkage will require the existing Participants to expend time and resources working with an applicant on both technical and policy issues. Therefore, the Commission believes that it is reasonable to place requirements on applicants that act as a safeguard to limit access to serious applicants fully committed to pursuing the development of an options market.

To this end, Amendment No. 5 proposes that in order to be eligible for interim access to the Linkage, proposed rules governing the trading of standardized options of an applicant must be published for comment by the Commission and the applicant must affirm that it is seriously pursuing the establishment of an options market. An applicant also must pay a refundable

[1] 15 U.S.C. 78k–1.

[2] 17 CFR 240.11Aa3–2.

[3] On July 28, 2000, the Commission approved a national market system plan for the purpose of creating and operating an intermarket options market linkage proposed by the Amex, CBOE, and ISE. *See* Securities Exchange Act Release No. 43086 (July 28, 2000), 65 FR 48023 (August 4, 2000). Subsequently, upon request by the Phlx and PCX, the Commission issued orders to permit these exchanges to participate in the Linkage Plan. *See* Securities Exchange Act Release Nos. 43573 (November 16, 2000), 65 FR 70850 (November 28, 2000) and 43574 (November 16, 2000), 65 FR 70851 (November 28, 2000).

[4] *See* Securities Exchange Act Release No. 47027 (December 18, 2002), 67 FR 78834.

[5] OPRA is a national market system plan approved by the Commission pursuant to section 11A of the Exchange Act, 15 U.S.C. 78k–1, and rule 11Aa3–2 thereunder, 17 CFR 240.11Aa3–2. *See* Securities Exchange Act Release No. 17638 (March 18, 1981). The OPRA Plan provides for the collection and dissemination of last sale and quotation information on options that are traded on the participant exchanges. The five signatories to the OPRA Plan that currently operate an options market are the AMEX, CBOE, ISE, PCX, and Phlx. The New York Stock Exchange is a signatory to the OPRA Plan, but sold its options business to the CBOE in 1997. *See* Securities Exchange Act Release No. 38542 (April 23, 1997), 62 FR 23521 (April 30, 1997).

[6] 15 U.S.C. 78k–1.

[7] 17 CFR 240.11Aa3–2.

deposit towards the participation fee. The Commission believes that these requirements are reasonably tailored to ensure that only serious applicants are given access to sensitive Linkage information before becoming a full participant.

Amendment No. 5 also proposes to limit the duration of interim access to one year. The Commission believes that this time frame is reasonable, and anticipates that one year will be sufficient for most applicants to be prepared to join the Linkage as full participants. The Commission notes that in the event that an applicant has not joined the Linkage after one year, Amendment No. 5 provides that it can request an additional period of access, and the Linkage participants will not unreasonably deny such a request.

In sum, the Commission believes that implementation of Amendment No. 5 will generally enhance competition by providing a potential new options market with earlier access to Linkage-related material and thus, facilitate its ability to prepare to join the Linkage.

IV. Conclusion

It is therefore ordered, pursuant to section 11A of the Act[8] and rule 11Aa3–2 thereunder,[9] that the proposed Linkage Plan amendment is approved.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[10]

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 03–2481 Filed 1–31–03; 8:45 am]

BILLING CODE 8010–01–P

SECURITIES AND EXCHANGE COMMISSION

[File No.500–1]

Sedona Software Solutions Inc.; Order of Suspension of Trading

January 29, 2003.

It appears to the Securities and Exchange Commission that there is a lack of current and accurate information concerning the securities of Sedona Software Solutions Inc. (''Sedona''), trading under the stock symbol SSSI. Questions have been raised regarding the accuracy and completeness of information about Sedona on Internet websites, in press releases, and in other sources publicly available to investors concerning, among other things, Sedona's planned merger with Renaissance Mining Corp. (''Renaissance''), a privately-held company; the assets and business operations of Renaissance; and trading in Sedona common stock in connection with the announced merger.

The Commission is of the opinion that the public interest and the protection of investors require a suspension of trading in the securities of the above listed company.

Therefore, it is ordered, pursuant to section 12(k) of the Securities Exchange Act of 1934, that trading in the above listed company is suspended for the period from 3 p.m. EST, January 29, 2003, through 11:59 p.m. EST, on February 11, 2003.

By the Commission.

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 03–2479 Filed 1–30–03; 10:43 am]

BILLING CODE 8010–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–47267; File No. SR–Amex–2002–113]

Self-Regulatory Organizations; Notice of Filing and Order Granting Accelerated Approval of Proposed Rule Change by the American Stock Exchange LLC Regarding Listing Standards for Closed-End Management Investment Companies Registered Under the Investment Company Act of 1940

January 28, 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 December 23, 2002, the American Stock Exchange LLC (''Amex'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in items I, II, and III below, which items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons and to grant accelerated approval to the proposed rule change.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange is proposing to make permanent its pilot regarding specific initial and continued listing standards applicable to closed-end management investment companies registered under the Investment Company Act of 1940 (''closed-end funds'').[3] The Amex is also proposing to renumber section 101(e) of the *Amex Company Guide* to section 101(f).[4]

The text of the proposed rule change is available at the Office of the Secretary, Amex, and at the Commission.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Amex included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to permanently amend sections 101 and 1003 of the *Amex Company Guide* to incorporate initial and continued listing standards specifically applicable to closed-end funds into the *Amex Company Guide*. The proposed listing standards were approved by the Commission on a five-month pilot basis on November 7, 2002.[5] Under the pilot, Amex permits the initial listing of a closed-end fund with a market value of publicly held shares or net assets of at least $20,000,000, which also satisfies the distribution criteria specified in

[8] 15 U.S.C. 78k–1.

[9] 17 CFR 240.11Aa3–2.

[10] 17 CFR 200.30–3(a)(29).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] The five-month pilot was approved by the Commission on November 7, 2002. *See* Securities and Exchange Act Release No. 46785, 67 FR 69578 (November 18, 2002) (approving File No. SR–Amex–2002–55).

[4] The Amex is renumbering the rule text to accommodate a proposed rule change submitted by the Amex on November 20, 2002. *See* Securities Exchange Act Release No. 47119 (January 3, 2003), 68 FR 1494 (January 10, 2003) (approving File No. SR–Amex–2002–97). Telephone conversation between Claudia Crowley, Assistant General Counsel, Amex, and Terri Evans, Assistant Director, Division of Market Regulation (''Division''), Commission, on January 27, 2003.

[5] *See* Securities and Exchange Act Release No. 46785 (November 7, 2002), 67 FR 69578 (November 18, 2002) (approving File No. SR–Amex–2002–55). Previously, closed-end funds were evaluated for listing pursuant to the general listing standards contained in section 101 of the *Amex Company Guide,* as well as specialized internal procedures applicable to closed-end funds.

section 102(a) of the *Amex Company Guide*.[6]

In addition, pursuant to the pilot, the Exchange permits the listing of a group of closed-end funds listed by a single ''fund family'' (*i.e.*, funds which have a common investment advisor or investment advisors who are ''affiliated persons'' as defined in section 2(a)(3) of the Investment Company Act of 1940, as amended),[7] subject to the following standards:

- The total group has a market value of publicly held shares or net assets of at least $75,000,000;
- The average market value of publicly held shares or net assets per fund of the group is at least $15,000,000; and
- No fund in the group has a market value of publicly held shares or net assets of less than $10,000,000.

The group standards would be applicable to any closed-end fund that is part of a ''fund family'' even if the closed-end fund is not listed concurrently with other funds in the family, as long as at the time of listing, the individual fund, the entire ''fund family'' is in compliance with the group standards. Therefore, all funds listed on the Amex which are part of the ''fund family'' will be evaluated in determining whether a fund applicant is eligible for listing. Each fund will also be individually subject to the distribution criteria specified in section 102(a) of the *Amex Company Guide*.[8] The Exchange will not have discretion to list a closed-end fund that does not satisfy the quantitative criteria set forth in section 101(e) of the *Amex Company Guide*, but will have discretion to exclude a closed-end fund that otherwise satisfies the criteria.

The Exchange represents that the ''fund family'' standards will enable the Exchange to accommodate the needs of fund sponsors, which often prefer to offer, issue, and list funds in groups. The Exchange believes that when a fund is part of a larger family, compliance with a $20,000,000 market value of publicly held shares or net asset requirement is not necessary for the fund to be suitable for listing, since the size of the fund family indicates that there is sufficient investor interest in the sponsor's funds.

The Exchange is also proposing to permanently amend section 1003 of the *Amex Company Guide* to specify that each closed-end fund (regardless of whether it is part of a ''fund family'') will be subject to delisting if its market value of publicly held shares and net assets are each less than $5,000,000 for more than 60 consecutive days, or it ceases to qualify as a closed-end fund (unless the resultant entity otherwise qualifies for listing).

The Exchange represents that the pilot program has enabled the Exchange to apply more objective and transparent listing criteria to closed-end funds without unnecessarily limiting the listing of specialized and smaller funds that are suitable for listing, and has provided greater clarity to listing applicants and investors as to the applicable Exchange listing standards. The Exchange represents that the pilot program has operated smoothly, and the Exchange is not aware of any problems or concerns that have developed since approval thereof. It should also be noted that the Exchange is aware of only one comment letter submitted with respect to the pilot program, which supports the proposed rule change.[9]

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with section 6(b) of the Act,[10] in general, and furthers the objectives of section 6(b)(5),[11] in particular, in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest, and is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers. Specifically, the Exchange believes that the proposed rule change will continue to provide greater transparency with respect to the listing of closed-end funds, and potentially provide a larger number of such funds and their investors with the benefits inherent in an Amex listing of comprehensive regulation, transparent price discovery and trade reporting to facilitate best execution, and increased depth and liquidity resulting from the confluence of order flow found in an auction market environment.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange has neither solicited nor received any written comments with respect to the proposed rule change.

III. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. 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 the filing will also be available for inspection and copying at the principal offices of the Amex. All submissions should refer to File No. SR–Amex–2002–113 and should be submitted by February 24, 2003.

IV. Comment Summary

As noted above, the Commission received one comment letter from the ICI regarding the five-month pilot program, which supported the pilot.[12] The ICI believed that the changes set forth in the five-month pilot program would facilitate the listing of closed-end funds on the Amex, particularly listings of closed-end funds from a single fund family. The ICI noted the adoption of listing eligibility criteria for closed-end funds should take into account that closed-end funds are structured and regulated differently from regular operating companies. Further, the ICI asserted that, in light of these

[6] Section 102(a) of the *Amex Company Guide* requires a minimum public distribution of (i) 500,000 shares and 800 public shareholders; or (ii) 1,000,000 shares and 400 public shareholders; or (iii) 500,000 shares and 400 public shareholders and average daily trading volume of approximately 2,000 shares for the six months preceding the date of application.

[7] 19 U.S.C. 80a–2(a)(3).

[8] *See supra* note 6.

[9] *See* letter from Ari Burstein, Associate Counsel, Investment Company Institute (''ICI''), to Jonathan G. Katz, Secretary, Commission, dated December 6, 2002 (''ICI Letter'').

[10] 15 U.S.C. 78f(b).

[11] 15 U.S.C. 78f(b)(5).

[12] *See* letter from Ari Burstein, Associate Counsel, Investment Company Institute, to Jonathan G. Katz, Secretary, Commission, dated December 6, 2002 (''ICI Letter'').

differences, it is appropriate to apply different financial standards to closed-end funds as compared to regular operating companies.[13]

V. Commission Findings and Order Granting Accelerated Approval of Proposed Rule Change

The Commission finds that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange.[14] Specifically, the Commission believes the proposal is consistent with the requirements under section 6(b)(5) of the Act [15] that the rules of an exchange be designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest.

The Commission believes that the proposed rule change will continue to allow the Amex to provide greater transparency to its listing process for closed-end funds. In addition, the Commission believes that the proposed rule change will continue to allow the Amex to strike a reasonable balance between the Exchange's obligation to protect investors and their confidence in the market and the Exchange's obligation to perfect the mechanism of a free and open market by listing funds, including fund families, on the Exchange. Further, the Commission believes that providing an alternative method to list closed-end funds on the Exchange should continue to accommodate the desire of fund families to list groups of closed-end funds on one marketplace. Finally, the Commission notes that it has no knowledge of any problems or regulatory concerns that have developed since the approval of the five-month pilot program.[16]

The Commission finds good cause for approving the proposed rule change prior to the 30th day after publication in the **Federal Register**. The Amex has requested accelerated approval of the proposed rule change to ensure that the proposal is effective on a permanent basis prior to the expiration of the existing pilot program, and because it raises no new or novel issues and is conceptually similar to existing New York Stock Exchange closed-end fund listing standards.[17] The Commission believes that the proposed rule change does not raise any new or significant regulatory issues, and that accelerated approval should permit the Exchange to continue listing funds and accommodating the desire of fund families to list groups of closed-end funds on one marketplace. The Commission notes that it received only one comment letter, which supported File No. Amex–2002–55,[18] in which the Amex originally proposed the changes set forth in this proposal on a five-month pilot basis.[19]

It is therefore ordered, pursuant to section 19(b)(2) of the Act,[20] that the proposed rule change (File No. SR–Amex–2002–113) is approved on an accelerated basis.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[21]

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 03–2483 Filed 1–31–03; 8:45 am]

BILLING CODE 8010–01–P

[13] *Id.*

[14] In approving this proposed rule change, the Commission notes that it has considered the proposed rule's impact on efficiency, competition, and capital formation. 15 U.S.C. 78c(f).

[15] 15 U.S.C. 78f(b)(5).

[16] Telephone conversation between Claudia Crowley, Assistant General Counsel, Amex, and Frank N. Genco, Attorney, Division, Commission, on January 17, 2003.

[17] *See* Securities Exchange Act Release No. 46163 (July 3, 2002), 67 FR 46559 (July 15, 2002) (File No. SR–NYSE–2001–45) (approving initial listing standards and allocation policy for closed-end funds).

[18] *See* ICI letter.

[19] *See* Securities Exchange Act Release No. 46785 (November 7, 2002) 67 FR 69578 (November 18, 2002) (approving File No. SR–Amex–2002–55).

[20] 15 U.S.C. 78s(b)(2).

[21] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–47258; File No. SR–CSE–2003–01]

Self-Regulatory Organizations; Notice of Filing of Proposed Rule Change and Amendment No. 1 Thereto by the Cincinnati Stock Exchange, Inc. To Amend Its Market Data Revenue Sharing Program for Tape B Securities

January 27, 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 January 6, 2003, the Cincinnati Stock Exchange, Inc. (''CSE'' 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 Exchange. On January 24, 2003 the CSE amended the proposal. [3] The Commission is publishing this notice to solicit comments on the proposed rule change, as amended, from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The CSE proposes to modify the Exchange's schedule of transaction fees to amend its market data revenue sharing program for Tape B securities (''Program'') traded on the Exchange. The text of the proposed rule change is below. Proposed new language is in italics; proposed deletions are in brackets.

Rule 11.10 National Securities Trading System Fees

A. Trading Fees

(a)–(j) (No change to text)

(k) Tape ''B'' Transactions. The CSE will not impose a transaction fee on Consolidated Tape ''B'' securities. In addition, Members will receive a 50 percent pro rata transaction credit of [Net]*gross* Tape ''B'' revenue; *provided that, however, calculation of the transaction credit will be based on net Tape ''B'' revenues in those fiscal quarters where the overall revenue retained by the Exchange does not offset actual expenses and working capital needs.* To the extent market data revenue from Tape ''B'' transactions is subject to year-end adjustment, credits provided under this program may be adjusted accordingly.

(l)–(r) (No change to text)

* * * * *

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. The Exchange has prepared summaries, set forth in Sections A, B, and C below, of the most significant aspects of such statements.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* January 23, 2003 letter from Jennifer M. Lamie, Esquire, CSE, to Katherine England, Assistant Director, Division of Market Regulation, Commission (''Amendment No. 1''). In Amendment No. 1, the CSE changed the text of the proposed rule to address omissions that were made in the original rule filing.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

Under Exchange Rule 11.10A(k), members have received a 50 percent pro rata transaction credit based on *net* Tape B revenue since July 2001.[4] Prior to that time, the Program was based on *gross* Tape B revenues. In keeping with recent trends in the securities industry, the Exchange is proposing to amend the Program so that the pro rata percentage is once again based on *gross* Tape B revenue, but only in those fiscal quarters where the Exchange's overall revenues (not just Tape B revenues) offset capital expenses and working capital needs. Otherwise, if capital expenses and working capital needs are not met, the calculation based on *net* Tape B revenues will continue to apply.

2. Statutory Basis

The proposed rule change is generally consistent with Section 6(b) of the Act.[5] The proposed rule also furthers the objectives of Section 6(b)(5) of the Act,[6] particularly, in that it is designed to promote just and equitable principles of trade and to remove impediments to and perfect the mechanism of a free and open market and a national market system and, generally, in that it protects investors and the public interest. The proposal also is consistent with Section 6(b)(4)[7] in that it is designed to provide for the equitable allocation of reasonable dues, fees, and other charges among Exchange members by crediting members on a pro rata basis.

B. Self-Regulatory Organization's Statement on Burden on Competition

The CSE does not believe that the proposed rule change will impose any inappropriate burden on competition.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received from Members, Participants or Others

No written comments were solicited or received with respect to the proposed rule change.

[4] *See* Securities Exchange Act Release No. 44579 (July 20, 2001), 66 FR 39068 (July 26, 2001) (SR–CSE–01–03) (among other things, added the word ''Net'' before the term ''Tape 'B' revenue'' to CSE Rule 11.10A(k)).

[5] 15 U.S.C. 78f(b).

[6] 15 U.S.C. 78f(b)(5).

[7] 15 U.S.C. 78f(b)(4).

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 35 days of the date of publication of this notice in the **Federal Register** or within such longer period (i) as the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the Exchange consents, the Commission will:

(A) By order approve such proposed rule change, or

(B) Institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. 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 CSE. All submissions should refer to file number SR–CSE–2003–01 and should be submitted by February 24, 2003.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[8]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 03–2405 Filed 1–31–03; 8:45 am]

BILLING CODE 8010–01–P

[8] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–47244; File No. SR–NASD–2002–166]

Self-Regulatory Organizations; Order Granting Approval of a Proposed Rule Change and Amendment No. 1 and Notice of Filing and Order Granting Accelerated Approval of Amendment No. 2 to the Proposed Rule Change by the National Association of Securities Dealers, Inc. With Respect to Margin Rule Amendments for Security Futures Contracts on a Pilot Basis

January 24, 2003.

I. Introduction

On November 15, 2002, the National Association of Securities Dealers, Inc. (''NASD'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') a proposed rule change, pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and rule 19b–4 thereunder,[2] to amend NASD rule 2520 (''Margin Requirements'') to establish margin rules for security futures contracts. On November 22, 2002, NASD filed Amendment No. 1 to the proposed rule change.[3] The proposal, as amended, was published in the **Federal Register** on December 24, 2002.[4] The Commission received one comment letter on the proposed rule change.[5] This commenter also submitted a comment letter on the NYSE's pilot to amend NYSE rule 431 to establish margin requirements for security futures contracts.[6] On January 15, 2003, NASD filed Amendment No.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* letter from Gary L. Goldsholle, Associate General Counsel, NASD to Katherine England, Assistant Director, Division of Market Regulation (''Division''), Commission, dated November 22, 2002 (''Amendment No. 1''). Amendment No. 1 makes technical changes to the proposed rule text.

[4] Securities Exchange Act Release No. 46995 (December 13, 2002), 67 FR 78543.

[5] *See* letter from Edward J. Joyce, President and Chief Operating Officer, Chicago Board Options Exchange (''CBOE''), to Jonathan G. Katz, Secretary, Commission, dated December 20, 2002.

[6] *See* letter from Edward J. Joyce, President and Chief Operating Officer, CBOE, to Jonathan G. Katz, Secretary, Commission, dated December 9, 2002. On November 7, 2002, the Commission approved, on a 60-day pilot basis, a proposed rule change by the New York Stock Exchange, Inc. (''NYSE'') amending NYSE rule 431 (''Margin Requirements'') to establish margin requirements for security futures contracts. *See* Securities Exchange Act Release No. 46782 (November 7, 2002), 67 FR 69052 (November 14, 2002) (SR–NYSE–2002–53). In January 2003, the NYSE pilot was extended for an additional 60 days, expiring on March 6, 2003. *See* Securities Exchange Act Release No. 47129 (January 6, 2002), 68 FR 2094 (January 15, 2003) (SR–NYSE–2003–01).

2 to the proposed rule change.[7] This order approves the proposed rule change, as amended, on a pilot basis until March 6, 2003.

II. Description of the Proposed Rule Change

NASD is proposing to amend NASD rule 2520 (''Margin Requirements'') to establish margin requirements for security futures contracts (''SFCs''). The proposed rule change is being made to make NASD's margin rule consistent with the margin rules for security futures adopted by the SEC and the Commodity Futures Trading Commission (''CFTC''), and the rules adopted by the NYSE, Nasdaq-Liffe Markets, and One Chicago, LLC.

The CFTC and SEC adopted customer margin requirements for SFCs (''SEC/CFTC Margin Regulations'') [8] pursuant to authority delegated to them by the Federal Reserve Board (''FRB'') under section 7(c)(2)(B) of the Act.[9] These margin regulations became effective on September 13, 2002. NASD is proposing to conform its margin rules to these new requirements, and to be comparable to the NYSE's margin requirements under NYSE rule 431.

NASD rule 2520 prescribes specific margin requirements for members of NASD that must be maintained in all accounts of their customers, based on the type of securities product held in such accounts. As proposed, NASD rule 2520(b) and (c) would provide that the amount of initial and maintenance margin required for long and short SFCs held in a securities account shall be 20 percent of the current market value of such SFC.

NASD rule 2520(e)(6) (''Broker/Dealer Accounts'') would permit introducing broker/dealers trading SFCs to deduct from their proprietary accounts the amount of any deficiency between the equity in the account and the haircut requirements pursuant to rule 15c3–1 under the Act (''Net Capital Rule'') [10] in computing the net capital of the member, in lieu of collecting margin.

NASD rule 2520(f)(11) (''Customer Margin Rules Relating to Security Futures'') would provide that transactions in SFCs in a securities account be subject to all other provisions of NASD rule 2520, including rule 2520(f)(8)(B) (''Day Trading''). Excluded from the margin requirements of the rule are arrangements between a creditor and a borrower, whereby the borrower is defined as an ''Exempted Person'' under rule 401(a)(9)[11] of the Act, and rule 41.43(a)(9)[12] under the Commodity Exchange Act. SFCs transacted in a futures account would not be subject to the requirements of NASD rule 2520.

NASD rule 2520(f)(11)(B)(iii) (''Permissible Offsets'') would permit margin lower than the 20 percent general requirement, and thereby recognize the hedged nature of certain offsetting positions involving SFCs and related positions. In doing so, margin levels for offsetting positions involving SFCs and related positions would be lower than would be required if those positions were margined separately. Further, the proposed rule change makes NASD's rule consistent with the table of offsets included in the recently adopted SEC/CFTC Margin Regulations.

NASD rule 2520(f)(11)(D) (''Security Futures Dealers'' Accounts''), NASD rule 2520(f)(11)(E) (''Approved Options Specialists'' or Market Maker's Accounts''), and NASD rule 2520(f)(11)(F) (''Approved Specialists'' Accounts'others'') would permit ''good faith'' margin treatment for specified hedged offset positions carried in the accounts noted above.[13] NASD rule 2520(f)(11)(G)(i) would permit money market mutual funds as defined in rule 2a–7 under the Investment Company Act of 1940 to be used for satisfying margin requirements for securities transactions, provided that the requirements of rule 404(b) [14] under the Act and rule 41.46(b)(2) [15] under the CEA are satisfied.[16]

III. Summary of Comments

As noted above, the Commission received one comment letter on the proposed rule change.[17] This commenter also submitted a comment letter on NYSE's proposal regarding margin requirements for securities futures contracts.[18] First, the commenter believes that both the NYSE and NASD rules on margin requirements for security futures should not be approved by the Commission on a permanent basis until the rules provide an exemption from the existing day trading provisions of NYSE rule 431. The commenter believes that applying the margin restrictions on day trading to security futures will create a disparity between security futures contracts that are held in a securities account and contracts that are held in a futures account, which is inconsistent with the principles of the Commodity Futures Modernization Act.

Second, the commenter would like to delete references in the proposed rule language to ''bona fide'' market maker or specialist transactions. Specifically, the commenter believes that the NYSE and NASD intend to determine which transactions of a ''*bona fide*'' market maker/specialist would fit within this definition. The commenter is concerned that NYSE and NASD may not rely on the other self-regulatory organizations' (''SROs'') rules regarding who is a market maker and that, therefore, the NYSE's and NASD's rules would not be consistent with the rules of these other SROs. This commenter believes that if the SEC approves an SRO rule regarding who as a market maker, the NYSE and NASD margin rules should defer to that SRO's rule in defining a market maker or specialist.

In response to these substantive concerns, NASD has requested that its proposal be approved as a pilot under

[7] *See* letter from Gary L. Goldsholle, Associate General Counsel, NASD, to Katherine A. England, Assistant Director, Division, Commission, dated January 15, 2003 (''Amendment No. 2''). In Amendment No. 2, NASD requested that the Commission approve the proposed rule change on a pilot basis under the same terms as the NYSE's pilot, pending the resolution of the issues raised by commenters.

[8] 17 CFR 242.400 through 406; 17 CFR 41.42 through 41.48.

[9] 15 U.S.C. 78g(c)(2)(B). As noted in the adopting release, section 7(c)(2) of the Act provides that the customer margin requirements for SFCs must satisfy four requirements: (1) They must preserve the financial integrity of markets trading security futures contracts; (2) they must prevent systemic risk; (3) they must (a) be consistent with the margin requirements for comparable options traded on an exchange registered pursuant to section 6(a) of the Act (15 U.S.C. 78f) and (b) provide for initial and maintenance margin that are not lower than the lowest level of margin, exclusive of premium, required for comparable exchange traded options; and (4) they must be and remain consistent with the margin requirements established by the FRB under Regulation T. *See* Securities Exchange Act Release no. 46292 (August 1, 2002), 67 FR 53146 (August 14, 2002).

[10] 17 CFR 240.15c3–1.

[11] 17 CFR 242.401(a)(9).

[12] 17 CFR 41.43(a)(9).

[13] NASD noted that, unlike the amendments proposed by other SROs, on security futures, it believes that its proposed amendment will permit members to accord offset treatment in accounts carried for such specialists, market makers and security futures dealers only when their activity is limited to bona fide specialist or market making transactions. According to NASD, the limitations imposed are consistent with NASD's belief that market makers bear the primary responsibility and obligation to maintain fair and orderly markets, and provide liquidity to the marketplace. Were a revenue or other test substituted for the affirmative obligation standard here proposed, NASD believes that entities other than qualified market makers would be permitted to receive the more favorable market maker margin treatment. NASD believes that such was not the Commission's or CFTC's intent when adopting the SEC/CFTC Margin Regulations.

[14] 17 CFR 242.404(b).

[15] 17 CFR 41.46(b)(2).

[16] Presently, money market mutual funds may be used as collateral to satisfy margin requirements under Regulation T in a securities margin account. The amendments to NASD rule 2520 would now permit the use of such funds as collateral for SFCs as is required by the new SEC/CFTC Margin Regulations described above.

[17] *See supra* note .

[18] For further details on SR–NYSE–2002–53, *see id.*

the same terms as the NYSE's proposal.[19] Under a pilot program, NASD will have the opportunity to consider comments it received on the proposal, and facilitate the trading in securities futures in securities accounts for those NASD members, who are not also members of the NYSE.

IV. Discussion

The Commission finds that the proposed rule change, as amended, is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities association.[20] In particular, the Commission believes that the proposed rule change is consistent with the requirements of section 15A(b)(6) of the Act,[21] which requires, among other things, to promote just and equitable principles of trade and, in general, to protect investors and the public interest. In addition, the Commission believes that the proposed rule change is consistent with section 7(c)(2)(B) of the Act,[22] which provides, among other things, that the margin requirements for security futures must preserve the financial integrity of markets trading security futures, prevent systemic risk, be consistent with the margin requirements for comparable exchange-traded options, and provides that the margin levels for security futures may be no lower than the lowest level of margin, exclusive of premium, required for any comparable exchange-traded option.

Moreover, the Commission believes that the proposed rule change is generally consistent with the customer margin rules for security futures adopted by the Commission and the CFTC. In particular, the Commission notes that, consistent with rule 403 under the Act, NASD's proposed rules provide a minimum margin level of 20% of current market value for all positions in security futures carried in a securities account. The Commission believes that 20% is the minimum margin level necessary to satisfy the requirements of section 7(c)(2)(B) of the Act. Rule 403 under the Act [23] also provides that a national securities association may set margin levels lower than 20% of the current market value of the security future for an offsetting position involving security futures and related positions, provided that an association's margin levels for offsetting positions meet the criteria set forth in section 7(c)(2)(B) of the Act. The offsets proposed by NASD are consistent with the strategy-based offsets permitted for comparable offset positions involving exchange-traded options and therefore consistent with section 7(c)(2)(B) of the Act.

The Commission also believes it is consistent with the Act for the NASD to exclude from its margin requirements positions in SFCs carried in a futures account. The Commission believes that by choosing to exclude such positions from the scope of rule 2520, the NASD's proposal will make compliance by members with the regulatory requirements of several SROs easier.

The NASD has asked the Commission in Amendment No. 2 to approve the proposed rule change on a pilot basis to accommodate the expeditious trading of security futures for NASD customers of broker-dealers who are subject to NASD margin rules. NASD also has requested that the Commission approve the proposed rule change on a pilot basis under the same terms as the NYSE's pilot, pending the resolution of the issues raised by commenters. The Commission believes that there is good cause to approve the proposed rule change, as amended, on a pilot basis until March 6, 2003. The Commission notes that NASD's proposed rule change is substantially the same as NYSE's filing on margin requirements for security futures. Thus, the Commission believes that it is appropriate to approve NASD's proposed rule change on a pilot basis to enable customers of broker-dealers who are subject to NASD margin rules to trade security futures in securities accounts without unnecessary delay. The Commission expects that, similar to the NYSE, NASD will file a proposed rule change to adopt its margin requirements for security futures on a permanent basis, and consider the comments it received on this proposal.

V. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning Amendment No. 2, including whether the proposed amendment 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 amendments that are filed with the Commission, and all written communications relating to the amendments 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 at the Commission's Public Reference Room. Copies of such filing also will be available for inspection and copying at the principal office of the NASD.

All submissions should refer to File No. SR–NASD–2002–166 and should be submitted by February 24, 2003.

VI. Conclusion

It is therefore ordered, pursuant to section 19(b)(2) of the Act,[24] that the proposed rule change (SR–NASD–2002–166) is approved on a pilot basis until March 6, 2003.

For the Commission, by the Division of Market Regulation, pursuant to the delegated authority.[25]

Jill M. Peterson,

Assistant Secretary.

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[19] *See supra* note .

[20] In approving this proposal, the Commission has considered its impact on efficiency, competition, and capital formation. 15 U.S.C. 78c(f).

[21] 15 U.S.C. 78o–3(b)(6).

[22] 15 U.S.C. 78g(c)(2)(B).

[23] 17 CFR 240.403(b)(2).

[24] 15 U.S.C. 78s(b)(2).

[25] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–47259; File No. SR–NASD–2001–47]

Self-Regulatory Organizations; National Association of Securities Dealers, Inc.; Order Approving Proposed Rule Change and Notice of Filing and Order Granting Accelerated Approval of Amendment No. 1 Thereto Relating to Audit Trail and Trading Halt Requirements for Alternative Trading Systems That Trade Security Futures

January 27, 2003.

I. Introduction

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 July 30, 2001, the National Association of Securities Dealers, Inc. (''NASD'' or ''Association''), through its subsidiary, NASD Regulation, Inc. (''NASD Regulation''), filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') the proposed rule change relating to audit trail and trading halt requirements for Alternative Trading Systems (''ATSs'') that trade security futures.[3] By letter dated August 14, 2002, the Association filed

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Release No. 44623 (July 30, 2001), 66 FR 41076 (August 6, 2001).

Amendment No. 1 to the proposed rule change.[4] The Commission received one comment letter.[5] The Commission approves the proposed rule change, as amended, and publishes this notice to solicit comments on Amendment No. 1. The Commission also approves Amendment No. 1 on an accelerated basis.

II. Description of the Proposed Rule Change

NASD Regulation proposes to add NASD rule 3115 to establish record-keeping requirements for ATSs that trade security futures[6] and to amend NASD rule 3340 to prohibit members and associated persons from publishing a quotation for a security future when there is a regulatory trade halt in effect for the underlying security.

Specifically, NASD Regulation proposes to establish audit trail requirements relating to ATSs for the trading of futures on single securities and narrow-based security indices consistent with the Commodity Futures Modernization Act of 2000 (''CFMA'').[7] Under section 6(h)(5) of the Act,[8] as added by the CFMA, a person[9] other than a national securities association or national securities exchange member may not maintain or provide a marketplace or facilities for bringing together purchasers and sellers of security future products unless it is a member of a national securities association or national securities exchange that has: (1) Procedures for coordinated surveillance, (2) rules to require an audit trail necessary or appropriate to facilitate coordinated surveillance, and (3) rules to require such person to coordinate trading halts with markets trading the securities underlying the security futures products and other markets trading related securities. The NASD, as a national securities association, proposes to meet these CFMA requirements to prepare for the trading of security futures by ATSs.

a. Requirements for Alternative Trading Systems

With respect to audit trails necessary to facilitate coordinated surveillance, the proposed rule change would require ATSs to record and report audit trail information on a T+1 basis in such form as the NASD requires. The NASD has based the required elements of the audit trail rule on Regulation ATS rule 302, the Commission's recordkeeping rule for ATSs.[10] The form of the reports will be designed to facilitate the NASD's sharing the reports with members of the Intermarket Surveillance Group, an organization whose purpose is to coordinate surveillance among financial markets. The proposed rule change would require that ATSs preserve such records in accordance with rule 17a–4(b) under the Act,[11] which requires preservation of records for at least three years, the first two years in an easily accessible place.

b. Trading Halts

With respect to coordinated trading halts, the proposed rule change would amend the NASD's existing rule prohibiting trading during a halt. Currently, NASD rule 3340 broadly prohibits broker-dealers and associated persons from effecting a ''transaction * * * in any security as to which a trading halt is currently in effect.'' The NASD proposes to amend this rule by adding a provision that prohibits member firms, including ATSs, from effecting any transaction or publishing a priced bid and/or unpriced indication of interest for: (a) A future on a single stock when the underlying stock is subject to a regulatory trading halt; and (b) a future on a narrow based securities index when one or more underlying securities that constitute 50 percent or more of the market capitalization of the index are subject to a regulatory trading halt.[12] Further, by limiting application of new NASD rule 3340(b) to regulatory trading halts, the NASD intends to exclude halts resulting from events such as an order imbalance or a systems failure.

III. Comments

The Commission received one comment letter from Island. Island recommended that the Commission require the NASD to: (1) More narrowly tailor the proposed recordkeeping requirements to be consistent with security futures and the regulatory framework governing security futures; and (2) conditionally exempt ATSs from certain aspects of the trading halt rule. Specifically, Island disputed that NASD rule 3115 governing recordkeeping requirements should mirror the existing audit trail rule in Regulation ATS designed for equity and debt securities. Island also noted its belief that the proposed recordkeeping requirements in NASD rule 3115 require far greater audit trail information than is necessary to perform coordinated surveillance to detect manipulation and insider trading as contemplated by the CFMA. In addition, Island did not believe it was appropriate to amend NASD rule 3340 to include ATSs trading security futures because the effective date of the rule had been delayed to clarify the NASD's interpretation of the rule. Island proposed that the rule be interpreted to exempt ATSs that: (1) Do not accept new orders in such security during a trading halt; and (2) have procedures in place reasonably designed to prevent the execution of orders during a trading halt.

In Amendment No. 1, the NASD responded to Island's comment letter. Specifically, the NASD stated that it reviewed the items required by NASD rule 3115 and the information provided by other markets that are expected to trade security futures products with respect to coordinated surveillance by the Intermarket Surveillance Group, and concluded that the NASD rule 3115 requirements are not unnecessarily broad or burdensome. Regarding the amendments to NASD rule 3340, the NASD noted that the rule has been in effect since October 9, 2001, and thus the proposed amendments, which supplement the rule to account for security futures, should be approved.

IV. Discussion

The Commission has reviewed carefully the proposed rule change, the comment letter, NASD's response to the comment letter, and the entire record herein, and finds that the proposed rule change, as amended, is consistent with the Act and the rules and regulations applicable to the Association.[13]

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[4] *See* letter from Gary Goldsholle, Associate General Counsel, NASD, to Katherine A. England, Assistant Director, Division of Market Regulation, Commission, dated August 13, 2002 (''Amendment No. 1''). In Amendment No. 1, the NASD responded to a comment letter from Island, added proposed NASD rule 3115(a)(15) to indicate that the ATS audit trail for security futures trading would include ''an account identifier that relates the order back to the account owner(s),'' and amended NASD rule 3340(b)(2) to increase the percentage of the market capitalization of underlying securities that trigger a trading halt in a narrow-based security index from 30% to 50%.

[5] *See* letter from Chris Concannon, Vice-President, Island, to Jonathan Katz, Secretary, Commission, dated August 20, 2001 (''Island Comment Letter'').

[6] Section 3(a)(55) of the Act defines a ''security future'' as a contract of sale for future delivery of a single security or of a narrow-based security index. Security futures are defined as ''securities'' under the Act, thus making the federal securities laws generally applicable to them.

[7] The CFMA was signed into law on December 21, 2000. Pub. L. No. 106–554, 114 Stat. 2763 (2000).

[8] *See* 15 U.S.C. 78f(h)(5).

[9] The term ''person'' means a natural person, company, government, or political subdivision, agency or instrumentality of a government. *See* 15 U.S.C. 78c(a).

[10] 17 CFR 242.302(c).

[11] 17 CFR 240.17a–4(b).

[12] *See* Amendment No. 1, *supra* note 4.

[13] In approving this proposal, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. 15 U.S.C. 78c(f).

The Commission finds that the proposed rule change, as amended, is consistent with section 15A.[14] Specifically, the Commission finds that the proposed rule change is consistent with section 15A(b)(6) of the Act which requires, among other things, that the Association's rules be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principals of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest.[15]

In addition, the Commission finds that the proposed rule change is consistent with section 15A(b)(11),[16] which requires that the rules of a registered national securities association be designed to produce fair and informative quotations, prevent fictitious or misleading quotations, and to promote orderly procedures for collecting, distributing, and publishing quotations.

The Commission also believes that proposed rule change, as amended, is consistent with subparagraphs (B) and (C) of section 6(h)(5) of the Act,[17] which sets forth the requirements that must be in place before ATSs provide a marketplace for trading security futures products. Island asserted that NASD rule 3115 requires that ATSs maintain more records than this statutory provision requires. In response, the NASD stated that the rule was not unnecessarily broad or burdensome. Pursuant to section 6(h)(5)(B) of the Act, the NASD, among other requirements, must have ''rules to require audit trails necessary or appropriate to facilitate the coordinated surveillance required [under the Act]'' before an ATS can trade security futures products.[18] The Commission believes that the proposed rule change satisfies this requirement and agrees with the NASD that it is not unnecessarily broad or burdensome.

The Commission also believes that the amendment to NASD rule 3340 meets the goals of section 6(h)(5)(C) of the Act,[19] which requires a national securities association to adopt rules to require its members ''to coordinate trading halts with markets trading the securities underlying the security future products and other markets trading related securities.''[20] Island suggested that the NASD exempt ATSs that: (1) Do not accept new orders in such security during a trading halt; and (2) have procedures in place reasonably designed to prevent the execution of orders during a trading halt. The Commission, however, does not believe that it is necessary for NASD Rule 3340 to provide for the suggested exemption in order for the rule to be consistent with the Act. The Commission also notes that to satisfy other regulatory requirements, some ATSs have been able to block the public dissemination of orders for individual securities on their limit order books. Accordingly, ATSs appear to have the technological capability to restrict the display or publication of orders on their books. Thus, in the Commission's view, the NASD's amendments to its trading halt rule to cover security futures are not overly burdensome or inappropriate.

Finally, the Commission believes that the proposed rule is consistent with the goals expressed in section 11A(a)(1)(C) of the Act,[21] which grants the Commission the authority to require rules designed to ensure appropriate protection of investors and the maintenance of fair and orderly markets to assure: (1) Economically efficient execution of securities transactions; (2) fair competition among brokers and dealers; (3) the availability to brokers, dealers and investors of information with respect to quotations and transactions in securities; (4) the practicability of brokers executing investors' orders in the best market; and (5) an opportunity for investors' orders to be executed without the participation of a dealer.

V. Commission's Findings and Order Granting Accelerated Approval of Proposed Rule Change

For the reasons discussed below, the Commission finds good cause for approving Amendment No. 1 to the proposed rule change prior to the 30th day after the date of publication of notice thereof in the **Federal Register**.

In Amendment No. 1, the NASD proposed NASD rule 3115(a)(15) to indicate that the ATS audit trail for security futures trading would include ''an account identifier that relates the order back to the account owner(s),'' and amended NASD rule 3340(b)(2) to increase the percentage of the market capitalization of underlying securities subject to a trading halt in a narrow-based security index from 30% to 50%. The NASD amended the rule to include the account identifier provision because the account identifier has traditionally been a key component of an audit trail. The percentage increase from 30% to 50% in the market capitalization of underlying securities that triggers a trading halt in futures on a narrow-based security index was also proposed to more closely mirror rules approved by the Commission and the Commodity Futures Trading Commission (''CFTC'') with respect to trading halts in security futures products.[22] As Amendment No. 1, does not raise any novel regulatory issues, the Commission finds that granting accelerated approval to Amendment No. 1 is appropriate and consistent with section 19(b)(2) of the Act.[23]

VI. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning Amendments No. 1 to NASD–2001–47, including whether the proposed amendment 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 NASD. All submissions should refer to Amendment No. 1 to File No. SR–NASD–2001–47 and should be submitted by February 24, 2003.

VII. Conclusion

For the foregoing reasons, the Commission finds that the proposal, as amended, is consistent with the requirements of the Act and rules and regulations hereunder.

[14] 15 U.S.C. 78*o*–3.

[15] 15 U.S.C. 78*o*–3(b)(6).

[16] 15 U.S.C. 78o–3(b)(11).

[17] 15 U.S.C. 78f(h)(5)(B) and (C).

[18] *See* 15 U.S.C. 78f(h)(5)(B).

[19] *See* 15 U.S.C. 78f(h)(5)(C).

[20] *See* 15 U.S.C. 78f(h)(5)(c).

[21] 15 U.S.C. 78k–1(a)(1)(C).

[22] *See* Securities and Exchange Act Release No. 34–45956 (May 17, 2002), 67 FR 36741 (May 24, 2002) (Cash Settlement and Regulatory Halt Requirements for Security Futures Products, Joint Final Rule of CFTC and the Commission).

[23] 15 U.S.C. 78s(b)(2).

It is therefore ordered, pursuant to section 19(b)(2) of the Act, [24] that the proposed rule change (SR–NASD–2001–47), as amended, is approved.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[25]

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 03–2485 Filed 1–31–03; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–47253; File No. SR–NYSE–2001–27]

Self-Regulatory Organizations; Notice of Filing of a Proposed Rule Change and Amendment No. 1 Thereto by the New York Stock Exchange, Inc. Relating to Amendments to Section 804 of the Listed Company Manual and Rule 499 of the Exchange

January 24, 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 August 17, 2001, the New York Stock Exchange, Inc. (''NYSE'' 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 NYSE. On January 22, 2003, the NYSE filed Amendment No. 1 to the proposed rule change with the Commission.[3] The Commission is publishing this notice to solicit comments on the proposed rule change, as amended, from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The NYSE proposes to amend Section 804 of the Listed Company Manual to specify that public directors will constitute a majority of the directors of the Committee for Review voting on final delisting determinations. The NYSE also proposes to codify this change in the parallel Exchange Rule 499, as well as make other minor conforming changes.

The text of the proposal is below. Proposed new language is in italics; proposed deletions are in brackets.

* * * * *

804.0 Procedure for Delisting

• If the Exchange staff should determine that a security be removed from the list, it will so notify the issuer in writing, describing the basis for such decision and the specific policy or criterion under which such action is to be taken. The Exchange will simultaneously (1) issue a press release disclosing the company's status and basis for the Exchange's determination and (2) begin daily dissemination of ticker and information notices identifying the security's status, and include similar information on the Exchange's web site.

• The notice to the issuer shall also inform the issuer of its right to a review of the determination by a Committee of the Board of Directors of the Exchange ([comprised of] a majority of *the members of such Committee voting on each determination must be* public Directors), provided a written request for such a review is filed with the Secretary of the Exchange within ten business days after receiving the aforementioned notice.

* * * * *

If a review is requested, the review will be scheduled for the first Review Day which is at least 25 business days from the date the request for review is filed with the Secretary of the Exchange, unless the next subsequent Review Day must be selected to accommodate the Committee's schedule. *The chairman of the Committee will disclose to the company and the staff at the commencement of the review which of the industry Directors present will be voting on the matter, although all directors will be entitled to participate in the discussion.* The Committee's review *and final decision* shall be based on oral argument (if any) and the written briefs and accompanying materials submitted by the parties.

* * * * *

Delisting of Securities

Suspension from Dealings or Removal from List by Action of the Exchange

* * * * *

Rule 499. Securities admitted to the list may be suspended from dealings or removed from the list at any time.

* * * Supplementary Material

* * * * *

.70 Procedure for Delisting

a. If the Exchange staff should determine that a security be removed from the list, it will so notify the issuer in writing, describing the basis for such decision and the specific policy or criterion under which such action is to be taken. The Exchange will simultaneously (1) issue a press release disclosing the company's status and basis for the Exchange's determination and (2) begin [appending a suffix to the security's ticker symbol identifying the security's status] *daily dissemination of ticker and information notices identifying the security's status, and include similar information on the Exchange's web site.* The notice to the issuer shall also inform the issuer of its right to a review of the determination by a Committee of the Board of Directors of the Exchange ([comprised of] a majority of *the members of such Committee voting on each determination must be* public Directors), provided a written request for such a review is filed with the Secretary of the Exchange within ten business days after receiving the aforementioned notice.

* * * * *

c. If a review is requested, the review will be scheduled for the first Review Day which is at least 25 business days from the date the request for review is filed with the Secretary of the Exchange, unless the next subsequent Review Day must be selected to accommodate the Committee's schedule. *The chairman of the Committee will disclose to the company and the staff at the commencement of the review which of the industry Directors present will be voting on the matter, although all directors will be entitled to participate in the discussion.* The Committee's review *and final decision* shall be based on oral argument (if any) and the written briefs and accompanying materials submitted by the parties.

* * * * *

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 NYSE included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The NYSE has prepared summaries, set forth in

[24] 15 U.S.C. 78s(b)(2).

[25] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* letter from Darla Stuckey, Corporate Secretary, NYSE, to Nancy Sanow, Assistant Director, Division of Market Regulation, Commission, dated January 17, 2003 (''Amendment No. 1''). In Amendment No. 1, the Exchange replaced its original proposal in its entirety. In part, the Exchange clarified its rotation system with respect to the industry directors voting on a particular matter, clarified the basis for a decision made by the Committee for Review, specified the quorum requirements for the Committee for Review, and made conforming changes to the Exchange's rule text.

Sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

Section 804 of the Listed Company Manual describes the procedures to be followed when the Exchange determines that a security should be removed from the list. It provides that the issuer has a right to request a review of the Exchange's determination by a Committee of the Board of Directors of the Exchange, and specifies that that committee is to be ''comprised of a majority of public Directors.'' This requirement was added as part of a larger revision of these procedures that became effective in 2000.[4] The Exchange represents that the Committee for Review has long been the committee of the Board that has reviewed both disciplinary and delisting matters, and it has often been comprised of equal numbers of public and industry directors.[5] The Exchange represents that when the Exchange began to implement the new delisting review procedures in 2000, it became necessary to reconcile the Committee's traditional composition with the new requirement that delisting matters be reviewed by a committee comprised of a majority of public directors. The Exchange also wanted to ensure that non-voting industry directors were not precluded from participating in discussions regarding delisting determinations as a result of the new requirement. Consequently, the Committee required that the quorum for delisting matters be two public directors and one industry director, and established a rotation system[6] with respect to industry director voting on delisting matters so that those voting are comprised of a majority of public directors and at least one industry director.

To insure that the Exchange's procedures are adequately described in the Listed Company Manual, the NYSE proposes to amend Section 804 of the Listed Company Manual to specify that public directors will constitute a majority of the directors voting on the delisting matter. The Exchange is also proposing to codify this change in the parallel Exchange Rule 499. Proposed NYSE Rule 499 also reflects a previous amendment to Section 804 of the Listed Company Manual that was inadvertently not added to NYSE Rule 499.

In addition, pursuant to the proposed rule change, the Chairman of the Committee would also be required to disclose to the issuer and the staff at the commencement of each delisting hearing which of the industry directors will be voting on the delisting matter. Furthermore, the decision relating to the delisting appeal would be required to identify by name which directors participated only and which directors voted on the matter. The written decision issued by the Committee would also be required to clearly state that, in reaching its decision, the Committee considered only the oral arguments, written briefs and accompanying materials presented by the parties at the time of the hearing.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,[7] in general, and furthers the objectives of Section 6(b)(5),[8] in particular, because it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to remove impediments to, and perfect the mechanism of a free and open market and, in general, to protect investors and the public interest.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will 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 neither solicited nor received written comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 35 days of the date of publication of this notice in the **Federal Register** or within such longer period (i) as the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the NYSE 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, as amended, 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 NYSE. All submissions should refer to File No. SR–NYSE–2001–27 and should be submitted by February 24, 2003.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[9]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 03–2404 Filed 1–31–03; 8:45 am]

BILLING CODE 8010–01–P

[4] *See* Securities Exchange Act Release No. 42863 (May 30, 2000); 65 FR 36488 (June 8, 2000).

[5] The Exchanges states that as is the composition of any other Board Committee, the composition of the Committee for Review is determined annually, based on availability and expertise of Board members.

[6] Pursuant to the rotation system, the Committee designates prior to each delisting hearing which industry director(s) shall vote. At all hearings, all public directors present shall vote. For example, at a Committee meeting attended by three (3) public directors and three (3) industry directors at which two delisting appeals are considered, all public directors present and industry directors 1 and 2 will vote on the first delisting matter and all public directors present and industry directors 3 and 1 will vote on the second delisting matter. If, on the Committee's next review date, the meeting is attended by two (2) public directors and three (3) industry directors and one delisting appeal is considered, all public directors present and industry director 2 will vote on the matter; industry directors 1 and 3 will not vote. If any of the industry directors designated to vote next is not present at a Committee meeting, the next succeeding industry director(s) will vote. The rotation system is subject to the composition of the Committee, which varies at each meeting as described above, depending upon each director's availability. As is the case with other procedures of the Committee, the rotation system may also be changed from time to time.

[7] 15 U.S.C. 78f(b).

[8] 15 U.S.C. 78f(b)(5).

[9] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–47257; File No. SR–NYSE–2002–59]

Self-Regulatory Organizations; New York Stock Exchange, Inc.; Order Approving Proposed Rule Change Relating to Mediation and Administrative Conferences

January 27, 2003.

On November 4, 2002, the New York Stock Exchange, Inc. (''Exchange'' or ''NYSE'') filed with the Securities and Exchange Commission (''Commission'' or ''SEC''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder,[2] a proposed rule change. On December 18, 2002, the NYSE submitted Amendment No. 1 to the proposal.[3] On December 27, 2002, the Exchange's rule proposal was published for comment in the **Federal Register**, as amended.[4] No comments letters were received on the proposal. This order approves the proposed rule change.

The NYSE proposes to allow its current pilot rules to expire and adopt amended rules for mediation and administrative conferences.[5] In particular, the Exchange's proposal would: (i) Allow parties to agree to mediation at their own expense; (ii) provide for the scheduling of an administrative conference at the request of the parties or discretion of the arbitrator(s) or Director of Arbitration; (iii) permit the Director to appoint a staff member or arbitrator to preside at the administrative conference which is to be held via telephone conference call and limited to procedural matters. The proposal also would amend NYSE Rules 628 (Agreement to Arbitrate) and 630 (Uniform Arbitration Code) to reflect these changes.

After careful review, the Commission finds that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange[6] and, in particular, the requirements of Section 6 and the rules and regulations thereunder.[7] Specifically, the Commission believes the proposal is consistent with the Section 6(b)(5) requirements that the rules of an exchange be designed to promote just and equitable principles of trade, to prevent fraudulent and manipulative acts, and, in general, to protect investors and the public interest. In particular, the Commission believes that the proposed rule change should help NYSE members, member organizations, and the public have a fair and impartial forum for the resolution of their disputes. Further, the Commission believes that the proposed rule is a reasonable effort by the Exchange to improve the efficiency of its dispute resolution arbitration process.

It is therefore ordered, pursuant to Section 19(b)(2) of the Act,[8] that the proposed rule change (File No. SR–NYSE–2002–59) is hereby approved.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[9]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 03–2406 Filed 1–31–03; 8:45 am]

BILLING CODE 8010–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–47273; File No. SR–NYSE–2003–03]

Self-Regulatory Organizations; Notice of Filing and Immediate Effectiveness of Proposed Rule Change by the New York Stock Exchange, Inc. Relating to Transaction Fees for Certain Exchange Traded Funds

January 29, 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 January 21, 2003, the New York Stock Exchange, Inc. (''NYSE'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') the proposed rule change as described in items I and II below, which items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to charge transaction fees for shares of Fresco[SM] Dow Jones STOXX 50 [SM] Fund and Fresco[SM] Dow Jones EURO STOXX 50[SM] Fund, that are listed and traded on the Exchange. The fees will be the same transaction fees charged for other exchange traded funds listed and traded on the Exchange. Proposed new language is *italicized*; proposed deletions are in [brackets].

* * * * *

TRANSACTION FEES

Exchange Traded Funds	Amount
Exchange Traded Funds—Public Agency and Principal Transactions Broker/Dealer—price per round-lot	$0.60
Maximum price per trade	100
System Orders under 5,100 shares[1]	No Charge.
Specialists and other on-floor proprietary trading—price per round-lot	0.63
Maximum price per trade	300
Exchange Traded Funds admitted to dealings on an unlisted trading privileges (UTP) basis	No Charge.[2]
[Specific NYSE Listed Exchange Traded Funds:	
Fresco[SM] Dow Jones STOXX 50[SM]	No Charge.[2]
Fresco[SM] Dow Jones EURO STOXX 50[SM]	No Charge.[2]]

[1] Not inclusive of orders of a member or member organization trading as an agent for the account of a non-member competing market maker.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* letter to Florence Harmon, Senior Special Counsel, SEC, from Darla Stuckey, Corporate Secretary, NYSE, dated December 17, 2002 (''Amendment No. 1'').

[4] *See* Securities Exchange Act Release No. 47025 (December 18, 2002), 67 FR 79214.

[5] On November 19, 1998, the Commission approved a two-year pilot program for mediation and administrative conferences in the Exchange's arbitration facility. *See* Securities Exchange Act Release No. 34–40695 (November 19, 1998); 63 FR 65834 (November 30, 2000), (SR–NYSE–98–27). On December 29, 2000, the Commission approved amendments to the pilot rules and granted a two-year extension. *See* Securities Exchange Act Release No. 34–47076 (December 29, 2000); 66 FR 1710 (January 9, 2001), (SR–NYSE–00–39). The Commission extended this pilot for an additional thirty days until January 31, 2003. *See* Securities Exchange Act Release No. 34–43785 (December 20, 2002); 67 FR 79680 (December 30, 2002), (SR–NYSE–2002–65).

[6] In approving this rule, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. 15 U.S.C. 78c(f).

[7] 15 U.S.C. 78f.

[8] 15 U.S.C. 78s(b)(2).

[9] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

Competing Market Maker: a specialist or market-maker registered as such on a registered stock exchange (other than the NYSE), or a market-maker bidding and offering over-the-counter, in a New York Stock Exchange-traded security.

[2] This ''fee holiday'' is intended to be temporary. The Exchange expects to file a specific schedule of transaction charges at a future date.

* * * * *

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 NYSE included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Fresco℠ Dow Jones STOXX 50℠ Fund and Fresco℠ Dow Jones EURO STOXX 50℠ (''Fresco Funds'') were listed and commenced trading on the Exchange on October 21, 2002.[3] At the time of listing, the Exchange implemented a temporary ''fee holiday,'' constituting zero transaction charges, for Fresco Funds for trading them on the Exchange.[4] The Exchange now proposes that starting February 1, 2003, transaction fees will be charged for trading of Fresco Funds. The fees will be the same transaction fees charged for other exchange traded funds listed and traded on the Exchange.[5]

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with section 6(b) of the Act[6] in general, and furthers the objectives of section 6(b)(4)[7] in particular, in that it provides for the equitable allocation of reasonable dues, fees and other charges among its members and other persons using its facilities.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

The Exchange has neither solicited nor received comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The proposed rule change has become effective pursuant to section 19(b)(3)(A) of the Act,[8] and rule 19b–4(f)(2) thereunder,[9] in that it establishes or changes a due, fee, or other charge imposed by the Exchange. At any time within 60 days of the filing of such 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 proposed rule change is consistent with the Act. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549–0609. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written 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 at the Commission's Public Reference Room. Copies of such filing will also be available for inspection and copying at the principal office of the Exchange. All submissions should refer to File No. SR–NYSE–2003–03 and should be submitted by February 24, 2003.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[10]

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 03–2482 Filed 1–31–03; 8:45 am]

BILLING CODE 8010–01–P

[3] Securities Exchange Act Release No. 46686 (October 18, 2002), 67 FR 65388 (October 24, 2002).

[4] Securities Exchange Act Release No. 46786 (November 7, 2002), 67 FR 69280 (November 15, 2002).

[5] 15 U.S.C. 78f(b)(4).

[6] 15 U.S.C. 78f(b).

[7] 15 U.S.C. 78f(b)(4).

[8] 15 U.S.C. 78s(b)(3)(A).

[9] 17 CFT 240.19b–4(f)(2).

[10] 17 CFR 200.30–3(a)(12).

SMALL BUSINESS ADMINISTRATION

[Declaration of Disaster #P005]

Federated States of Micronesia

As a result of the President's major disaster declaration for Public Assistance on January 6, 2003, the U.S. Small Business Administration is activating its disaster loan program only for private non-profit businesses that provide essential services of a governmental nature. I find that the State of Chuuk within the Federated States of Micronesia constitutes a disaster area due to damages caused by Typhoon Pongsona occurring from December 5, 2002, and continuing through December 7, 2002. Applications for loans for physical damage as a result of this disaster may be filed until the close of business on March 7, 2003 at the address listed below or other locally announced locations: Small Business Administration, Disaster Area 4 Office, P.O. Box 13795, Sacramento, CA 95853–4795.

The interest rates are:

	Percent
For Physical Damage:	
Non-Profit Organizations Without Credit Available Elsewhere	3.324
Non-Profit Organizations With Credit Available Elsewhere	5.500

The number assigned to this disaster for physical damage is P00508.

(Catalog of Federal Domestic Assistance Program Nos. 59008)

Dated: January 23, 2003.

Herbert L. Mitchell,

Associate Administrator For Disaster Assistance.

[FR Doc. 03–2400 Filed 1–31–03; 8:45 am]

BILLING CODE 8025–01–P

DEPARTMENT OF STATE

[Public Notice 4259]

Bureau of Political-Military Affairs: Defense Trade Controls; Notifications to the Congress of Proposed Commercial Export Licenses

AGENCY: Department of State.

ACTION: Notice.

SUMMARY: Notice is hereby given that the Department of State has forwarded the attached Notifications of Proposed Export Licenses to the Congress on the dates shown on the attachments pursuant to sections 36(c) and 36(d) and in compliance with section 36(f) of the Arms Export Control Act (22 U.S.C. 2776).

EFFECTIVE DATE: As shown on each of the three letters.

FOR FURTHER INFORMATION CONTACT: Mr. Robert W. Maggi, Deputy Assistant Secretary for Defense Trade Controls, Bureau of Political-Military Affairs, Department of State (202–663–2700).

SUPPLEMENTARY INFORMATION: Section 36(f) of the Arms Export Control Act mandates that notifications to the Congress pursuant to sections 36(c) and 36(d) must be published in the **Federal Register** when they are transmitted to Congress or as soon thereafter as practicable.

Dated: January 17, 2003.

Robert W. Maggi,

Deputy Assistant Secretary, Defense Trade Controls, Bureau of Political-Military Affairs, Department of State.

November 15, 2002.

The Honorable Henry J. Hyde,

Chairman, Committee on International Relations, House of Representatives.

Dear Mr. Chairman: Pursuant to Section 36(c) of the Arms Export Control Act, I am transmitting, herewith, certification of a proposed license for the temporary export of defense articles or defense services sold commercially under a contract in the amount $50,000,000 or more.

The transaction described in the attached certification involves the temporary export of one (1) 601 HP Commercial Communications Satellite (Galaxy XIII), spare parts/ground support equipment, and fuel to international waters in the Pacific Ocean for Sea Launch or to Kourou, French Guiana on an Ariane Launch Vehicle.

The United States Government is prepared to license the export of these items having taken into account political, military, economic, human rights, and arms control considerations.

More detailed information is contained in the formal certification which, though unclassified, contains business information submitted to the Department of State by the applicant, publication of which could cause competitive harm to the United States firm concerned.

Sincerely,

Paul V. Kelly,

Assistant Secretary, Legislative Affairs.

Enclosure: Transmittal No. DTC 246–02.

November 15, 2002.

The Honorable J. Dennis Hastert,

Speaker of the House of Representatives.

Dear Mr. Speaker: I am transmitting, herewith, certification of a proposed issuance of an export license pursuant to Section 126.14 of the International Traffic in Arms Regulations concerning a major program authorization (MPA) and Section 36(c) of the Arms Export Control Act.

The transaction contained in the attached certification involves the export of electronic power generating systems to Germany, Italy, Spain and the United Kingdom in support of the Eurofighter program.

The United States Government is prepared to license the export of these items having taken into account political, military, economic, human rights and arms control considerations.

More detailed information is contained in the formal certification which, though unclassified, contains business information submitted to the Department of State by the applicant, publication of which could cause competitive harm to the United States firm concerned.

Sincerely,

Paul V. Kelly,

Assistant Secretary, Legislative Affairs.

Enclosure: Transmittal No. DTC 282–02.

November 18, 2002.

The Honorable Henry J. Hyde,

Chairman, Committee on International Relations, House of Representatives.

Dear Mr. Chairman: Pursuant to Section 36(c) of the Arms Export Control Act, I am transmitting, herewith, certification of a proposed technical assistance agreement for the export of defense articles or defense services sold commercially under a contract in the amount $50,000,000 or more.

The transaction contained in the attached certification involves the export of technical data and assistance related to or involved with the sale of the TELEKOM–2 commercial communications satellite to Indonesia, jointly with Canada, and its launch from French Guiana.

The United States Government is prepared to license the export of these items having taken into account political, military, economic, human rights and arms control considerations.

More detailed information is contained in the formal certification, which, though unclassified contains business information submitted to the Department of State by the applicant, publication of which could cause competitive harm to the United States firm concerned.

Sincerely,

Paul V. Kelly,

Assistant Secretary, Legislative Affairs.

Enclosure: Transmittal No. DTC 177–02.

[FR Doc. 03–2436 Filed 1–31–03; 8:45 am]

BILLING CODE 4710–25–P

DEPARTMENT OF STATE

[Public Notice 4258]

Culturally Significant Objects Imported for Exhibition; Determinations: ''Art of the First Cities: The Third Millennium B.C. From the Mediterranean to the Indus''

AGENCY: Department of State.

ACTION: Notice.

SUMMARY: Notice is hereby given of the following determinations: Pursuant to the authority vested in me by the Act of October 19, 1965 (79 Stat. 985; 22 U.S.C. 2459), Executive Order 12047 of March 27, 1978, the Foreign Affairs Reform and Restructuring Act of 1998 (112 Stat. 2681, *et seq.*; 22 U.S.C. 6501 note, *et seq.*), Delegation of Authority No. 234 of October 1, 1999 (64 FR 56014), and Delegation of Authority No. 236 of October 19, 1999 (64 FR 57920), as amended, I hereby determine that the objects to be included in the exhibition, ''Art of the First Cities: The Third Millennium B.C. from the Mediterranean to the Indus,'' imported from abroad for temporary exhibition within the United States, are of cultural significance. These objects are imported pursuant to loan agreements with foreign lenders. I also determine that the exhibition or display of the exhibit objects at the Metropolitan Museum of Art, New York, New York, from on or about May 5, 2003, to on or about August 17, 2003, and at possible additional venues yet to be determined, is in the national interest. Public Notice of these determinations is ordered to be published in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: For further information, including a list of exhibit objects, contact Paul W. Manning, Attorney-Adviser, Office of the Legal Adviser, 202/619–5997, and the address is United States Department of State, SA–44, Room 700, 301 4th Street, SW., Washington, DC 20547–0001.

Dated: January 28, 2003.

Patricia S. Harrison,

Assistant Secretary for Educational and Cultural Affairs, Department of State.

[FR Doc. 03–2437 Filed 1–31–03; 8:45 am]

BILLING CODE 4710–08–P

DEPARTMENT OF STATE

[Public Notice 4222]

Advisory Committee on Historical Diplomatic Documentation; Notice of Meeting

The Advisory Committee on Historical Diplomatic Documentation will meet in the Department of State, 2201 ''C'' Street NW., Washington, DC, February 24–25, 2003, in Conference Room 1107. Prior notification and a valid photo are mandatory for entrance into the building. One week before the meeting, members of the public planning to attend must notify Gloria Walker, Office of the Historian (202–663–1124) to provide relevant dates of birth, Social Security numbers, and telephone numbers.

The Committee will meet in open session from 1:30 p.m. through 3 p.m. on Monday, February 24, 2003, to discuss declassification and transfer of Department of State electronic records to the National Archives and Records Administration and the status of the Foreign Relations series. The remainder of the Committee's sessions from 3:15 p.m. until 4:30 p.m. on Monday, February 24, 2003, and 9 a.m. until 1 p.m. on Tuesday, February 25, 2003, will be closed in accordance with section 10(d) of the Federal Advisory Committee Act (Pub. L. 92–463). The agenda calls for discussions of agency declassification decisions concerning the Foreign Relations series and other declassification issues. These are matters not subject to public disclosure under 5 U.S.C. 552b(c)(1) and the public interest requires that such activities be withheld from disclosure.

Questions concerning the meeting should be directed to Marc J. Susser, Executive Secretary, Advisory Committee on Historical Diplomatic Documentation, Department of State, Office of the Historian, Washington, DC, 20520, telephone (202) 663–1123, (e-mail *history@state.gov*).

Dated: January 21, 2003.

Marc J. Susser,

Executive Secretary, Advisory Committee on Historical Diplomatic Documentation, Department of State.

[FR Doc. 03–2438 Filed 1–31–03; 8:45 am]

BILLING CODE 4710–11–P

OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE

Request for Comments on the Operation and Implementation of the World Trade Organization's Agreement on Technical Barriers to Trade

AGENCY: Office of the United States Trade Representative.

ACTION: Request for comments on the operation and implementation of the World Trade Organization's agreement on technical barriers to trade.

SUMMARY: The interagency Trade Policy Staff Committee (TPSC) is seeking public comment on the operation and implementation of the World Trade Organization's (WTO) Agreement on Technical Barriers to Trade (TBT). The WTO Committee on Technical Barriers to Trade, in which the United States is represented, is obliged to conclude a review of the Agreement no later than the end of 2003. The TBT Agreement disciplines the development and application of standards, technical regulations and conformity assessment procedures to prevent unnecessary obstacles to international trade. The text of the Agreement is available at *http://www.wto.org*.

DATES: Written comments are due by noon Friday, February 28.

ADDRESSES: *Submissions by electronic mail: FR0066@ustr.gov*.

Submissions by facsimile: Gloria Blue, Executive Secretary, Trade Policy Staff Committee, at 202/395–6143.

The public is strongly encouraged to submit documents electronically rather than by facsimile. (See requirements for submissions below.)

FOR FURTHER INFORMATION CONTACT: For procedural questions concerning written comments, contact Gloria Blue, (202) 395–3475. Further information on the World Trade Organization and the Agreement on Technical Barriers to Trade can be obtained via Internet at the WTO Web site *http://www.wto.org* and the Office of the U.S. Trade Representative at *http://www.ustr.gov*. Questions on the Agreement on Technical Barriers to Trade and its review should be directed to Suzanne Troje, Director for Technical Barriers to Trade, at the Office of the United States Trade Representative (202) 395–3063.

SUPPLEMENTARY INFORMATION:

1. Background

The TPSC is seeking public comment on the operation and implementation of the WTO TBT Agreement to inform the U.S. position and approach to the Third Triennial Review. Article 15.4 of the Agreement requires such a review and this will be the third conducted by the TBT Committee since the inception of the World Trade Organization in 1995. Article 15.4 requires the Committee to:

> review the operation and implementation of this Agreement, including the provisions relating to transparency, with a view to recommending an adjustment of the rights and obligations of this Agreement where necessary to ensure mutual economic advantage and balance of rights and obligations, without prejudice to the provisions of Article 12 (Special and Differential Treatment for Developing Country Members). Having regard, inter alia, to the experience gained in the implementation of the Agreement, the Committee shall, where appropriate, submit proposals for amendments to the text of this Agreement to the Council for Trade in Goods.

The results of the earlier reviews are available at *www.wto.org:* G/TBT/5 (19 November 1997), First Triennial Review of the Operation and Implementation of the Agreement on Technical Barriers to Trade, and G/TBT/9 (13 November 2000), for the Second Triennial Review.

Since the conclusion of the Second Triennial Review, the Committee has had follow-up discussions on technical assistance and labeling:

Technical Assistance: G/TBT/W/178, Questionnaire for a Survey to Assist Developing Country Members to Identify and Prioritize their Specific Needs in the TBT-Field was developed by the TBT Committee with a view to eliciting information on the priority needs of Members. To date, some 46 WTO members have provided a response. Although the responses are not publically available, the WTO Secretariat presented some information on them in G/TBT/W/186 (14 October 2002). In March 2003 the Committee will host a workshop on technical assistance to discuss issues arising from the survey results and Committee discussions. The Second Triennial Review requires the Committee to assess its progress in implementing its work program in the context of the Third Triennial Review.

Labeling: The Second Triennial Review, under ''other elements'' noted that many trade issues were raised at meetings of the Committee concerning labeling and reiterated the importance of compliance with the Agreement. The Committee has held informal discussions largely on the basis of submissions by Members: G/TBT/W/150 (European Commission), G/TBT/W/162 (Switzerland), G/TBT/W/165 (United States), G/TBT/W/174/Rev.1 (Canada), G/TBT/W/175 (European Commission), and G/TBT/W/176 (Japan). At the request of the Committee and to provide a factual background for its future

discussions, the Secretariat prepared two papers: one, identifying specific trade concerns related to labeling brought to the attention of the TBT Committee since 1995 (G/TBT/W/184); and, one compiling summary information on all of the notifications made under the Agreement since 1995 related to labeling (G/TBT/W/183). In follow-up to a proposal originating in the Canadian paper, the Committee is currently discussing possible topics for a workshop on labeling to be held in conjunction with its June 2003 meeting.

Comments are welcome related to these topics or any other relevant to the operation and implementation of the Agreement.

2. Requirements for Submissions

In order to facilitate prompt processing of submissions, the Office of the United States Trade Representative strongly urges and prefers electronic (e-mail) submissions in response to this notice. In the event that an e-mail submission is impossible, submissions should be made by facsimile.

Persons making submissions by e-mail should use the following subject line: ''WTO TBT Review.'' Documents should be submitted as either WordPerfect, MSWord, or text (.TXT) files. For any document containing business confidential information submitted electronically, the file name of the business confidential version should begin with the characters ''BC–'', and the file name of the public version should begin with the characters ''P–''. The ''P'' or ''BC–'' should be followed by the name of the submitter. Persons who make submissions by e-mail should not provide separate cover letters; information that might appear in a cover letter should be included in the submission itself. To the extent possible, any attachments to the submission should be included in the same file as the submission itself, and not as separate files.

Written comments will be placed in a file open to public inspection pursuant to 15 CFR 2003.5, except business confidential information exempt from public inspection in accordance with 15 CFR 2003.6. Business confidential information submitted in accordance with 15 CFR 2003.6 must be clearly marked ''BUSINESS CONFIDENTIAL'' at the top of each page, including any cover letter or cover page, and must be accompanied by a nonconfidential summary of the confidential information. All public documents and nonconfidential summaries shall be available for public inspection in the USTR Reading Room. The USTR Reading Room is open to the public, by appointment only, from 10 a.m. to 12 noon and 1 p.m. to 4 p.m., Monday through Friday. An appointment to review the file may be made by calling (202) 395–6186. Appointments must be scheduled at least 48 hours in advance.

General information concerning the Office of the United States Trade Representative may be obtained by accessing its Internet server (*http://www.ustr.gov*).

Carmen Suro-Bredie,

Chairman, Trade Policy Staff Committee.

[FR Doc. 03–2356 Filed 1–31–03; 8:45 am]

BILLING CODE 3190–01–P

DEPARTMENT OF TRANSPORTATION

Coast Guard

[USCG 2003–14360]

Collection of Information Under Review by Office of Management and Budget (OMB): OMB Control Number 2115–0614

AGENCY: Coast Guard, DOT.

ACTION: Request for comments.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the Coast Guard intends to seek the approval of OMB for the renewal of one Information Collection Request (ICR). The ICR concerns Alteration of Unreasonably Obstructive Bridges. Before submitting the ICR to OMB, the Coast Guard is inviting comments on it.

DATES: Comments must reach the Coast Guard on or before April 4, 2003.

ADDRESSES: To make sure that your comments and related material do not enter the docket [USCG 2003–14360] more than once, please submit them by only one of the following means:

(1) By mail to the Docket Management Facility, U.S. Department of Transportation (DOT), room PL–401, 400 Seventh Street SW., Washington, DC 20590–0001. Caution: Because of recent delays in the delivery of mail, your comments may reach the Facility more quickly if you choose one of the other means described below.

(2) By delivery to 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.

(3) By fax to the Facility at 202–493–2251.

(4) Electronically through the Web site for the Docket Management System at *http://dms.dot.gov.*

The Facility maintains the public docket for this notice. Comments and material received from the public, as well as documents mentioned in this notice as being available in the docket, will become part of this docket and will be available for inspection or copying at 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. You may also find this docket on the Internet at *http://dms.dot.gov.*

Copies of the complete ICR are available through this docket on the Internet at *http://dms.dot.gov,* and also from Commandant (G–CIM–2), U.S. Coast Guard Headquarters, room 6106 (Attn: Barbara Davis), 2100 Second Street SW., Washington, DC 20593–0001. The telephone number is 202–267–2326.

FOR FURTHER INFORMATION CONTACT: Barbara Davis, Office of Information Management, 202–267–2326, for questions on this document; or Dorothy Beard, Chief, Documentary Services Division, U.S. Department of Transportation, 202–366–5149, for questions on the docket.

Request for Comments

The Coast Guard encourages interested persons to submit comments. Persons submitting comments should include their names and addresses, identify this document [USCG 2003–14360], and give the reasons for the comments. Please submit all comments and attachments in an unbound format no larger than 8½ by 11 inches, suitable for copying and electronic filing. Persons wanting acknowledgment of receipt of comments should enclose stamped self-addressed postcards or envelopes.

Information Collection Request

Title: Alteration of Unreasonably Obstructive Bridges.

OMB Control Number: 2115–0614.

Summary: The collection of information requires the owner of a bridge whose bridge the Coast Guard has found to be an unreasonable obstruction to navigation to prepare, and submit to the Coast Guard, general plans and specifications of that bridge.

Need: Under 33 U.S.C. 494, 502, 511, and 513, the Coast Guard may determine whether a bridge is an unreasonable obstruction to navigation and may require the owner of the bridge to submit information to determine the apportionment of cost between the U.S. and the owner for alteration of that bridge.

Respondents: Owners of bridges.

Frequency: On occasion.

Burden: The estimated burden is 120 hours a year.

Dated: January 27, 2003.

C.I. Pearson,

Rear Admiral, Coast Guard, Director of Information and Technology.

[FR Doc. 03–2424 Filed 1–31–03; 8:45 am]

BILLING CODE 4910–15–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Summary Notice No. PE–2003–03]

Petition for Exemption; Summary of Petition Received

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of petition for exemption received.

SUMMARY: Pursuant to FAA's rulemaking provisions governing the application, processing, and disposition of petitions for exemption part 11 of Title 14, Code of Federal Regulations (14 CFR), this notice contains a summary of a certain petition seeking relief from specified requirements of 14 CFR. The purpose of this notice is to improve the public's awareness of, and participation in, this aspect of FAA's regulatory activities. Neither publication of this notice nor the inclusion or omission of information in the summary is intended to affect the legal status of any petition or its final disposition.

DATES: Comments on petitions received must identify the petition docket number involved and must be received on or before February 24, 2003.

ADDRESSES: Send comments on any petition to the Docket Management System, U.S. Department of Transportation, Room Plaza 401, 400 Seventh Street, SW., Washington, DC 20590–0001. You must identify the docket number FAA–2003–14212 at the beginning of your comments. If you wish to receive confirmation that FAA received your comments, include a self-addressed, stamped postcard.

You may also submit comments through the Internet to *http://dms.dot.gov*. You may review the public docket containing the petition, any comments received, and any final disposition in person in the Dockets Office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The Dockets Office (telephone 1–800–647–5527) is on the plaza level of the NASSIF Building at the Department of Transportation at the above address. Also, you may review public dockets on the Internet at *http://dms.dot.gov*.

FOR FURTHER INFORMATION CONTACT: Mike Brown, Office of Rulemaking (ARM–1), Federal Aviation Administration, 800 Independence Avenue, SW., Washington, DC 20591. Tel. (202) 267–7653.

This notice is published pursuant to 14 CFR 11.85 and 11.91.

Issued in Washington, DC, on January 29, 2003.

Donald P. Byrne,

Assistant Chief Counsel for Regulations.

Petition for Exemption

Docket No.: FAA–2003–14212.

Petitioner: Honeywell Aerospace Electronic Systems.

Section of 14 CFR Affected: 14 CFR 21.621.

Description of Relief Sought: To allow for the continued production and support of Technical Standard Order Authorization (TSOA) products manufactured by Baker Electronics, Inc. Honeywell's immediate acquisition of Baker Electronics would allow Honeywell to make required changes on TSOA drawings and apply for approval of the name change to its current Quality Control System.

[FR Doc. 03–2417 Filed 1–31–03; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

RTCA Special Committee 198: Next-Generation Air/Ground Communications System (NEXCOM)

AGENCY: Federal Aviation Administration (FAA) DOT.

ACTION: Notice of RTCA Special Committee 198 meeting.

SUMMARY: The FAA is issuing this notice to advise the public of a meeting of RTCA Special Committee 198: Next-Generation Air/Ground Communications System (NEXCOM).

DATES: The meeting will be held on February 18–19, 2003, starting at 9 a.m.

ADDRESSES: The meeting will be held at RTCA, 1828 L Street, Suite 805, Washington, DC, 20036.

FOR FURTHER INFORMATION CONTACT: RTCA Secretariat, 1828 L Street, NW., Suite 805, Washington, DC, 20036; telephone (202) 833–9339; fax (202) 833–9434; Wed site *http://www.rtca.org*.

SUPPLEMENTARY INFORMATION: Pursuant to section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463, 5 U.S.C., Appendix 2), notice is hereby given for a Special Committee 198 meeting. The agenda will include:

- February 18:
  - Opening Plenary Session (Welcome and Introductory Remarks, Review Agenda and Minutes of Previous Meeting)
  - Status of RTCA Program Management Committee (PMC) review of the NEXCOM Safety and Performance Requirements (SPR) Documents
  - Discussion of SPR comments for Change 1 and guidance from PMC regarding SPR
  - Status of Working Group-4 (WG), Very High Frequency Digital Link-3 Implementation
  - Status of WG–6, Interoperability of NEXCOM
  - Status of additional work for WG–5 for Plenary Approval
  - Presentation of draft WG–4 Transition Document to Plenary for approval
- February 19:
  - Continuation of Plenary, if needed, to conclude WG–4 review of final draft.
  - WG–4 to finalize document for submission for final review and comment (FRAC)
  - WG–5 continue to review and draft Change 1 to SPR
  - Closing Plenary Session (Date and Place of Next Meeting)

Attendance is open to the interested public but limited to space availability. With the approval of the chairmen, members of the public may present oral statements at the meeting. Persons wishing to present statements or obtain information should contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section. Members of the public may present a written statement to the committee at any time.

Issued in Washington, DC, on January 28, 2003.

Janice L. Peters,

FAA Special Assistant, RTCA Advisory Committee.

[FR Doc. 03–2420 Filed 1–31–03; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Notice of Intent To Rule on Application To Impose and Use the Revenue From a Passenger Facility Charge (PFC) at Dallas-Fort Worth International Airport, DFW Airport, Texas

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of intent to rule on application.

SUMMARY: The FAA proposes to rule and invites public comment on the application to impose and use the revenue from a PFC at Dallas-Fort Worth International Airport under the provisions of the Aviation Safety and Capacity Expansion Act of 1990 (Title IX of the Omnibus Budget Reconciliation Act of 1990) (Pub. L. 101–508) and part 158 of the Federal Aviation Regulations (14 CFR part 158).

DATES: Comments must be received on or before March 5, 2003.

ADDRESSES: Comments on this application may be mailed or delivered in triplicate copies to the FAA at the following address: Mr. G. Thomas Wade, Federal Aviation Administration, Southwest Region, Airports Division, Planning and Programming Branch, ASW–611, Fort Worth, Texas 76193–0610.

In addition, one copy of any comments submitted to the FAA must be mailed or delivered to Mr. Jeffrey P. Fegan, Airport Manager of Dallas-Fort Worth International Airport at the following address: Dallas-Fort Worth International Airport, P.O. Drawer 619428, 3200 East Airfield Drive, DFW Airport, Texas 75261–9428.

Air carriers and foreign air carriers may submit copies of the written comments previously provided to the Airport under § 158.23 of part 158.

FOR FURTHER INFORMATION CONTACT: Mr. G. Thomas Wade, Federal Aviation Administration, Southwest Region, Airports Division, Planning and Programming Branch, ASW–611, Fort Worth, Texas 76193–0610, (817) 222–5613.

The application may be reviewed in person at this same location.

SUPPLEMENTARY INFORMATION: The FAA proposes to rule and invites public comment on the application to impose and use the revenue from a PFC at Dallas-Fort Worth International Airport under the provisions of the Aviation Safety and Capacity Expansion Act of 1990 (Title IX of the Omnibus Budget Reconciliation Act of 1990) (Pub. L. 101–508) and part 158 of the Federal Aviation Regulations (14 CFR part 158).

On January 22, 2003, the FAA determined that the application to impose and use the revenue from a PFC submitted by the Airport was substantially complete within the requirements of § 158.25 of part 158. The FAA will approve or disapprove the application, in whole or in part, no later than April 22, 2003.

The following is a brief overview of the application.

Level of the proposed PFC: $3.00.

Proposed charge effective date: January 1, 2021.

Proposed charge expiration date: May 1, 2021.

Total estimated PFC revenue: $51,900,495.

PFC application number: 03–06–C–00–DFW.

Brief description of proposed project(s):

Projects To Impose and Use PfC's

1. Install Source Isolation Deicing System.

Proposed class or classes of air carriers to be exempted from collecting PFC's: Air Taxi/Commercial Operators under Part 135 filing FAA Form 1800–31.

Any person may inspect the application in person at the FAA office listed above under **FOR FURTHER INFORMATION CONTACT** and at the FAA regional Airports office located at: Federal Aviation Administration, Southwest Region, Airports Division, Planning and Programming Branch, ASW–610, 2601 Meacham Blvd., Fort Worth, Texas 76137–4298.

In addition, any person may, upon request, inspect the application, notice and other documents germane to the application in person at Dallas-Fort Worth International Airport.

Issued in Fort Worth, Texas on January 23, 2003.

William J. Flanagan,

Acting Manager, Airports Division.

[FR Doc. 03–2419 Filed 1–31–03; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Notice of Intent To Rule on Application To Impose and Use the Revenue From a Passenger Facility Charge (PFC) at Jackson International Airport, Jackson, MS

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of intent to rule on application.

SUMMARY: The FAA proposes to rule and invites public comment on the application to impose and use the revenue from a PFC at Jackson International Airport under the provisions of the Aviation Safety and Capacity Expansion Act of 1990 (Title IX of the Omnibus Budget Reconciliation Act of 1990) (Pub. L. 101–508) and Part 158 of the Federal Aviation Regulations (14 CFR part 158).

DATES: Comments must be received on or before March 5, 2003.

ADDRESSES: Comments on this application may be mailed or delivered in triplicate to the FAA at the following address: Jackson Airports District Office, 100 West Cross Street, Jackson, Mississippi 39208–2307.

In addition, one copy of any comments submitted to the FAA must be mailed or delivered to Dirk Vanderleest, Executive Director of the Jackson Municipal Airport Authority at the following address: Post Office Box 98109, Jackson, MS 39298–8109.

Air carriers and foreign air carriers may submit copies of written comments previously provided to the Jackson Municipal Airport Authority under § 158.23 of Part 158.

FOR FURTHER INFORMATION CONTACT: David Shumate, Program Manager, Jackson Airports District Office, 100 West Cross Street, Jackson, Mississippi, (601) 664–9882. The application may be reviewed in person at this same location.

SUPPLEMENTARY INFORMATION: The FAA proposes to rule and invites public comment on the application to impose and use the revenue from a PFC at Jackson International Airport under the provisions of the Aviation Safety and Capacity Expansion Act of 1990 (Title IX of the Omnibus Budget Reconciliation Act of 1990) (Pub. L. 101–508) and Part 158 of the Federal Aviation Regulations (14 CFR part 158).

On January 7, 2003, the FAA determined that the application to impose and use the revenue from a PFC submitted by Jackson Municipal Airport Authority was substantially complete within the requirements of § 158.25 of part 158. The FAA will approve or disapprove the application, in whole or in part, no later than May 6, 2003.

The following is a brief overview of the application.

PFC Application No.: 03–04–C–00–JAN.

Level of the proposed PFC: $3.00.

Proposed charge effective date: February 1, 2007.

Proposed charge expiration date: June 1, 2010.

Total estimated net PFC revenue: $6,211,722.

Brief description of proposed project(s): Runway Sweeper; Tricherator; Local Share & Engineering West Parallel Lights; Local Share & Engineering West Taxiway Overlay; Local Share Air Cargo Road; Local Share Air Cargo Apron/Taxiway; H. F. Environmental Assessment; Metes & Bounds Survey; Surface Transportation System; Rehab International Drive

Class or classes of air carriers which the public agency has requested not be required to collect PFCs: All air taxi/commercial operators (ATCO) are requested to be excluded from the collection of a PFC.

Any person may inspect the application in person at the FAA office listed above under **FOR FURTHER INFORMATION CONTACT.**

In addition, any person may, upon request, inspect the application, notice and other documents germane to the application in person at the Jackson Municipal Airport Authority.

Issued in Jackson, Mississippi on January 27, 2003.

David Shumate,

Acting Manager, Jackson Airports District Office Southern Region.

[FR Doc. 03–2421 Filed 1–31–03; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Notice To Intend To Rule on Application 03–05–C–00–ISP To Impose and Use the Revenue From a Passenger Facility Charge (PFC) at Long Island MacArthur Airport, Ronkonkoma, NY

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice to intend to rule on application.

SUMMARY: The FAA proposes to rule and invites public comment on the application to impose and use a PFC at Long Island MacArthur Airport under the provisions of the Aviation Safety and Capacity Act of 1990 (Title IX of the Omnibus Budget Reconciliation Act of 1990) (Pub. L. 101–508) and part 158 of the Federal Aviation Regulations (14 CFR part 158).

DATES: Comments must be received on or before March 5, 2003.

ADDRESSES: Comments on this Application may be mailed or delivered in triplicate to the FAA at the following address: Mr. Dan Vornea, Project Manager, New York District Office, 600 Old Country Road, Suite 446, Garden City, N.Y. 11530.

In addition, one copy of any comments submitted to the FAA must be mailed or delivered to Mr. Alfred Werner, Airport Manager, of the Long Island MacArthur Airport at the following address: Long Island MacArthur Airport, 100 Arrival Avenue, Ronkonkoma, N.Y. 11779.

Air carriers and foreign air carriers may submit copies of their written comments previously provided to Long Island MacArthur Airport under § 158.23 of Part 158.

FOR FURTHER INFORMATION CONTACT: Dan Vornea, Project Manager, New York Airports District Office, 600 Old Country Road, Suite 446, Garden City, N.Y. 11530, Telephone No. (516) 227–3812. The application may be reviewed in person at this same location.

SUPPLEMENTARY INFORMATION: The FAA proposes to rule and invites public comment on the application to impose and use a PFC at Long Island MacArthur Airport under the provisions of the Aviation Safety and Capacity Expansion Act of 1990 (Title IX of the Omnibus Budget Reconciliation Act of 1990) (Pub. L. 101–508) and part 158 of the Federal Aviation Regulations (14 CFR part 158).

On January 28, 2003 the FAA determined that the application to impose and use a PFC submitted by the Town of Islip was substantially completed within the requirements of section 158.25 of part 158. The FAA will approve or disapprove the application, in whole or in part, no later than May 28, 2003.

The following is a brief overview of the application:

Application Number: 03–05–C–00–ISP.

Level of Proposed PFC: $3.00.

Proposed Charge Effective Date: August 1, 2005.

Proposed Charge Expiration Date: October 1, 2005.

Total Estimated PFC Revenue: $493,001

Brief Description of Proposed Projects:

—Rehabilitation of Runway 6–24 (Impose and Use).
—Wildlife Hazard Management Assessment and Management Plan (Impose and Use).
—Acquire two (2) Snow Removal Brooms (Impose and Use).
—Purchase one (1) Passenger Boarding Assistance Device (Impose and Use).
—Airport Security Enhancement Items (Impose and Use).

Class or classes of air carriers which the public agency has requested not to be required to collect PFS's are: Non-Scheduled/On Demand Air Carriers filing FAA Form 1800–31.

Any person may inspect the Application in person at the FAA office listed above under **FOR FURTHER INFORMATION CONTACT** and at the FAA Regional Office: 1 Aviation Plaza, Jamaica, N.Y. 11434–4809.

In addition, any person may, upon request, inspect the appliation notice and other documents germane to the application in person at the Long Island MacArthur Airport.

Issued in Garden City, New York on January 28, 2003.

Philip Brito,

Manager, NYADO Eastern Region.

[FR Doc. 03–2418 Filed 1–31–03; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[U.S. DOT Docket Number NHTSA–2002–14108]

Reports, Forms, and Recordkeeping Requirements

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation.

ACTION: Request for public comment on proposed collection of information.

SUMMARY: Before a Federal agency can collect certain information from the public, it must receive approval from the Office of Management and Budget (OMB). Under procedures established by the Paperwork Reduction Act of 1995, before seeking OMB approval, Federal agencies must solicit public comment on proposed collections of information, including extensions and reinstatement of previously approved collections.

This document describes one collection of information for which NHTSA intends to seek OMB approval.

DATES: Comments must be received on or before April 4, 2003.

ADDRESSES: Comments must refer to the docket notice numbers cited at the beginning of this notice and be submitted to Docket Management, Room PL–401, 400 Seventh Street, SW., Washington, DC 20590. Please identify the proposed collection of information for which a comment is provided, by referencing its OMB clearance number. It is requested, but not required, that two copies of the comment be provided. The Docket Section is open on weekdays from 10 a.m. to 5 p.m.

FOR FURTHER INFORMATION CONTACT: Gary Toth, Office of Crash Investigation (NPO–122), Room 6115, 400 Seventh Street, SW., Washington, DC 20590. Mr. Toth's telephone number is (202) 366–5378. Please identify the relevant collection of information by referring to its OMB Control Number.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995, before an agency submits a proposed collection of information to OMB for approval, it must first publish a document in the **Federal Register**

providing a 60-day comment period and otherwise consult with members of the public and affected agencies concerning each proposed collection of information. The OMB has promulgated regulations describing what must be included in such a document. Under OMB's regulation (at 5 CFR 1320.8(d)), an agency must ask for public comment on the following:

(i) 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) 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) How to enhance the quality, utility, and clarity of the information to be collected;

(iv) How to minimize the burden of the collection of information on those who are to respond including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.* permitting electronic submission of responses.

In compliance with these requirements, NHTSA asks for public comments on the following proposed collections of information:

Title: National Automotive Sampling System (NASS).

Type of Request: Extension of a currently approved collection.

OMB Control Number: 2127–0021.

Affected Public: Passenger motor vehicle operators.

Abstract: The collection of crash data that support the establishment and enforcement of motor vehicle regulations that reduce the severity of injury and property damage caused by motor vehicle crashes is authorized under the National Traffic and Motor Vehicle Safety Act of 1966 (Pub. L. 89–563, title 1, sec. 106, 108, and 112). The National Automotive Sampling System (NASS) Crashworthiness Data System (CDS) of the National Highway Traffic Safety Administration investigates high severity crashes. Once a crash has been selected for investigation, researchers locate, visit, measure, and photograph the crash scene; locate, inspect, and photograph vehicles; conduct a telephone or personal interview with the involved individuals or surrogate; and obtain and record injury information received from various medical data sources. NASS CDS data are used to describe and analyze circumstances, mechanisms, and consequences of high severity motor vehicle crashes in the United States. The collection of interview data aids in this effort.

Estimated Annual Burden: 5,807 hours.

Number of respondents: 13,500.

Raymond P. Owings,

Associate Administrator for Advanced Research and Analysis.

[FR Doc. 03–2460 Filed 1–31–03; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[Docket NHTSA–99–5087]

Rulemaking Program Meeting

AGENCY: National Highway Traffic Safety Administration (DOT).

ACTION: Notice of NHTSA rulemaking status meeting.

SUMMARY: This notice announces a public meeting at which NHTSA will answer questions from the public and the automobile industry regarding the agency's vehicle regulatory program.

DATES: The Agency's regular public meeting relating to its vehicle regulatory program will be held on Thursday, April 3, 2003, beginning at 9:45 a.m. and ending at approximately 12 p.m. at the Best Western Gateway International Hotel 9191 Wickham, Romulus, Michigan. Questions relating to the vehicle regulatory program must be submitted in writing with a diskette (Microsoft Word) by Wednesday, March 12, 2003, to the address shown below or by e-mail. If sufficient time is available, questions received after March 12, may be answered at the meeting. The individual, group or company submitting a questions(s) does not have to be present for the questions(s) to be answered. A consolidated list of the questions submitted by March 12, 2003, and the issues to be discussed will be posted on NHTSA's Web site (*www.nhtsa.dot.gov*) by Monday, April 1, 2003, and also will be available at the meeting. The agency will hold a second public meeting on April 3, devoted exclusively to a presentation of research and development programs. This meeting will begin at 1:30 p.m. and end at approximately 5 p.m. This meeting is described more fully in a separate announcement. The next NHTSA Public Meeting will take place on Thursday, July 17, 2003, at the Hyatt Regency in Baltimore, on the Inner Harbor, 300 Light Street Baltimore, MD 21202.

ADDRESSES: Questions for the April 3, NHTSA Rulemaking Status Meeting, relating to the agency's vehicle regulatory program, should be submitted to Delia Lopez, NVS–100, National Highway Traffic Safety Administration, Room 5401, 400 Seventh Street, SW., Washington, DC 20590, Fax Number 202–366–4329, e-mail *dlopez@nhtsa.dot.gov*. The meeting will be held at the Best Western Gateway International Hotel, Romulus, Michigan 48174, the telephone number is (734) 728–2800.

FOR FURTHER INFORMATION CONTACT: Delia Lopez, (202) 366–1810.

SUPPLEMENTARY INFORMATION: NHTSA holds regular public meetings to answer questions from the public and the regulated industries regarding the agency's vehicle regulatory program. Questions on aspects of the agency's research and development activities that relate directly to ongoing regulatory actions should be submitted, as in the past, to the agency's Rulemaking Office. Transcripts of these meetings will be available for public inspection in the DOT Docket in Washington, DC, within four weeks after the meeting. Copies of the transcript will then be available at ten cents a page, (length has varied from 80 to 150 pages) upon request to DOT Docket, Room PL–401, 400 Seventh Street, SW., Washington, DC 20590. The DOT Docket is open to the public from 10 a.m. to 5 p.m. The transcript may also be accessed electronically at *http://dms.dot.gov*, at docket NHTSA–99–5087. Questions to be answered at the public meeting should be organized by categories to help us process the questions into an agenda form more efficiently.

Sample format:

I. Rulemaking
  A. Crash avoidance
  B. Crashworthiness
  C. Other Rulemakings
II. Consumer Information
III. Miscellaneous

NHTSA will provide auxiliary aids to participants as necessary. Any person desiring assistance of ''auxiliary aids'' (*e.g.*, sign-language interpreter, telecommunications devices for deaf persons (TDDs), readers, taped texts, brailled materials, or large print materials and/or a magnifying device), please contact Delia Lopez on (202) 366–1810, by COB Monday, April 1, 2003.

Issued: January 24, 2003.

Stephen R. Kratzke,

Associate Administrator for Rulemaking.

[FR Doc. 03–2427 Filed 1–31–03; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[Docket No. NHTSA–03–14395]

NHTSA's Activities under the United Nations Economic Commission for Europe 1998 Global Agreement

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation.

ACTION: Notice of activities under the 1998 Global Agreement and request for comments.

SUMMARY: NHTSA is publishing this notice to inform the public of the tentative schedule of meetings of the World Forum for the Harmonization of Vehicle Regulations (WP.29) and its working parties of experts for calendar year 2003. In addition, this notice informs the public about the 1998 Global Agreement program of work that was agreed to by the Executive Committee of the Agreement and adopted by WP.29. Finally, NHTSA is seeking comments regarding a draft U.S. proposal for the development of a global technical regulation on door locks and door retention components under the 1998 Global Agreement. Publication of this information is consistent with NHTSA's Statement of Policy regarding Agency Policy Goals and Public Participation in the Implementation of the 1998 Agreement on Global Technical Regulations.

DATES: Written comments may be submitted to this agency and must be received by March 5, 2003.

ADDRESSES: You may submit your comments in writing to: Docket Management, Room PL–401, 400 Seventh Street, SW., Washington, DC, 20590. Alternatively, you may submit your comments electronically by logging onto the Dockets Management System Web site at *http://dms.dot.gov.* Click on ''Help & Information'' or ''Help/Info'' to view instructions for filing your comments electronically. Regardless of how you submit your comments, you should mention the docket number of this document.

FOR FURTHER INFORMATION CONTACT: Ms. Julie Abraham, Director of the Office of International Policy and Harmonization (NPP–01), National Highway Traffic Safety Administration, 400 Seventh Street, SW., Washington, DC, 20590; phone number (202) 366–2114, fax number (202) 366–2559.

SUPPLEMENTARY INFORMATION:

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VI. Appendix

I. Introduction

On August 23, 2000, NHTSA published in the **Federal Register** (65 FR 51236) a statement of policy indicating that the agency would provide each calendar year a list of scheduled meetings of WP.29 and the working parties of experts, as well as meetings of the Executive Committee of the 1998 Global Agreement. Further, in that policy statement, the agency stated that it would keep the public informed about a program of work under the Agreement (*i.e.*, the agreed subjects for which a global technical regulations should be developed) as well as a list of candidate global technical regulations that have been formally proposed by a contracting party and referred to a working party of experts. NHTSA also indicated that before submitting a draft U.S. proposal for the development of a global technical regulation to WP.29, NHTSA would publish a notice requesting public comments on the draft proposal.

On July 18, 2000, NHTSA published in the **Federal Register** (65 FR 44565) a notice seeking public comments on its preliminary recommendations for the first motor vehicle safety technical regulations to be considered for establishment under the Agreement. On January 18, 2001, the agency, after consideration of the comments, published in the **Federal Register** (66 FR 4893) a notice outlining its final recommendations. In that notice, the agency stated that it would present those recommendations to WP.29 and propose them for consideration by other contracting parties of the 1998 Global Agreement concerning the adoption of a program of work under the Agreement. The agency also stated that it would report to the public the final outcome of the deliberations.

II. List of Tentative Meetings of WP.29 and Its Working Parties of Experts

The following list contains meetings tentatively scheduled for calendar year 2003. The meeting dates are subject to confirmation by the Inland Transport Committee during its February 2003 session. The agency does not anticipate any changes to the schedule. In addition, working parties of experts may schedule, if necessary, informal meetings in addition to their regularly scheduled ones in order to address specific regulations.

Schedule of Meetings of WP.29 and Its Working Parties of Experts

January

13–17 Working Party on Pollution and Energy (GRPE) (45th session).

February

3–7 Working Party on Brakes and Running Gear (GRRF) (53rd session).

March

10 Administrative Committee for the Coordination of Work (WP.29/AC.2) (81st session).
11–14 World Forum for Harmonization of Vehicle Regulations (WP.29)—(129th session) and Administrative Committee to the 1958 Agreement (AC.1) (23rd session) and Executive Committee of the 1998 Agreement (AC.3) (seventh session).

April

7–11 Working Party on Lighting and Light-Signalling (GRE) (50th session).

May

5–9 Working Party on General Safety Provisions (GRSG) (84th session).
20–23 Working Party on Pollution and Energy (GRPE) (46th session).

June

2–6 Working Party on Passive Safety (GRSP) (33rd session).
23 Administrative Committee for the Coordination of Work (WP.29/AC.2) (82nd session).
24–27 World Forum for Harmonization of Vehicle Regulations (WP.29) (130th session) and AC.1 (24th session) and AC.3 (eighth session).

September

15–19 Working Party on Lighting and Light-Signalling (GRE) (51st session).

October

6–8 Working Party on Brakes and Running Gear (GRRF) (54th session).
9–10 Working Party on Noise (GRB) (38th session).
21–24 Working Party on General Safety Provisions (GRSG) (85th session).

November

10 Administrative Committee for the Coordination of Work (WP.29/AC.2) (83rd session).

11–14 World Forum for Harmonization of Vehicle Regulations (WP.29) (131st session) and AC.1 (25th session) and AC.3 (ninth session).

December

8–12 Working Party on Passive Safety (GRSP) (34th session).

III. Program of Work of the 1998 Global Agreement

In March 2001, NHTSA submitted to WP.29 and the Executive Committee of the 1998 Global Agreement its final recommendations for the first motor vehicle safety technical regulations to be considered for establishment under that Agreement. The Administrative Committee for the Coordination of Work of WP.29 (AC.2) reviewed the recommendations made by various contracting parties, including the United States, Canada, the European Union, Japan, and Russia, as well as those made by other interested parties and reached agreement on a Program of Work, taking into account the workload of the working parties of experts under WP.29. AC.2 then submitted the Program of Work to the Executive Committee of the 1998 Global Agreement (AC.3). The AC.3 approved the Program of Work and requested that contracting parties volunteer to sponsor each listed regulation by submitting a formal proposal as required by Article 6 of the 1998 Global Agreement. WP.29 formally adopted the Program of Work at its session in March 2002. During the June and November 2002 sessions of WP.29, several contracting parties stepped forward as sponsors for the individual work items. The following table lists the subjects and the sponsoring contracting party.

PROGRAM OF WORK OF THE 1998 GLOBAL AGREEMENT

Working party of experts	Subject	Sponsoring contracting party
GRE	Installation of Lighting and Light-Signalling Devices	Canada.
GRRF	Motorcycle Brakes	Canada.
	Passenger Vehicle Brakes	To be determined.
GRSG	Safety Glazing	Germany.
	Controls and Displays	Canada.
	Vehicle Classification, Masses and Dimensions	Japan.
GRSP	Pedestrian Safety	European Community.
	Lower Anchorages and Tethers for Child Safety Seats	TBD.
	Door Locks and Door Retention Components	U.S.A.
	Head Restraints	TBD.
GRPE	Worldwide Heavy-Duty Certification Procedure	European Community.
	Worldwide Motorcycle Emission Test Cycle	TBD.
	Heavy-Duty On-Board Diagnostics	U.S.A.
	Off-Cycle Emissions	U.S.A.
	Non-Road Mobile Machinery	European Community.

In addition, the contracting parties will begin exchanges of information in the following areas: tires, under the GRRF; field of vision (GRSG); side-impact dummy and compatibility (GRSP); fuel cells and worldwide light-duty vehicle test procedures (GRPE); and intelligent vehicle systems (WP.29).

IV. Formal Proposals for the Development of Global Technical Regulations Submitted by Contracting Parties

As of December 2002, pursuant to Article 6 of the 1998 Global Agreement, which sets forth the process and conditions under which a contracting party may make proposals for the establishment of global technical regulations, there had been two formal proposals for global technical regulations. One proposal addresses controls and displays, and the other one addresses on-board diagnostics for heavy-duty vehicles and machinery. A copy of the former, which was proposed by Canada, is available in the docket for this notice. Both proposals can be found on the UN/ECE Web site *http://www.unece.org/trans/main/wp29/wp29wgs/wp29gen/gen2002.html* as UNECE documents Trans/WP.29/2002/29 and Trans/WP.29/2002/26, respectively.

V. Request for Comments on U.S. Draft Proposal for a GTR

During the upcoming meeting of WP.29 and the Executive Committee of the 1998 Global Agreement in March 2003, NHTSA will formalize its sponsorship of the regulation on Door Locks and Door Retention Components, as identified in the Program of Work of the 1998 Global Agreement. The draft proposal describes the objective of the global technical regulation and identifies in general terms issues to be considered during the development of the regulation. Please provide public comments on the draft proposal set forth in the appendix to this notice. NHTSA will take all public comments into account before submitting the proposal to WP.29 during its March 2003 session.

Appendix—U.S. Proposal for the Development of a Global Technical Regulation on Door Locks and Door Retention Components, To be Submitted to the Executive Committee of the 1998 Global Agreement (AC.3), March 2003

A. Objective of the Proposal

In the U.S., between 1994 and 1999, complete and partial ejections resulted in approximately 9,864 fatalities and 9,767 serious injuries per year. Door ejections accounted for 1,668 of those fatalities (19%) and 1,976 of the serious injuries (22%). Hinged side door openings accounted for approximately 90% of all door ejection fatalities and 93% of all door ejection serious injuries. This situation is likely to be a problem elsewhere.

The objective of this proposal is to develop a global technical regulation regarding door locks and door retention components intended to reduce door latch system failures. In view of the 1998 Global Agreement, we now have an opportunity to develop an improved and harmonized door locks and door retention components regulation. Moreover, the work on the global regulation will provide an opportunity

to consider in the new regulation most, if not all, international safety concerns as well as available technological developments.

The U.S. is currently looking into upgrading its door locks and door retention components regulation to provide more stringent requirements. The current regulation was designed to test for door openings in vehicles that were built in the 1960s. Changes in vehicle latch designs common in the 1960s and 1970s have rendered the existing regulations largely obsolete. Likewise, the ECE regulation is now over 30 years old. Neither regulation has been amended significantly since their original adoption. Accordingly, the existing regulations have become less effective and likely do not provide many safety benefits at this time.

In light of the U.S. regulatory upgrade effort, we believe that this would be an excellent opportunity for the international community to develop a GTR concurrently with the U.S. Everyone could benefit from harmonization and new technology-based improvements of the door locks and door retention components regulation. The benefits to the governments would be the improvement of the door locks and door retention components adoption of the best safety practices, the leveraging of resources, and the harmonization of requirements. Manufacturers would benefit from reduction of the cost of development, testing and fabrication process of new models. Finally the consumer would benefit by having better choice of vehicles built to higher, globally recognized standards providing a better level of safety at a lower price.

B. Description of the Proposal to Develop a Regulation

The current requirements only test individual latch components without regard to how those components interact with each other, with other portions of the door, or with the directions of force loading conditions occurring in real world crashes. Door openings are frequently caused by a combination of longitudinal and lateral forces during the crash, which can subject the latch system to compressive longitudinal and tensile lateral forces. These forces often result in structural failures of the latch system as well as other non-latch systems such as hinge strike supports, door frame and door sheet metal. Hence, it would be beneficial to consider developing full system requirements. In addition, current requirements have no test procedure for evaluating the safety of sliding doors. Consideration of such requirements would be valuable.

The GTR will be applicable for passenger vehicles, multi-purpose vehicles as well as trucks. The performance and test requirements for the door latch, striker and hinges will be based on the stringency needed to attain reasonable safety benefits in a cost effective manner. The GTR will be developed based in part on existing national regulations, directives of contracting parties as well as the international standards and regulations listed below. The U.S. prepared a table to facilitate comparison of the present U.S. and ECE regulations, which are currently being widely used by many contracting parties. The table is available in the docket for this notice.

The results of additional research and testing conducted by any contracting parties since the existing regulations were promulgated will also be factored into the requirements of the draft GTR and may result in the proposal of new requirements.

Elements of the GTR, which cannot be resolved by the Working Party will be identified and dealt with in accordance with protocol established by AC.3 and WP.29. The proposed GTR will be drafted in the format adopted by WP.29 (TRANS/WP.29/882).

C. Existing Regulations and Directives

Though there are no regulations currently contained in the Compendium of Candidates, the following regulations and standards will be taken into account during development of the new global technical regulation regarding door locks and door retention components.

- UN/ECE Regulation 11—Uniform provisions concerning the approval of vehicles with regard to door latches and door retention components.
- U.S. Code of Federal Regulations (CFR) Title 49: Transportation; Part 571.206: Door locks and door retention components.
- EU Directive 70/387/EEC, concerning the doors of motor vehicles and their trailers.
- Canada Motor Vehicle Safety Regulation No. 206—Door locks and door retention components.
- Japan Safety Regulation for Road Vehicle Article 25—Entrance.
- Australian Design Rule 2/00—Side Door Latches and Hinges.

D. Existing International Voluntary Standards

The following international voluntary standards will be taken into account during development of the new global technical regulation regarding door locks and door retention components.

- SAE J839, September 1998—Passenger Car Side Door Latch Systems.
- SAE J934, September 1998—Vehicle Passenger Door Hinge Systems.

Issued on: January 29, 2003.

Rose A. McMurray,

Associate Administrator for Planning, Evaluation and Budget.

[FR Doc. 03–2367 Filed 1–31–03; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[Docket No. NHTSA 2002–13242; Notice 2]

Goodyear Tire & Rubber Company, Grant of Application for Decision That Noncompliance Is Inconsequential to Motor Vehicle Safety

Goodyear Tire & Rubber Company (Goodyear) has determined that approximately 2,400 of the 66,697 P275/55R20 Eagle LS and P245/70R16 Wrangler SRA tires manufactured and shipped during the period May 25, 2002 to June 16, 2002, do not meet the labeling requirements mandated by Federal Motor Vehicle Safety Standard (FMVSS) No. 109, ''New pneumatic tires.''

Pursuant to 49 U.S.C. 30118(d) and 30120(h), Goodyear has petitioned for a determination that this noncompliance is inconsequential to motor vehicle safety and has filed an appropriate report pursuant to 49 CFR part 573, ''Defect and Noncompliance Reports.'' Notice of receipt of the application was published, with a 30-day comment period, on September 5, 2002, in the **Federal Register** (67 FR 56873). NHTSA received no comment on this application.

FMVSS No. 109 (S4.3(d)) requires that each tire shall have permanently molded the generic name of each cord material used in the plies (both sidewall and tread area) of the tire.

From May 25, 2002, to June 16, 2002, Goodyear produced and cured a maximum of 2,400 tires with an erroneous marking. These tires were marked with the cord material identified as polyester when it was actually nylon.

Goodyear states that the subject tires have been tested and the results indicate that all performance requirements of FMVSS No. 109 were met or exceeded. Goodyear considers this to be an isolated case. Goodyear has put into effect additional quality steps to ensure that only the correct fabric and its corresponding marking are used in the

future. Goodyear stated that the noncompliance is one solely of labeling.

The Transportation Recall, Enhancement, Accountability, and Documentation (TREAD) Act (Pub. L. 106–414) required, among other things, that the agency initiate rulemaking to improve tire label information. In response, the agency published an Advance Notice of Proposed Rulemaking (ANPRM) in the **Federal Register** on December 1, 2000. (65 FR 75222). The agency received more than 20 comments on the tire labeling information required by 49 CFR §§ 571.109 and 119, part 567, part 574, and part 575. With regard to the tire construction labeling requirements of FMVSS 109, S4.3(d), most commenters indicated that the information was of little or no safety value to consumers. However, according to the comments, when tires are processed for retreading or repairing, it is important for the retreader or repair technician to understand the make-up of the tires and the types of plies. This enables them to select the proper repair materials or procedures for retreading or repairing the tires. A steel cord radial tire can experience a circumferential or ''zipper'' rupture in the upper sidewall when it is operated underinflated or overloaded. If information regarding the number of plies and cord material is incorrect or removed from the sidewall, technicians cannot determine if the tire has a steel cord sidewall ply. This information is critical when determining if the tire is a candidate for a zipper rupture. In this case, since the tires are not of steel cord construction, but are actually nylon (though marked polyester), this potential safety concern does not exist.

In addition, the agency conducted a series of focus groups, as required by the Tread Act, to examine consumer perceptions and understanding of tire labeling. Few of the focus group participants had knowledge of tire labeling beyond the tire brand name, tire size, and tire pressure.

Based on the information obtained from comments to the ANPRM and the consumer focus groups, we have concluded that it is likely that few consumers have been influenced by the tire construction information (*e.g.*, cord material in the sidewall) provided on the tire sidewall when deciding to buy a motor vehicle or tire.

The agency believes that the true measure of inconsequentiality to motor vehicle safety in this case is the effect of the noncompliance on the operational safety of vehicles on which these tires are mounted. This labeling noncompliance has no effect on the performance of the subject tires.

In consideration of the foregoing, NHTSA has decided that the applicant has met its burden of persuasion that the noncompliance is inconsequential to motor vehicle safety. Accordingly, its application is granted and the applicant is exempted from providing the notification of the noncompliance as required by 49 U.S.C. 30118, and from remedying the noncompliance, as required by 49 U.S.C. 30120.

Authority: (49 U.S.C. 30118, 30120; delegations of authority at 49 CFR 1.50 and 501.8)

Issued on: January 28, 2003.

Stephen R. Kratzke,

Associate Administrator for Rulemaking.

[FR Doc. 03–2425 Filed 1–31–03; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[Docket No. NHTSA–2003–14229]

Kawasaki Motors Corporation, U.S.A., Notice of Application for Decision of Inconsequential Noncompliance

Kawasaki Motors Corporation U.S.A. of Irvine, California (''KMC''), has determined that some 2002 and 2003 model year Kawasaki motorcycles produced for sale in the U.S. fail to comply with a requirement in Federal Motor Vehicle Safety Standards (FMVSS) No. 123, ''Motorcycle Controls and Displays.'' The motorcycles in question have ignition switches which are not labeled with the word ''ignition.'' Pursuant to 49 U.S.C. 30118(d) and 30120(h), KMC has petitioned for a determination that this noncompliance is inconsequential to motor vehicle safety so that KMC would be exempted from recall and remedy requirements.

KMC filed an appropriate report with the agency pursuant to 49 CFR part 573, ''Defect and Noncompliance Reports.'' The report indicates that KMC produced 7,630 noncompliant motorcycles, all of which are Vulcan 1500 models. That includes 4,450 model VN1500–P1 (MY2002) and 3,180 model VN1500–P2 (MY2003) motorcycles with this noncompliance as of October 18, 2002.

We are publishing this notice of receipt of the KMC application as required by 49 U.S.C. 30118 and 30120. This action does not represent any agency decision or other exercise of judgment concerning the merits of the application.

FMVSS No. 123 standardizes motorcycle controls to minimize the risk of crashes resulting from operator errors in the use of controls. In FMVSS No. 123, paragraph S5.2.3 specifies that certain motorcycle components must be labeled as listed in Table 3 of the Standard. Table 3, Item no. 1, specifies that the ignition shall be labeled with the word ''ignition'' as well as the word ''off'' at the appropriate ignition switch position. Proper labeling of the ignition helps to ensure that a rider who needs to quickly turn off a motorcycle for safety reasons will be able to locate, identify, and operate the ignition control.

KMC described the operation of the motorcycles with the noncompliance as follows:

> The ignition switch is located in a pod positioned immediately in front of the operator, just ahead of the fuel filler opening on the top of the fuel tank. The switch is operated by an ignition key and has three positions, sequentially in a clockwise direction: ''off'' where the ignition is disabled; ''on'' where the ignition is enabled; and ''park'' where the ignition is disabled but minimal lighting functions are enabled. These ignition switch positions are labeled on a metal plate that surrounds the ignition switch and which also contains the turn signal indicator lamps, neutral and high beam indicators. Unlike standard automotive practice, the ignition switch does not operate the starter motor—the starter button is located on the handlebar. Starting the motorcycle involves insertion of the key into the switch and turning the ignition to the ''on'' position, then operating the separate starter button. An operator would not be able to start the engine inadvertently by using only the ignition switch.

KMC stated the following in support of its application for inconsequential noncompliance:

> No safety consequences attach to the omission of the ''ignition'' identification for the switch. Operators are familiar with the function and location of the ignition switch as well as the use of the ignition key to operate the switch. The location of the switch, in combination with frequently referenced displays such as turn signal, neutral, and high beam indicators means that the operator is quite familiar with the switch and its location, and experiences no adverse consequences from the lack of ''ignition'' identification for the switch. In fact, an operator unable to identify the ignition switch, due to the lack of labeling, would be unable to start or operate the motorcycle in the first place.

The other ignition switch labeling, *i.e.*, the word ''off'' at the appropriate switch position, is present as required, and the remainder of the vehicle controls and displays otherwise meet the requirements of FMVSS No. 123.

KMC is not aware of any accidents, injuries, owner complaints or field reports for the subject vehicles related to

this condition and has received no communications of any kind from owners, dealers, or anyone else indicating any awareness of the missing label.

Interested persons are invited to submit written data, views, and arguments on the application described above. Comments should refer to the docket number and be submitted to: U.S. Department of Transportation, Docket Management, Room PL–401, 400 Seventh Street, SW., Washington, DC 20590. It is requested that two copies be submitted.

All comments received before the close of business on the closing date indicated below will be considered. The application and supporting materials, and all comments received after the closing date, will also be filed and will be considered to the extent possible. When the application is granted or denied, the notice will be published in the **Federal Register** pursuant to the authority indicated below. Comment closing date: March 5, 2003.

(49 U.S.C. 301118, 301120; delegations of authority at 49 CFR 1.50 and 501.8)

Issued on: January 27, 2003.

Stephen R. Kratzke,

Associate Administrator for Rulemaking.

[FR Doc. 03–2426 Filed 1–31–03; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[Docket No. NHTSA–03–14197; Notice 1]

Shelby American, Inc.; Application for Temporary Exemption From Federal Motor Vehicle Safety Standard No. 208

Shelby American, Inc., of Las Vegas, Nevada (''Shelby''), on behalf of its wholly-owned subsidiary Shelby Series One, Inc., has applied for a three-year exemption from the automatic restraint provisions of Federal Motor Vehicle Safety Standard No. 208 *Occupant Crash Protection* (S4.1.5.3). The basis of the application is that compliance would cause substantial economic hardship to a manufacturer that has tried in good faith to comply with the standard.

This notice of receipt of the petition is published in accordance with agency regulations on the subject and does not represent any judgment by the agency about the merits of the petition.

Shelby is a Texas corporation, privately held and owned by Carroll H. Shelby and Venture Holdings, Inc. Its current business activities are conducted by four wholly-owned subsidiaries. The first of these subsidiaries is Shelby Series One, Inc., the unit that produces the passenger cars which are the subject of this application for a temporary exemption. The current vehicle is designated Series 1 and its successor will be Series 2. The second Shelby subsidiary is Shelby CSX4000, Inc., which produces ''component vehicles'' sold without engine or transmission. The third subsidiary is Shelby Original 427 S/Cs, Inc., whose business is to assemble automobiles ''from certain new old stock parts surviving from the original 1965 Shelby Cobra production run * * * supplemented by newly manufactured parts utilizing original tooling.'' The fourth subsidiary, Shelby Performance, Inc., does not assemble vehicles but offers aftermarket products.

Shelby informed us that, as of the date of its petition, July 29, 2002, it had produced a total of 256 Series 1 vehicles, and ''one or two'' vehicles annually assembled from 1965 stock parts. These vehicles ''are sold for off-road (racing) or museum display purposes only, and under current regulatory restrictions may not be licensed for street use.'' Shelby has also produced something over 270 ''component vehicles,'' without power trains, whose manufacture is completed by an entity other than Shelby. With respect to these vehicles, Shelby invites prospective purchasers to ''call for the name of a Recognized Shelby American Dealer who can build one for you.''

The Series 1 and Series 2 are two-passenger convertible passenger cars. The Series 2 ''is a face lifted version of the Series 1, utilizing the same chassis components as the Series 1, with modified exterior body panels and trim details.'' It will enter production when the planned 500-unit production run of the Series 1 is completed. The company was previously granted NHTSA Temporary Exemption No. 99–1 from the automatic restraint provisions of Standard No. 208 for the Series 1, which expired on January 1, 2001 (64 FR 6736). Shelby had hoped to meet the standard by January 1, 2000, but anticipated sales did not materialize with the funds needed to sustain the air bag development project. In fact, only 256 of the planned 500 Series 1 vehicles had been sold as of the date of the petition. Since submitting its first petition in May 1998, Shelby stated that it has ''spent an estimated total of 800 man-hours and $150,000 related to the installation of a passenger and driver's side airbag system on the Series 1.'' Its efforts are now devoted to development of an advanced air bag system which it hopes to implement at the end of 2005, well before September 1, 2006 when Standard No. 208 requires it to comply. The Series 1 is equipped with a three-point driver and passenger restraint system.

Based on quotations it has received, the ''total projected cost for [a] subcontractor to develop a driver and passenger-side advanced airbag system for the Shelby Series 1 and 2 is $6,005,000.'' The unaudited balance sheet of Shelby American, Inc., shows cumulative net losses exceeding $23,000,000 for its last three fiscal years, almost $6,000,000 of which are those of Shelby Series 1, Inc. for its most recent fiscal year.

Shelby stated that ''without a temporary exemption, which will enable the company to generate funds through the sale of vehicles, Shelby American will not be able to sustain the airbag development program and will have to discontinue the Shelby Series 1 and 2 programs, causing substantial hardship to the company.'' For fiscal/calendar 2003, the company projects a net income exceeding $15,000,000 if an exemption is granted, and a net loss of over $6,000,000 if it is not.

The applicant argues that ''the production of the Shelby Series 1 is in the best interest of the public and the U.S. economy.'' The company opened a new 100,000 square foot facility in June 1998 in Las Vegas to produce the Series 1, and has employed ''up to 103 individuals'' there. The car will be sold through select dealers ''* * * providing employment to many sales and service personnel at the dealership level.'' Most major components are produced in the United States, including the engine (Oldsmobile), tires (Goodyear), and transmission (ZF, from RBT, a U.S. company). The Series 1 is technically advanced, combining ''an aluminum chassis with a carbon-fiber body, a new concept amongst production vehicles, which provides strength and durability while minimizing weight.'' Shelby believes that the reduced weight achieved with this vehicle will translate into a new standard for improved emissions and fuel efficiency. Aside from Standard No. 208, the car will be certified as conforming to all applicable Federal motor vehicle safety standards.

Interested persons are invited to submit comments on the application described above. Comments should refer to the docket and notice number, and be submitted to: Docket Management, National Highway Traffic Safety Administration, room PL–401, 400 Seventh Street, SW., Washington, DC 20590. It is requested that two copies be submitted.

All comments received before the close of business on the comment closing date below will be considered, and will be available for examination in the docket at the above address both before and after that date, between the hours of 10 a.m. and 5 p.m. To the extent possible, comments filed after the closing date will also be considered. Notice of final action on the petition will be published in the **Federal Register** pursuant to the authority indicated below.

Comment closing date: March 5, 2003.

Authority: 49 U.S.C. 30113; delegations of authority at 49 CFR 1.50 and 501.4.

Issued on: January 27, 2003.

Stephen R. Kratzke,

Associate Administrator for Rulemaking.

[FR Doc. 03–2357 Filed 1–31–03; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[Docket No. NHTSA 2002–13357; Notice 2]

Uniroyal Goodrich Tire Manufacturing, Grant of Application for Decision That Noncompliance Is Inconsequential to Motor Vehicle Safety

Uniroyal Goodrich Tire Manufacturing (Uniroyal) has determined that a total 11,262 P155/80R 13 79S Uniroyal Tiger Paw AWP tires do not meet the labeling requirements mandated by Federal Motor Vehicle Safety Standard (FMVSS) No. 109, ''New Pneumatic Tires.''

Pursuant to 49 U.S.C. 30118(d) and 30120(h), Uniroyal has petitioned for a determination that this noncompliance is inconsequential to motor vehicle safety and has filed an appropriate report pursuant to 49 CFR Part 573, ''Defect and Noncompliance Reports.''

Notice of receipt of the application was published, with a 30-day comment period, on October 1, 2002, in the **Federal Register** (67 FR 61724). NHTSA received no comment on this application.

During the period of the 5th through the 48th weeks of 2000, the Woodburn, Indiana plant of Uniroyal Goodrich Tire Manufacturing produced and cured a total of 11,262 tires with erroneous marking. Of this total, no more than 3,796 may have been delivered to end-users. The remaining tires have been isolated in Uniroyal warehouses and will be brought into compliance.

FMVSS No. 109 (S4.3(e)) requires that each tire shall have permanently molded into or onto both sidewalls the actual number of plies in the sidewall, and the actual number of plies in the tread area if different.

The noncompliance with S4.3(e) relates to the mold number. The tires were marked: SIDEWALL 2 Plies instead of the required marking of: SIDEWALL 1 Ply.

Uniroyal does not believe that this marking error will impact motor vehicle safety because the tires meet all applicable Federal Motor Vehicle Safety performance standards, and the noncompliance is one of labeling.

The Transportation Recall, Enhancement, Accountability, and Documentation (TREAD) Act (Pub. L. 106–414) required, among other things, that the agency initiate rulemaking to improve tire label information. In response, the agency published an Advance Notice of Proposed Rulemaking (ANPRM) in the **Federal Register** on December 1, 2000 (65 FR 75222). The agency received more than 20 comments on the tire labeling information required by 49 CFR Sections 571.109 and 119, Part 567, Part 574, and Part 575. With regard to the tire construction labeling requirements of FMVSS 109, S4.3(d) and (e), most commenters indicated that the information was of little or no safety value to consumers. However, according to the comments, when tires are processed for retreading or repairing, it is important for the retreader or repair technician to understand the make-up of the tires and the types of plies. This enables them to select the proper repair materials or procedures for retreading or repairing the tires. A steel cord radial tire can experience a circumferential or ''zipper'' rupture in the upper sidewall when it is operated underinflated or overloaded. If information regarding the number of plies and cord material is removed from the sidewall, technicians cannot determine if the tire has a steel cord sidewall ply. This information is critical when determining if the tire is a candidate for a zipper rupture. In this case, since the steel cord construction is properly identified on the sidewall, the technician will have sufficient notice.

In addition, the agency conducted a series of focus groups, as required by the TREAD Act, to examine consumer perceptions and understanding of tire labeling. Few of the focus group participants had knowledge of tire labeling beyond the tire brand name, tire size, and tire pressure.

Based on the information obtained from comments to the ANPRM and the consumer focus groups, we have concluded that it is likely that few consumers have been influenced by the tire construction information (number of plies and cord material in the sidewall and tread plies) provided on the tire sidewall when deciding to buy a motor vehicle or tire.

The agency believes that the true measure of inconsequentiality to motor vehicle safety in this case is the effect of the noncompliance on the operational safety of vehicles on which these tires are mounted. This labeling noncompliance has no effect on the performance of the subject tires.

In consideration of the foregoing, NHTSA has decided that the applicant has met its burden of persuasion that the noncompliance is inconsequential to motor vehicle safety. Accordingly, its application is granted and the applicant is exempted from providing the notification of the noncompliance as required by 49 U.S.C. 30118, and from remedying the noncompliance, as required by 49 U.S.C. 30120.

Authority: (49 U.S.C. 30118, 30120; delegations of authority at 49 CFR 1.50 and 501.8)

Issued on: January 28, 2003.

Stephen R. Kratzke,

Associate Administrator for Rulemaking.

[FR Doc. 03–2428 Filed 1–31–03; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF TRANSPORTATION

Research and Special Programs Administration

Pipeline Safety: Required Submission of Data to the National Pipeline Mapping System Under the Pipeline Safety Improvement Act of 2002

AGENCY: Research and Special Programs Administration (RSPA), DOT.

ACTION: Notice; issuance of advisory bulletin.

SUMMARY: The Office of Pipeline Safety (OPS) is issuing this advisory bulletin to owners and operators of natural gas transmission and hazardous liquid pipeline systems. The purpose of this bulletin is to advise pipeline operators of their responsibilities in complying with the Pipeline Safety Improvement Act of 2002. Specifically, this bulletin indicates the process for making new submissions of geospatial and operator contact information, updating previous submissions to the National Pipeline Mapping System (NPMS), and providing future submissions.

FOR FURTHER INFORMATION CONTACT: Sam Hall, (202) 493–0591; or by email, *samuel.hall@rspa.dot.gov.* Steve Fischer, (202) 366–6267; or by email at *steven.fischer@rspa.dot.gov.* This document can be viewed at the OPS

home page at *http://ops.dot.gov/new.htm.* Additional information about the NPMS and the ''National Pipeline Mapping System Standards for Pipeline and Liquefied Natural Gas Operator Submissions'' can be found at *http://www.npms.rspa.dot.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

The National Pipeline Mapping System (NPMS) is a geographic information system (GIS) database that contains the locations and selected attributes of hazardous liquid and natural gas transmission pipelines, break-out tanks, and liquefied natural gas (LNG) facilities operating in onshore and DOT jurisdictional offshore territories of the United States. The NPMS was developed as a joint effort between the U.S. Department of Transportation, Research and Special Programs Administration's OPS, other Federal and State agencies, and the pipeline industry. The NPMS originally consisted of pipeline and LNG facility data voluntarily submitted by pipeline operators. The data collected for the NPMS is necessary for regulatory oversight and for monitoring the security of the pipelines. Therefore, public access to the data is limited.

The Pipeline Safety Improvement Act of 2002 (Pub. L. 107–355), 49 U.S.C. 60132, ''National Pipeline Mapping System,'' enacted on December 17, 2002, requires the following:

(a) *Information to be Provided*—Not later than six months after the date of enactment of this section, the operator of a pipeline facility (except distribution lines and gathering lines) shall provide to the Secretary of Transportation the following information with respect to the facility:

(1) Geospatial data appropriate for use in the National Pipeline Mapping System or data in a format that can be readily converted to geospatial data.

(2) The name and address of the person with primary operational control to be identified as its operator for purposes of this chapter.

(3) A means for a member of the public to contact the operator for additional information about the pipeline facilities it operates.

(b) *Updates*—A person providing information under subsection (a) shall provide to the Secretary updates of the information to reflect changes in the pipeline facility owned or operated by the person and as otherwise required by the Secretary.

In complying with this statutory requirement, please do the following:

Subsection (a): *Information To Be Provided*—Submit all pipeline data and contact information in accordance with the guidelines set forth in the NPMS operator standards document entitled ''National Pipeline Mapping System Standards for Pipeline and Liquefied Natural Gas Operator Submissions'' dated 2003. A complete data submission includes the geospatial data, attribute data, and metadata for all liquefied natural gas (LNG) and hazardous liquid and natural gas transmission pipeline systems operated by a company. The standards document is available for download from the NPMS website at *http://www.npms.rspa.dot.gov/submissions/standards.htm.*

Subsection (a)(1): If a complete data submission was made to the NPMS prior to December 17, 2001, and any pipeline system modifications have occurred since the last submission, submit complete data to the NPMS by June 17, 2003. If a complete data submission was made to the NPMS prior to December 17, 2001, and no pipeline system modifications have occurred, send an email to *opsgis@rspa.dot.gov* stating that fact. If a complete data submission was made to the NPMS on or after December 17, 2001, and if pipeline system modifications representing more than 5% of the total system mileage to be submitted to the NPMS have occurred, submit new complete data by June 17, 2003. If changes to the data submitted on or after December 17, 2001, affect less than 5% of the total system mileage submitted to the NPMS, submit an email to *opsgis@rspa.dot.gov* stating that fact by June 17, 2003. If only a partial data submission was made to the NPMS, before or after December 17, 2001, submit complete data to the NPMS by June 17, 2003. For LNG facilities, if any modifications to previously submitted data have occurred, submit new complete data by June 17, 2003. System modifications include pipelines or LNG facilities added or removed from a pipeline system and changes to any of the NPMS attributes (*e.g.*, operator name, system name, commodity, status, etc.).

Pipeline operators may submit updated data in one of two ways depending on the format of their submission. For digital data, submit replacement data for an entire system. It is easier for pipeline operators submitting digital data to submit the entire pipeline system rather than making a partial update submission. In this case, all data that was previously submitted under the same operator ID will be updated with the new submission. For paper maps, submit replacement maps for those portions of a pipeline system that have changed. This option is available only for those pipeline operators who have to submit hard-copy maps.

Subsection (a)(2): Regardless of prior complete or partial data submissions to the NPMS, provide pipeline operator contact information for the pipelines submitted to the NPMS. The pipeline operator should identify and submit to the NPMS, contact information that the Office of Pipeline Safety will make available to the public for its' use in contacting the operator. The format and procedures for submitting this contact information is available on the NPMS website and in the NPMS operator standards document.

Subsection (a)(3): OPS is developing an Internet-based tool that will allow the public to identify pipeline operators within a specific geographic area. The information provided to the NPMS under subsection (a)(2) will allow the public to contact pipeline operators with questions regarding their pipelines. The Internet-based tool will display a list of operator contacts, within the geographic area specified by the user, but will not render a map of the pipelines.

Subsection (b): Updates—Once a submission is made to comply with the June 17, 2003, statutory deadline, operators are required to make update submissions every twelve (12) months if any system modifications have occurred. If no modifications have occurred since the last complete submission (including operator contact information), send an email to *opsgis@rspa.dot.gov* stating that fact. Include operator contact information with all updates. Pipeline operators may update previous NPMS submissions in one of two ways. For digital data, submit replacement data for an entire system. For paper maps, submit replacement maps for those portions of pipeline systems that have changed. This option is available only for those pipeline operators who have to submit paper maps.

II. Advisory Bulletin (ADB–03–02)

To: Owners and Operators of Natural Gas Transmission and Hazardous Liquid Pipeline Systems.

Subject: Required Submission of Data to the National Pipeline Mapping System Under the Pipeline Safety Improvement Act of 2002.

Purpose: To advise pipeline operators of their responsibilities in complying with the Pipeline Safety Improvement Act of 2002. This bulletin describes the process for making new submissions of geospatial and operator contact information and updating previous

submissions to the National Pipeline Mapping System (NPMS).

Advisory: Subsection (a): Submit geospatial and contact information in accordance with the guidelines set forth in the NPMS standards document entitled ''National Pipeline Mapping System Standards for Pipeline and Liquefied Natural Gas Operator Submissions' dated 2003. The operators standards document is available for download from the NPMS website at *http://www.npms.rspa.dot.gov/submissions/standards.htm.*

Subsection (a)(1): If a complete data submission was made to the NPMS prior to December 17, 2001, and any pipeline system modifications have occurred since the last submission, submit complete data to the NPMS by June 17, 2003. If a complete data submission was made to the NPMS prior to December 17, 2001, and no pipeline system modifications have occurred, send an email to *opsgis@rspa.dot.gov* stating that fact. If a complete data submission was made to the NPMS on or after December 17, 2001, and if pipeline system modifications representing more than 5% of the total system mileage to be submitted to the NPMS have occurred, submit new complete data by June 17, 2003. If changes to the data submitted on or after December 17, 2001, affect less than 5% of the total system mileage submitted to the NPMS, submit an email to *opsgis@rspa.dot.gov* stating that fact by June 17, 2003. If only a partial data submission was made to the NPMS, before or after December 17, 2001, submit complete data to the NPMS by June 17, 2003. For LNG facilities, if any modifications since the last submission have occurred, submit new complete data by June 17, 2003.

Subsection (a)(2): Regardless of prior geospatial submissions to the NPMS, submit contact information for the pipelines represented in geospatial data submitted to the NPMS. The format for submitting this contact information is available in the NPMS operator standards document. This contact information will be in the public domain.

Subsection (a)(3): OPS is developing an Internet-based tool that will allow the public to identify pipeline operators within a specific geographic area. The information provided to the NPMS under subsection (a)(2) will allow the public to contact pipeline operators with questions regarding their pipelines. The Internet-based tool will display a list of operator contacts, within the geographic area specified by the user, but will not render a map of the pipelines.

Subsection (b): Once a submission is made to comply with the June 17, 2003, statutory deadline, operators are required to make update submissions every 12 months if any system modifications have occurred. If no modifications have occurred since the last complete submission (including operator contact information), send an email to *opsgis@rspa.dot.gov* stating that fact. Include operator contact information with all updates.

Issued in Washington, DC on January 24, 2003.

Stacey L. Gerard,

Associate Administrator for Pipeline Safety.

[FR Doc. 03–2449 Filed 1–31–03; 8:45 am]

BILLING CODE 4910–60–P

DEPARTMENT OF THE TREASURY

Submission for OMB Review; Comment Request

January 23, 2003.

The Department of Treasury has submitted the following public information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104–13. Copies of the submission(s) may be obtained by calling the Treasury Bureau Clearance Officer listed. Comments regarding this information collection should be addressed to the OMB reviewer listed and to the Treasury Department Clearance Officer, Department of the Treasury, Room 11000, 1750 Pennsylvania Avenue, NW., Washington, DC 20220.

DATES: Written comments should be received on or before March 5, 2003, to be assured of consideration.

Financial Crimes Enforcement Network (FinCEN)

OMB Number: 1506–0006.

Form Number: FinCEN 102.

Type of Review: Revision.

Title: Suspicious Activity Report by Casinos.

Description: Treasury is requiring casinos and card clubs with annual gaming revenue of more than $1,000,000 to report suspicious activities.

Respondents: Business or other for-profit, State, Local or Tribal Government.

Estimated Number of Respondents/Recordkeepers: 550.

Estimated Burden Hours Per Respondent/Recordkeeper: 45 minutes.

Estimated Total Reporting/Recordkeeping Burden: 1,550 hours.

Clearance Officer: Steve Rudzinski, Financial Crimes Enforcement Network, 2070 Chain Bridge Road, Suite 200, Vienna, VA 22182, (703) 905–3845.

OMB Reviewer: Joseph F. Lackey, Jr., Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503, (202) 395–7316.

Lois K. Holland, Departmental Reports

Management Officer.

[FR Doc. 03–2407 Filed 1–31–03; 8:45 am]

BILLING CODE 4810–02–P

DEPARTMENT OF THE TREASURY

Submission for OMB Review; Comment Request

January 23, 2003.

The Department of Treasury has submitted the following public information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104–13. Copies of the submission(s) may be obtained by calling the Treasury Bureau Clearance Officer listed. Comments regarding this information collection should be addressed to the OMB reviewer listed and to the Treasury Department Clearance Officer, Department of the Treasury, Room 11000, 1750 Pennsylvania Avenue, NW., Washington, DC 20220.

DATES: Written comments should be received on or before March 5, 2003, to be assured of consideration.

Internal Revenue Service (IRS)

OMB Number: 1545–1530.

Form Number: None.

Type of Review: Extension.

Title: Tip Rate Determination Agreement (Gaming Industry).

Description: Information is required by the Internal Revenue Service in its Compliance efforts to assist employers and their employees in understanding and complying with section 6053(a), which requires employees to report all their tips monthly to their employers.

Respondents: Business or other for-profit.

Estimated Number of Respondents/Recordkeepers: 100.

Estimated Burden Hours Per Respondent/Recordkeeper: 43 hours, 40 minutes.

Frequency of Response: On occasion.

Estimated Total Reporting/Recordkeeping Burden: 4,367 hours.

OMB Number: 1545–1670.

Regulation Project Number: REG–105606–99 NPRM.

Type of Review: Extension.

Title: Credit for Increasing Research Activities.

Description: The proposed regulations address the computation of the credit for increasing research activities for members of a controlled group and the allocation of the credit under section 41(f) of the Internal Revenue Code.

Respondents: Business or other for-profit.

Estimated Number of Respondents: 10.

Estimated Burden Hours Per Respondent: 20 hours.

Frequency of Response: On occasion.

Estimated Total Reporting Burden: 200 hours.

OMB Number: 1545–1676.

Regulation Project Number: REG–113572–99 Final.

Type of Review: Extension.

Title: Qualified Transportation Fringe Benefits.

Description: These regulations provide guidance to employers that provide qualified transportation fringe benefits under section 132(f), including guidance to employers that provide cash reimbursement for qualified transportation fringes and employers that offer qualified transportation fringes in lieu of compensation. Employers that provide cash reimbursement are required to keep records of documentation received from employees who receive reimbursement. Employers that offer qualified transportation fringes in lieu of compensation are required to keep records of employee compensation reduction elections.

Respondents: Business or other for-profit, individual or households, not-for-profit institutions, Federal Government, State, Local or Tribal Government.

Estimated Number of Respondents/Recordkeepers: 7,530,313.

Estimated Burden Hours Per Respondent/Recordkeeper: 8 hours.

Frequency of Response: Monthly.

Estimated Total Reporting/Recordkeeping Burden: 12,968,728 hours.

OMB Number: 1545–1678.

Regulation Project Number: REG–161424–01 Final and REG–105316–98 Final.

Type of Review: Extension.

Title: REG–161424–01 Final: Information Reporting for Qualified Tuition and Related Expenses; Magnetic Media Filing Requirements for Information Returns, and *REG–105316–98 Final:* Information Reporting for Payments of Interest on Qualified Education Loans; Magnetic Media Filing Requirements for Information Returns.

Description: These regulations related to the information reporting requirements in section 6050S of the Internal Revenue Code of the Internal Revenue code for payments of qualified tuition and related expenses and interest on qualified education loans. These regulations provide guidance to eligible education institutions, insurers, and payees required to file information returns and to furnish information statements under section 6050S.

Respondents: Not-for-profit, business or other for-profit.

Estimated Number of Respondents: 1.

Estimated Burden Hours Per Respondent: 1 hour.

Estimated Total Reporting Burden: 1 hour.

Clearance Officer: Glenn Kirkland, Internal Revenue Service, Room 6411–03, 1111 Constitution Avenue, NW., Washington, DC 20224, (202) 622–3428.

OMB Reviewer: Joseph F. Lackey, Jr., Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503, (202) 395–7316.

Lois K. Holland,

Departmental Reports Management Officer.

[FR Doc. 03–2408 Filed 1–31–03; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Submission for OMB Review; Comment Request

January 21, 2003.

The Department of Treasury has submitted the following public information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Pub. L. 104–13. Copies of the submission(s) may be obtained by calling the Treasury Bureau Clearance Officer listed. Comments regarding this information collection should be addressed to the OMB reviewer listed and to the Treasury Department Clearance Officer, Department of the Treasury, Room 11100, 1750 Pennsylvania Avenue, NW., Washington, DC 20220.

DATES: Written comments should be received on or before March 5, 2003 to be assured of consideration.

Bureau of Alcohol, Tobacco and Firearms (BATF)

OMB Number: 1512–0096.

Form Number: ATF 5130.12 (1689).

Type of Review: Extension.

Title: Beer for Exportation.

Description: Untaxpaid beer may be removed from a brewery for exportation without payment of the excise tax normally due on removal. In order to ensure that exportation took place as claimed and that untaxpaid beer does not reach domestic market, ATF requires certification on Form 5130.12.

Respondents: Business or other for-profit.

Estimated Number of Respondents: 392.

Estimated Burden Hours Per Respondent: 1 hour, 39 minutes.

Frequency of Response: On occasion.

Estimated Total Reporting Burden: 38,808 hours.

OMB Number: 1512–0298.

Recordkeeping Requirement ID Number: ATF REC 5120/1.

Type of Review: Extension.

Title: Usual and Customary Business Records Relating to Wine.

Description: ATF routinely inspects wineries' usual and customary business records to insure the proper payment of wine excise taxes due to the Federal government.

Respondents: Business or other for-profit.

Estimated Number of Respondents: 3,131.

Estimated Burden Hours Per Respondent: 10 minutes.

Frequency of Response: On occasion.

Estimated Total Reporting Burden: 313 hours.

OMB Number: 1512–0536.

Form Number: None.

Type of Review: Extension.

Title: Notification of Fire Marshal and Chief, Law Enforcement Officer of Storage of Explosive Materials.

Description: Title 18 U.S.C., Chapter 40, gives the Secretary of Treasury authority to issue regulations intended to help prevent accidents involving explosives. The collection of information contained herein is necessary for the safety of emergency response personnel responding to fires at sites where explosives are stored.

Respondents: Business or other for-profit, individuals or households, farms, State, Local or Tribal Government.

Estimated Number of Respondents: 10,057.

Estimated Burden Hours Per Respondent: 90 minutes.

Frequency of Response: Semi-annually.

Estimated Total Reporting Burden: 60,342 hours.

OMB Number: 1512–0537.

Form Number: ATF F 5154.3.

Type of Review: Extension.

Title: Bond for Drawback Under 26 U.S.C. 5131.

Description: Business that use taxpaid alcohol to manufacture nonbeverage products may file a claim for drawback (refund or remittance). Claims may be filed monthly or quarterly. Monthly claimants must file a bond on ATF

5154.3 to protect the Government's interest.

Respondents: Business or other for-profit.

Estimated Number of Respondents: 60.

Estimated Burden Hours Per Respondent: 12 minutes.

Frequency of Response: On occasion.

Estimated Total Reporting Burden: 12 hours.

Clearance Officer: Jacqueline White (202) 927–8930, Bureau of Alcohol, Tobacco and Firearms, Room 3200, 650 Massachusetts Avenue, NW.

OMB Reviewer: Joseph F. Lackey, Jr. (202) 396–7316, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503.

Mary A. Able,

Department Reports Management Officer.

[FR Doc. 03–2409 Filed 1–31–03; 8:45 am]

BILLING CODE 4810–31–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0205]

Agency Information Collection Activities Under OMB Review

AGENCY: Veterans Health Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C., 3501 *et seq.*), this notice announces that the Veterans Health Administration (VHA), Department of Veterans Affairs, has submitted the collection of information abstracted below to the Office of Management and Budget (OMB) for review and comment. The PRA submission describes the nature of the information collection and its expected cost and burden; it includes the actual data collection instrument.

DATES: Comments must be submitted on or before March 5, 2003.

FOR FURTHER INFORMATION OR A COPY OF THE SUBMISSION CONTACT: Denise McLamb, Records Management Service (005E3), Department of Veterans Affairs, 810 Vermont Avenue, NW., Washington, DC 20420, (202) 273–8030, FAX (202) 273–5981 or e-mail: *denise.mclamb@mail.va.gov.* Please refer to ''OMB Control No. 2900–0205.''

Send comments and recommendations concerning any aspect of the information collection to VA's OMB Desk Officer, OMB Human Resources and Housing Branch, New Executive Office Building, Room 10235, Washington, DC 20503 (202) 395–7316. Please refer to ''OMB Control No. 2900–0205'' in any correspondence.

SUPPLEMENTARY INFORMATION: *Titles:*

a. VA Form 10–2850, Application for Physicians, Dentists, Podiatrists and Optometrists.

b. VA Form 10–2850a, Application for Nurses and Nurse Anesthetists.

c. VA Form 10–2850b, Application for Residents.

d. VA Form 10–2850c, Application for Associated Health Occupations.

e. VA Form FL 10–341a, Appraisal of Applicant.

OMB Control Number: 2900–0205.

Type of Review: Extension of a currently approved collection.

Abstract: VA Forms 10–2850 and 10–2850a through c are applications designed specifically to elicit appropriate information about each candidate's qualifications for employment with VA. VHA officials use the information to evaluate education, professional experience and credentials and to determine suitability and grade level of applications of physicians, dentists, podiatrists, optometrists, nurses and nurse anesthetists, residents, and associated health occupations, and appraisal of applicants. The forms require disclosure of details about all licenses ever held, Drug Enforcement Administration certification, board certification, clinical privileges, revoked certification or registrations, liability insurance history, and involvement in malpractice proceedings. Form Letter 10–341a is a pre employment reference form used to elicit information concerning the prior education and/or performance of the Title 38 applicant.

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 **Federal Register** Notice with a 60-day comment period soliciting comments on this collection of information was published on October 15, 2002, at pages 63733—63734.

Affected Public: Individuals or Households, Business or other for-profit, Not-for-profit institutions, Federal Government, State, Local or Tribal Government.

Estimated Annual Burden: 75,471 hours.

a. VA Form 10–2850, Application for Physicians, Dentists, Podiatrists and Optometrists—7,095 hours.

b. VA Form 10–2850a, Application for Nurses and Nurse Anesthetists—28,380 hours.

c. VA Form 10–2850b, Application for Residents—15,136 hours.

d. VA Form 10–2850c, Application for Associated Health Occupations—9,460 hours.

e. VA Form FL 10–341a, Appraisal of Applicant—15,400 hours.

Estimated Average Burden Per Respondent: 27 minutes.

a. VA Form 10–2850, Application for Physicians, Dentists, Podiatrists and Optometrists—30 minutes.

b. VA Form 10–2850a, Application for Nurses and Nurse Anesthetists—30 minutes.

c. VA Form 10–2850b, Application for Residents—30 minutes.

d. VA Form 10–2850c, Application for Associated Health Occupations—30 minutes.

e. VA Form FL 10–341a, Appraisal of Applicant—20 minutes.

Frequency of Response: On Occasion.

Estimated Number of Respondents: 166,342.

a. VA Form 10–2850, Application for Physicians, Dentists, Podiatrists and Optometrists—14,190.

b. VA Form 10–2850a, Application for Nurses and Nurse Anesthetists—56,760.

c. VA Form 10–2850b, Application for Residents—30,272.

d. VA Form 10–2850c, Application for Associated Health Occupations—18,920.

e. VA Form FL 10–341a, Appraisal of Applicant—46,200.

Dated: January 14, 2003.

By direction of the Secretary.

Loise A. Russell,

Acting Director, Records Management Service.

[FR Doc. 03–2353 Filed 1–31–03; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

Cost-of-Living Adjustments and Headstone or Marker Allowance Rate

AGENCY: Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: As required by law, the Department of Veterans Affairs (VA) is hereby giving notice of cost-of-living adjustments (COLAs) in certain benefit rates and income limitations. These COLAs affect the pension, parents' dependency and indemnity compensation (DIC), and spina bifida, and birth defects programs. These adjustments are based on the rise in the Consumer Price Index (CPI) during the one-year period ending September 30, 2002. VA is also giving notice of the maximum amount of reimbursement that may be paid for headstones or markers purchased in lieu of

Government-furnished headstones or markers in Fiscal Year 2003, which began on October 1, 2002.

DATES: These COLAs are effective December 1, 2002. The headstone or marker allowance rate is effective October 1, 2002.

FOR FURTHER INFORMATION CONTACT: Paul Trowbridge, Consultant, Compensation and Pension Service (212B), Veterans Benefit Administration, Department of Veterans Affairs, 810 Vermont Avenue, NW., Washington, DC 20420, (202) 273–7218.

SUPPLEMENTARY INFORMATION: Under 38 U.S.C. 2306(d), VA may provide reimbursement for the cost of non-government headstones or markers at a rate equal to the actual cost or the average actual cost of government-furnished headstones or markers during the fiscal year preceding the fiscal year in which the non-government headstone or marker was purchased, whichever is less.

Section 8041 of Public Law 101–508 amended 38 U.S.C. 2306(d) to eliminate the payment of the monetary allowance in lieu of VA-provided headstones or markers for deaths occurring on or after November 1, 1990. However, in a precedent opinion (O. G. C. Prec. 17–90), VA's General Counsel held that there is no limitation period applicable to claims for benefits under the provisions of 38 U.S.C. 2306(d).

The average actual cost of government-furnished headstones or markers during any fiscal year is determined by dividing the sum of VA costs during that fiscal year for procurement, transportation, and miscellaneous administration, inspection and support staff by the total number of headstones and markers procured by VA during that fiscal year and rounding to the nearest whole dollar amount.

The average actual cost of government-furnished headstones or markers for Fiscal Year 2002 under the above computation method was $101. Therefore, effective October 1, 2002, the maximum rate of reimbursement for non-government headstones or markers purchased during Fiscal Year 2003 is $101.

Cost of Living Adjustments

Under the provisions of 38 U.S.C. 5312 and section 306 of Pub. L. 95–588, VA is required to increase the benefit rates and income limitations in the pension and parents' DIC programs by the same percentage, and effective the same date, as increases in the benefit amounts payable under title II of the Social Security Act. The increased rates and income limitations are also required to be published in the **Federal Register**.

The Social Security Administration has announced that there will be a 1.4 percent cost-of-living increase in Social Security benefits effective December 1, 2002. Therefore, applying the same percentage and rounding up in accordance with 38 CFR 3.29, the following increased rates and income limitations for the VA pension and parents' DIC programs will be effective December 1, 2002:

TABLE 1.—IMPROVED PENSION

Maximum annual rates
(1) Veterans permanently and totally disabled (38 U.S.C. 1521):
Veteran with no dependents, $9,690
Veteran with one dependent, $12,692
For each additional dependent, $1,653
(2) Veterans in need of aid and attendance (38 U.S.C. 1521):
Veteran with no dependents, $16,169
Veteran with one dependent, $19,167
For each additional dependent, $1,653
(3) Veterans who are housebound (38 U.S.C. 1521):
Veteran with no dependents, $11,843
Veteran with one dependent, $14,844
For each additional dependent, $1,653
(4) Two veterans married to one another, combined rates (38 U.S.C. 1521):
Neither veteran in need of aid and attendance or housebound, $12,692
Either veteran in need of aid and attendance, $19,167
Both veterans in need of aid and attendance, $24,973
Either veteran housebound, $14,844
Both veterans housebound, $16,998
One veteran housebound and one veteran in need of aid and attendance, $21,317
For each dependent child, $1,653
(5) Surviving spouse alone and with a child or children of the deceased veteran in custody of the surviving spouse (38 U.S.C. 1541):
Surviving spouse alone, $6,497
Surviving spouse and one child in his or her custody, $8,507
For each additional child in his or her custody, $1,653
(6) Surviving spouses in need of aid and attendance (38 U.S.C. 1541):
Surviving spouse alone, $10,387
Surviving spouse with one child in custody, $12,393
Surviving Spouse of Spanish-American War veteran alone, $11,058
Surviving Spouse of Spanish-American War veteran with one child in custody, $13,063
For each additional child in his or her custody, $1,653
(7) Surviving spouses who are housebound (38 U.S.C. 1541):
Surviving spouse alone, $7,942
Surviving spouse and one child in his or her custody, $9,948
For each additional child in his or her custody, $1,653
(8) Surviving child alone (38 U.S.C. 1542), $1,653

Reduction for income. The rate payable is the applicable maximum rate minus the countable annual income of the eligible person. (38 U.S.C. 1521, 1541 and 1542).

Mexican border period and World War I veterans. The applicable maximum annual rate payable to a Mexican border period or World War I veteran under this table shall be increased by $2,197 (38 U.S.C. 1521(g)).

Parents' DIC

DIC shall be paid monthly to parents of a deceased veteran in the following amounts (38 U.S.C. 1315):

One parent. If there is only one parent, the monthly rate of DIC paid to such parent shall be $464 reduced on the basis of the parent's annual income according to the following formula:

TABLE 2

For each $1 of annual income		
The $464 monthly rate shall be reduced by	Which is more than	But not more than
$0.00	0	$800
.08	$800	11,024

No DIC is payable under this table if annual income exceeds $11,024.

One parent who has remarried. If there is only one parent and the parent has remarried and is living with the parent's spouse, DIC shall be paid under Table 2 or under Table 4, whichever shall result in the greater benefit being paid to the veteran's parent. In the case of remarriage, the total combined annual income of the parent and the parent's spouse shall be counted in determining the monthly rate of DIC.

Two parents not living together. The rates in Table 3 apply to (1) two parents who are not living together, or (2) an unmarried parent when both parents are living and the other parent has remarried. The monthly rate of DIC paid to each such parent shall be $334 reduced on the basis of each parent's annual income, according to the following formula:

TABLE 3

For each $1 of annual income		
The $334 monthly rate shall be reduced by	Which is more than	But not more than
$0.00	0	$800
.06	$800	900
.07	900	1,100
.08	1,100	11,024

No DIC is payable under this table if annual income exceeds $11,024.

Two parents living together or remarried parents living with spouses. The rates in Table 4 apply to each parent living with another parent; and each remarried parent, when both parents are alive. The monthly rate of DIC paid to such parents will be $314 reduced on the basis of the combined annual income of the two parents living together or the remarried parent or parents and spouse or spouses, as computed under the following formula:

TABLE 4

For each $1 of annual income		
The $314 monthly rate shall be reduced by	Which is more than	But not more than
$.00	0	$1,000
.03	$1,000	1,500
.04	1,500	1,900
.05	1,900	2,400
.06	2,400	2,900
.07	2,900	3,200
.08	3,200	14,817

No DIC is payable under this table if combined annual income exceeds $14,817.

The rates in this table are also applicable in the case of one surviving parent who has remarried, computed on the basis of the combined income of the parent and spouse, if this would be a greater benefit than that specified in Table 2 for one parent.

Aid and attendance. The monthly rate of DIC payable to a parent under Tables 2 through 4 shall be increased by $250 if such parent is (1) a patient in a nursing home, or (2) helpless or blind, or so nearly helpless or blind as to need or require the regular aid and attendance of another person.

Minimum rate. The monthly rate of DIC payable to any parent under Tables 2 through 4 shall not be less than $5.

TABLE 5.—SECTION 306 PENSION INCOME LIMITATIONS

(1) Veteran or surviving spouse with no dependents, $11,024 (Pub. L. 95–588, section 306(a)).

TABLE 5.—SECTION 306 PENSION INCOME LIMITATIONS—Continued

(2) Veteran with no dependents in need of aid and attendance, $11,524 (38 U.S.C. 1521(d) as in effect on December 31, 1978).
(3) Veteran or surviving spouse with one or more dependents, $14,817 (Pub. L. 95–588, section 306(a)).
(4) Veteran with one or more dependents in need of aid and attendance, $15,317 (38 U.S.C. 1521(d) as in effect on December 31, 1978).
(5) Child (no entitled veteran or surviving spouse), $9,011 (Pub. L. 95–588, section 306(a)).
(6) Spouse income exclusion (38 CFR 3.262), $3,517 (Pub. L. 95–588, section 306(a)(2)(B)).

TABLE 6.—OLD-LAW PENSION INCOME LIMITATIONS

(1) Veteran or surviving spouse without dependents or an entitled child, $9,650 (Pub. L. 95–588, section 306(b)).
(2) Veteran or surviving spouse with one or more dependents, $13,912 (Pub. L. 95–588, section 306(b)).

Spina Bifida Benefits

Section 421 of Public Law 104–204 added a new chapter 18 to title 38, United States Code, authorizing VA to provide certain benefits, including a monthly monetary allowance, to children born with spina bifida who are the natural children of veterans who served in the Republic of Vietnam during the Vietnam era. Pursuant to 38 U.S.C. 1805(b)(3), spina bifida rates are subject to adjustment under the provisions of 38 U.S.C. 5312, which provides for the adjustment of certain VA benefit rates whenever there is an increase in benefit amounts payable under title II of the Social Security Act (42 U.S.C. 401 *et seq.*). Effective December 1, 2002, spina bifida monthly rates are as follows:

Level I: $232
Level II: $804
Level III: $1,373

Birth Defects Benefits

Section 401 of Public Law 106–419 authorizes the payment of monetary benefits to, or on behalf of, children of female Vietnam veterans born with certain birth defects. Rates are subject to adjustment under the provisions of 38 U.S.C. 5312, which provides for the adjustment of certain VA benefit rates whenever there is an increase in benefit amounts payable under title II of the Social Security Act (42 U.S.C. 401 *et seq.*). Effective December 1, 2002, birth defects monthly rates are as follows:

Level I: $105
Level II: $232
Level III: $804
Level IV: $1,373

Dated: January 23, 2003.

Anthony J. Principi,

Secretary of Veterans Affairs.

[FR Doc. 03–2352 Filed 1–31–03; 8:45 am]

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Corrections

Federal Register

Vol. 68, No. 22

Monday, February 3, 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 9031]

RIN 1545–BB02

Reduced Maximum Exclusion of Gain From Sale or Exchange of Principal Residence

Correction

In rule document 02–32280 beginning on page 78367 in the issue of Tuesday, December 24, 2002 make the following correction:

On page 78369, in the second column, under the heading ''*7. Effective Date''*, in the third line, ''December 24, 2003'' should read, ''December 24, 2002''.

[FR Doc. C2–32280 Filed 1–31–03; 8:45 am]

BILLING CODE 1505–01–D

Federal Register

Monday,

February 3, 2003

Part II

Securities and Exchange Commission

17 CFR Parts 240, 249, et al.

Certification of Management Investment Company Shareholder Reports and Designation of Certified Shareholder Reports as Exchange Act Periodic Reporting Forms; Disclosure Required by Sections 406 and 407 of the Sarbanes-Oxley Act of 2002; Final Rule

SECURITIES AND EXCHANGE COMMISSION

17 CFR Parts 240, 249, 270 and 274

[Release Nos. 34–47262; IC–25914; File Nos. S7–33–02; S7–40–02]

RIN 3235–AI63; RIN 3235–AI66

Certification of Management Investment Company Shareholder Reports and Designation of Certified Shareholder Reports as Exchange Act Periodic Reporting Forms; Disclosure Required by Sections 406 and 407 of the Sarbanes-Oxley Act of 2002

AGENCY: Securities and Exchange Commission.

ACTION: Final rule.

SUMMARY: The Securities and Exchange Commission is adopting rule and form amendments that require registered management investment companies to file certified shareholder reports on Form N–CSR with the Commission, and designating these certified reports as reports that are required under Sections 13(a) and 15(d) of the Securities Exchange Act of 1934 and Section 30 of the Investment Company Act of 1940. The amendments require each registered management investment company's principal executive and financial officers to certify the information contained in these reports in the manner specified by Section 302 of the Sarbanes-Oxley Act of 2002. We are providing that, for registered management investment companies other than small business investment companies, Form N–SAR will be filed under the Investment Company Act of 1940 only and not the Securities Exchange Act of 1934. We are also removing the requirement that Form N–SAR be certified by a registered investment company's principal executive and financial officers. We are also adopting a new rule to require registered management investment companies to maintain disclosure controls and procedures designed to ensure that the information required in reports on Form N–CSR is recorded, processed, summarized, and reported on a timely basis.

In addition, we are adopting forms and amendments that require registered management investment companies to include new disclosures on Form N–CSR or Form N–SAR in order to implement the requirements of Sections 406 and 407 of the Sarbanes-Oxley Act of 2002. First, the rules require a registered management investment company to disclose whether it has adopted a code of ethics that applies to the company's principal executive officer and senior financial officers. An investment company disclosing that it has not adopted such a code must disclose this fact and explain why it has not done so. An investment company also will be required to disclose amendments to, and waivers from, the code of ethics relating to any of those officers. Second, the rules require a registered management investment company to disclose whether it has at least one ''audit committee financial expert'' serving on its audit committee, and if so, the name of the expert and whether the expert is independent of management. An investment company that does not have an audit committee financial expert must disclose this fact and explain why it has no such expert.

DATES: *Effective Date:* March 1, 2003, except that the effective date of the removal of the certification requirement from Form N–SAR for registered management investment companies other than small business investment companies is May 1, 2003.

Compliance Date: See Section III of this release for information on Transition Provisions and Compliance Dates.

FOR FURTHER INFORMATION CONTACT: John M. Faust, Attorney, Katy Mobedshahi, Senior Counsel, Tara L. Royal, Attorney, or Paul G. Cellupica, Assistant Director, Office of Disclosure Regulation, Division of Investment Management, (202) 942–0721, at the Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549–0506.

SUPPLEMENTARY INFORMATION: The Securities and Exchange Commission (''Commission'') is adopting new rules 30a–3 [17 CFR 270.30a–3] and 30d–1 [17 CFR 270.30d–1] under the Investment Company Act of 1940 [15 U.S.C. 80a–1 *et seq.*] (''Investment Company Act''); amendments to rules 8b–15 [17 CFR 270.8b–15], 30a–1 [17 CFR 270.30a–1], 30a–2 [17 CFR 270.30a–2], 30b1–1 [17 CFR 270.30b1–1], 30b1–3 [17 CFR 270.30b1–3], and 30b2–1 [17 CFR 270.30b2–1] under the Investment Company Act; and amendments to rules 12b–25 [17 CFR 240.12b–25], 13a–15 [17 CFR 240.13a–15], and 15d–15 [17 CFR 240.15d–15], and Form 12b–25 [17 CFR 249.322] under the Securities Exchange Act of 1934 [15 U.S.C. 78a *et seq.*] (''Exchange Act''). The Commission also is adopting amendments to Form N–SAR [17 CFR 249.330; 17 CFR 274.101] under the Exchange Act and the Investment Company Act. Finally, the Commission is adopting new Form N–CSR [17 CFR 249.331; 17 CFR 274.128] under the Exchange Act and the Investment Company Act.

I. Introduction and Background

On July 30, 2002, the Sarbanes-Oxley Act of 2002 (''Sarbanes-Oxley Act'') was enacted.[1] Section 302 of the Sarbanes-Oxley Act, entitled ''Corporate Responsibility for Financial Reports,'' required the Commission to adopt final rules to be effective by August 29, 2002, 30 days after the date of enactment, under which the principal executive officer or officers and the principal financial officer or officers, or persons performing similar functions, of an issuer each must certify the information contained in the issuer's quarterly and annual reports filed or submitted under Section 13(a) or 15(d) of the Exchange Act.[2] Form N–SAR currently is the form designated for registered investment companies to comply with their reporting requirements under Sections 13(a) and 15(d) of the Exchange Act, as well as periodic reporting requirements under Sections 30(a) and 30(b)(1) of the Investment Company Act.[3]

On August 28, 2002, the Commission implemented the certification requirement of Section 302 of the Sarbanes-Oxley Act with respect to registered investment companies by adopting new rule 30a–2 under the Investment Company Act and the Sarbanes-Oxley Act.[4] Rule 30a–2 requires a registered investment company that files periodic reports under Section 13(a) or 15(d) of the Exchange Act, *i.e.*, Form N–SAR, to

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[1]

[2] Section 13(a) of the Exchange Act requires every issuer of a security registered pursuant to Section 12 of the Exchange Act to file with the Commission such annual reports and such quarterly reports as the Commission may prescribe. 15 U.S.C. 78m(a). Section 15(d) of the Exchange Act requires each issuer that has filed a registration statement that has become effective pursuant to the Securities Act of 1933 (''Securities Act'') to file such supplementary and periodic information, documents, and reports as may be required pursuant to Section 13 of the Exchange Act in respect of a security registered pursuant to Section 12. 15 U.S.C. 78o(d). The duty of an issuer to file under Section 15(d) is automatically suspended for any fiscal year, other than a fiscal year in which its registration statement becomes effective, if an issuer's securities are held of record by less than 300 persons. 15 U.S.C. 78o(d).

[3] General Instruction A to current Form N–SAR; current Rule 30a–1 under the Investment Company Act [17 CFR 270.30a–1]. See Investment Company Act Release No. 14299 (Jan. 4, 1985) [50 FR 1442 (Jan. 11, 1985)] (release adopting Form N–SAR). Face-amount certificate companies do not file reports on Form N–SAR, but rather file periodic reports on Forms 10–K and 10–Q. See Investment Company Act Release No. 14080 (Aug. 6, 1984) [49 FR 32370, 32372 (Aug. 14, 1984)] (face-amount certificate companies are required to file reports on other forms prescribed under the Exchange Act rather than Form N–SAR).

[4] Investment Company Act Release No. 25722 (Aug. 28, 2002) [67 FR 57276 (Sept. 9, 2002)].

include the certification specified by Section 302 in those periodic reports.

In a companion release, we also proposed to require registered management investment companies to file certified shareholder reports with the Commission on new Form N–CSR and to designate these certified shareholder reports as reports that are required under Sections 13(a) and 15(d) of the Exchange Act and Section 30 of the Investment Company Act.[5] As we noted in that release, we believe that the certification requirement of Section 302 of the Sarbanes-Oxley Act was intended to improve the quality of the disclosure that a company provides regarding its financial condition in its reports to investors.[6] For registered management investment companies, the required reports to shareholders, rather than reports on Form N–SAR, are the primary vehicle for providing financial information to investors. We believe that the information in these reports to shareholders should be certified, and today we are adopting amendments to our forms and rules to require this certification.

In October 2002, we proposed amendments to proposed Form N–CSR and Form N–SAR to implement Sections 406 and 407 of the Sarbanes-Oxley Act with respect to registered investment companies, similar to disclosure requirements that we proposed at the same time with respect to operating companies.[7] Section 406 directs the Commission to adopt rules requiring an issuer to disclose whether or not it has adopted a code of ethics for the issuer's senior financial officers, as well as any change to, or waiver of, that code of ethics. Section 407 directs the Commission to adopt rules: (1) Requiring an issuer to disclose whether or not its audit committee includes at least one member who is a financial expert; and (2) defining the term ''financial expert.'' Earlier this month, we adopted disclosure requirements to implement these provisions with respect to operating companies.[8] Today, we adopt similar disclosure requirements for registered management investment companies.

In the same release in which we proposed to implement Sections 406 and 407, we also proposed amendments to implement Section 404 of the Sarbanes-Oxley Act, relating to internal control reports, with respect to operating companies, as well as certain technical amendments to our rules and forms implementing Section 302 of the Sarbanes-Oxley Act for registered investment companies.[9] We have deferred adoption of the final rules to implement Section 404 to a separate release to be issued at a later date,[10] and we will also consider the technical amendments to our rules and forms implementing Section 302 for registered investment companies at that time.

II. Discussion

The Commission today is adopting new rules, rule and form amendments, and new Form N–CSR under the Investment Company Act to better implement the certification requirement of Section 302 of the Sarbanes-Oxley Act for registered management investment companies, with modifications to address commenters' concerns.[11] Our amendments will require a registered management investment company to file semi-annual reports on Form N–CSR, and will require the certification specified by Section 302 of the Sarbanes-Oxley Act in these semi-annual reports. Further, our amendments will remove the certification requirement from Form N–SAR, with respect to all registered investment companies.[12] In addition, we are adopting rules to require registered management investment companies to maintain, and regularly evaluate the effectiveness of, controls and procedures designed to ensure that the information required in reports on Form N–CSR is recorded, processed, summarized, and reported on a timely basis. Finally, we are adopting amendments to Form N–CSR and Form N–SAR to implement Sections 406 and 407 of the Sarbanes-Oxley Act with respect to registered management investment companies, similar to amendments that we adopted earlier this month to implement these provisions with respect to operating companies.

A. Section 302 of the Sarbanes-Oxley Act—Certification Requirements

1. Certified Shareholder Reports

We are adopting, as proposed, an amendment to rule 30b2–1 under the Investment Company Act, which currently requires registered investment companies to file copies of reports transmitted to shareholders with the Commission within 10 days of their transmission to shareholders. The amendment will require a registered management investment company to file a report with the Commission on new Form N–CSR (''certified shareholder report'') containing (i) a copy of any required shareholder report, (ii) additional information regarding disclosure controls and procedures, and (iii) the certification required by the Sarbanes-Oxley Act.[13] As adopted, new

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[5] *See* Investment Company Act Release No. 25723 (Aug. 30, 2002) [67 FR 57298 (Sept. 9, 2002)] (''Form N–CSR Proposing Release''). The Commission proposed amendments to Form N–CSR in Investment Company Act Release No. 25739 (Sept. 20, 2002) [67 FR 60828 (Sept. 26, 2002)] (proxy voting disclosure); Investment Company Act Release No. 25775 (Oct. 22, 2002) [67 FR 66208 (Oct. 30, 2002)] (code of ethics and financial expert disclosure) (''Section 406/407 Proposing Release''); Investment Company Act Release No. 25838 (Dec. 2, 2002) [67 FR 76780 (Dec. 13, 2002)] (auditor independence provisions of the Sarbanes-Oxley Act); Investment Company Act Release No. 25845 (Dec. 10, 2002) [67 FR 77593 (Dec. 18, 2002)] (revisions to rule 10b–18 under the Exchange Act); Investment Company Act Release No. 25870 (Dec. 18, 2002) [68 FR 160 (Jan. 2, 2003)] (shareholder reports and quarterly portfolio disclosure); and Investment Company Act Release No. 25885 (Jan. 8, 2003) [68 FR 2637 (Jan. 17, 2003)] (standards relating to listed company audit committees).

A management investment company is an investment company other than a unit investment trust or face-amount certificate company. *See* Section 4 of the Investment Company Act [15 U.S.C. 80a–4]. Management investment companies typically issue shares representing an undivided proportionate interest in a changing pool of securities, and include open-end and closed-end companies. *See* T. Lemke, G. Lins, A. Smith III, Regulation of Investment Companies, Vol. I, ch. 4, § 4.04, at 4–5 (2002).

[6] Form N–CSR Proposing Release, *supra* note , 67 FR at 57299.

[7] Section 406/407 Proposing Release, *supra* note 5, 67 FR at 66213–14 and 66217–18.

[8] Securities Act Release No. 8177 (January 23, 2003) (''Section 406/407 Adopting Release'').

[9] Section 406/407 Proposing Release, *supra* note 5, 67 FR at 66222–23.

[10] Section 406/407 Adopting Release, *supra* note 8.

[11] We received 18 comment letters on the Form N–CSR Proposing Release from 17 commenters. The commenters included ten mutual funds, investment advisers, and financial advisers; one trade association; five law firms, law professors, attorneys, and bar associations; and one domestic government agency. These comment letters and a summary of the comments are available for public inspection and copying in our Public Reference Room, 450 Fifth Street, NW., Washington, DC 20549, in File No. S7–33–02. Public comments submitted electronically and a summary of the comments are available on our Web site <*http://www.sec.gov*>.

We received over 200 comment letters on the Section 406/407 Proposing Release, including 23 comment letters on the proposed amendments applicable to investment companies. The commenters included 12 mutual funds and investment advisers; one trade association; four law firms, bar associations, and accounting firms; and six independent directors of investment companies. These comment letters are available for public inspection and copying in our Public Reference Room, 450 Fifth Street, NW., Washington, DC 20549, in File No. S7–40–02. Public comments submitted electronically are available on our Web site <*http://www.sec.gov*>.

[12] Amendments to Item 133 and instructions to Items 77Q3, 102P3, and 133 of Form N–SAR.

[13] Rule 30b2–1(a) under the Investment Company Act [17 CFR 270.30b2–1(a)]; 17 CFR 249.331; 17 CFR 274.128; Items 1, 9, and 10(b) of Form N–CSR. In addition, we are amending rule 30a–2 under the Investment Company Act [17 CFR 270.30a–2] to require Form N–CSR to include the certification required by Section 302 of the Sarbanes-Oxley Act. No certified shareholder report on Form N–CSR

Continued

Form N–CSR requires certified shareholder reports to contain the exact form of the certification prescribed by the form. The certification is required of each principal executive officer and financial officer, and the form of this certification parallels the form of the certification we have prescribed for other Exchange Act reporting forms, such as Forms 10–K and 10–Q. The certification must be filed as an exhibit to a report on Form N–CSR.[14] In addition to the signature required on the certification, the report must be signed by the registrant, and on behalf of the registrant by its principal executive officer or officers and its principal financial officer or officers.[15] The certification requirement will also apply to amendments of certified shareholder reports on Form N–CSR.[16] In addition, we are adopting new rule 30d–1 under the Investment Company Act, designating reports on Form N–CSR as periodic reports filed with the Commission under Section 13(a) or 15(d) of the Exchange Act.[17]

The requirement to file certified shareholder reports will apply to registered management investment companies, regardless of whether they are subject to Section 13(a) or 15(d) of the Exchange Act.[18] By its terms, Section 302 of the Sarbanes-Oxley Act directs the Commission to adopt rules that will apply to companies filing periodic reports under Section 13(a) or 15(d) of the Exchange Act.[19] We believe, however, that it is important for the certification requirement, like our other reporting rules, to apply consistently to all registered investment companies, regardless of whether they fall within the periodic reporting requirements of the Exchange Act.[20]

In light of the adoption of Form N–CSR as an Exchange Act reporting form, we are amending our rules and forms to provide that, for registered management investment companies, Form N–SAR will be filed under the Investment Company Act only and not the Exchange Act.[21] We were persuaded by commenters who argued that certification of both Form N–SAR and shareholder reports would impose an unjustified burden on management investment companies. These commenters noted that Form N–SAR does not contain financial statements; that although Form N–SAR is publicly available, it was developed primarily to elicit information for use by the Commission in its compliance and inspections program; and that the information in Form N–SAR is not generally relied upon by investors.[22] In light of the fact that registered management investment companies will be filing Form N–CSR under the Exchange Act, we do not believe that it is necessary for these companies to continue to file Form N–SAR under the Exchange Act or to certify Form N–SAR under the Sarbanes-Oxley Act.[23] We believe that this is appropriate because, for registered management investment companies, the required reports to shareholders contained in Form N–CSR, rather than Form N–SAR, are the primary vehicle for providing financial statements and other information to investors.[24] The certification requirement was intended to improve the quality of the disclosure that a company provides about its financial condition in its periodic reports to investors.[25]

2. Scope of Certification Requirement

We are adopting, as proposed, the requirement that all of the information filed on Form N–CSR, including all of the information in a shareholder report filed as part of Form N–CSR, be certified. This would include information that is included voluntarily, as well as that required by Form N–CSR. In addition to financial statements, annual reports to shareholders of open-end management investment companies, or mutual funds, typically contain Management's Discussion of Fund Performance (''MDFP''), although, at present, they are not required to do so.[26] MDFP includes narrative disclosure of the factors that materially affected a fund's performance during the reporting period, a line graph comparing the fund's performance to that of an appropriate broad-based market index, and a table of average annual total returns for the fund. In addition, the annual report to shareholders of a management investment company must contain other information, including certain basic information about the investment company's directors.[27]

would be required with respect to a report to shareholders that is not required under rule 30e–1 under the Investment Company Act [17 CFR 270.30e–1], *e.g.*, voluntary quarterly reports. These reports to shareholders would continue to be filed with the Commission as they are presently. Rule 30b2–1(b) under the Investment Company Act [17 CFR 270.30b2–1(b)].

[14] *See* Item 10(b) of Form N–CSR. The EDGAR document type must be EX–99.CERT for an exhibit filed in response to Item 10(b). All certifications in a filing on Form N–CSR should be included in a single EDGAR exhibit document.

[15] *See* General Instruction E to Form N–CSR.

[16] Rule 8b–15 under the Investment Company Act [17 CFR 270.8b–15].

[17] We are also adopting a technical conforming amendment that would delete the language in current rule 30a–1 [17 CFR 270.30a–1] stating that a registered management investment company required to file an annual report pursuant to Section 13(a) or 15(d) of the Exchange Act and Section 30(a) of the Investment Company Act shall be deemed to have satisfied its requirement to file an annual report by the filing of semi-annual reports on Form N–SAR. The amendments rename rule 30a–1 in order to specify that it relates to annual reports by registered unit investment trusts, and rename rule 30b1–1 [17 CFR 270.30b1–1] in order to specify that it relates to semi-annual reports of registered management investment companies.

[18] Rule 30b2–1(a) [17 CFR 270.30b2–1(a)].

[19] *See supra* note (description of Exchange Act reporting requirements).

[20] *Cf.* General Instruction A to Form N–SAR (Form N–SAR is to be used for semi-annual and annual reports by all registered investment companies that have filed a registration statement that has become effective pursuant to the Securities Act, with the exception of face amount certificate companies.).

[21] *See* Rule 30b1–1 under the Investment Company Act [17 CFR 270.30b1–1]; 17 CFR 249.330; 17 CFR 274.101; General Instruction A to Form N–SAR.

[22] *See* Investment Company Act Release No. 14299 (Jan. 4, 1985) [50 FR 1442 (Jan. 11, 1985)] (release adopting Form N–SAR); Investment Company Act Release No. 14080 (Aug. 6, 1984) [49 FR 32370 (Aug. 14, 1984)] (release proposing Form N–SAR).

[23] Instructions to item 77Q3 of Form N–SAR (amended to remove certification); rule 30b1–3 under the Investment Company Act [17 CFR 270.30b1–3] (removing the certification requirement from transition reports on Form N–SAR).

[24] Sections 30(e) and (f) of the Investment Company Act (15 U.S.C. 80a–29(e) and (f)) (requiring a registered investment company to transmit to its stockholders, at least semi-annually, reports containing financial statements and other information prescribed by the Commission).

[25] *See, e.g.*, S. Rep. No. 107–205, at 2 (2002) (''The bill also requires steps to enhance the direct responsibility of senior corporate management for financial reporting and for the quality of financial disclosures made by public companies.''); 148 Cong. Rec. S7355 (July 25, 2002) (statement of Sen. Enzi) (''With respect to section 302, the conference recognizes that results presented in financial statements often necessarily require accompanying disclosures in order to apprise investors of the company's true financial condition and results of operations. The supplemental information contained in these additional disclosures increases transparency for investors. Accordingly, the relevant officers must certify that the financial statements together with the disclosures contained in the periodic report, taken as a whole, are appropriate and fairly represent, in all material respects, the operations and financial condition of the issuer.''); 148 Cong. Rec. S6760 (July 15, 2002) (statement of Sen. Akaka) (''The legislation also requires additional corporate governance procedures to make Chief Executive Officers and Chief Financial Officers more directly responsible for the quality of financial reporting made to investors.'').

[26] Item 5 of Form N–1A. Management's Discussion of Fund Performance must be included in a fund's prospectus unless the fund is a money market fund or the information in the MDFP is included in the fund's annual report to shareholders under rule 30e–1 [17FR 270.30e–1]. A fund that includes MDFP in its annual report must disclose in its prospectus that its annual report contains additional performance information that will be made available upon request and without charge. Item 1(b)(1) of Form N–1A. We recently proposed to require the MDFP to be included in a mutual fund's annual report to shareholders. Investment Company Act Release No. 25870 (Dec. 18, 2002) [68 FR 160, 170 (Jan. 2, 2003)].

[27] Items 13(a)(1) and 22(b)(5) of Form N–1A; Item 18.1 and Instruction 4.e. to Item 23 of Form N–2;

Many commenters objected to our proposal to require certification of all of the information contained in shareholder reports, and instead suggested that the certification should apply only to the financial statements and other financial information in shareholder reports. Commenters argued that the narrative disclosure commonly found in shareholder reports, including the narrative section of MDFP as well as a fund president's letter to shareholders, interviews with portfolio managers, and other similar information that is intended to assist investors in understanding fund performance and portfolio composition, is not analogous to Management's Discussion & Analysis (MD&A) in Form 10–K, and is not the type of objective financial information that the certification requirement of Section 302 was intended to cover.[28] The MD&A, commenters noted, is intended to provide a narrative explanation of an operating company's financial statements and to provide the context within which the financial statements should be analyzed, while the MDFP is simply a narrative explanation of an investment company's performance comparative to the market. These commenters argued that the narrative disclosure in the shareholder reports, including that in the MDFP, does not lend itself to meaningful personal certification by an investment company's principal executive and financial officers, and that requiring certification of the entire shareholder report could have the unintended consequence of encouraging investment companies to reduce the scope of the narrative discussion provided voluntarily in shareholder reports, or even ceasing to provide it altogether.

We are not persuaded by these comments. Section 302 of the Sarbanes-Oxley Act does not limit the scope of the certification to financial information filed by a registrant. The MDFP and other narrative disclosure is relied upon by investors to explain the investment operations and performance of a mutual fund, which is as significant for investors in the fund as management's discussion and analysis of financial condition and results of operations is for investors in an operating company. In its integrated reviews of mutual fund prospectuses and shareholder reports, the staff has identified instances where MDFP has provided insufficient substantive discussion of the factors that affected the fund's performance during the most recent fiscal year. [29] The Commission has asked the staff, in its review of a mutual fund's disclosure documents, to continue to focus on areas where funds' MDFP disclosure has been deficient.[30] We believe that a requirement that MDFP, if included in shareholder reports, must be certified by the mutual fund's principal executive and financial officers, would encourage funds to include a more complete and accurate discussion of the factors that affected fund performance in their MDFP. Further, we note that in the operating company context, reports on Form 10–K contain certain required non-financial information that must be certified.[31]

We also note that the only statement made in the certification with respect to this narrative information is that, based on the certifying officer's knowledge, the report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by the report.[32] This certification is consistent with the current obligation of registrants under the Exchange Act not to file reports that are materially misleading.[33] Therefore, we believe that it is appropriate for the certifying officers to provide assurances to investors that the reports a fund files under the Exchange Act meet this standard.

3. Application of Certification Requirements to Unit Investment Trusts and Small Business Investment Companies

To address commenters' concerns, we are amending Form N–SAR to eliminate the requirement that unit investment trusts (''UITs'') and small business investment companies (''SBICs'') certify their reports on Form N–SAR.[34] Commenters noted that Form N–SAR, which does not contain financial statements, contains little, if any, information regarding a UIT that is of relevance or interest to investors. We agree. Form N–SAR requires both UITs and SBICs to include only limited financial and other information.[35] Because Form N–SAR contains very limited information for UITs and SBICs and is not required to be sent to investors, certification of this information would not promote the intent of Section 302 of the Sarbanes-Oxley Act, which is to improve the quality of the disclosure that a company provides about its financial condition in its periodic reports to investors. We

Item 20(a) and Instruction 4(v) to Item 27(a) of Form N–3.

[28] *See* Item 303 of Regulation S–K [17 CFR 229.303] (Management's Discussion and Analysis).

[29] *See In the Matter of Davis Selected Advisers—NY, Inc.,* Investment Advisers Act Release No. 2055 (Sept. 4, 2002) (fund violated Section 34(b) of the Investment Company Act [15 U.S.C. 80a–34(b)] by failing to disclose the material impact that investments in initial public offerings had on its performance during its previous fiscal year in its MDFP); Tom Lauricella and Aaron Lucchetti, *What's Your Fund Doing? Some Managers Don't Say,* The Wall Street Journal, Oct. 7, 2002, at R23 (describing inadequate discussions in investment companies' MDFP).

[30] Investment Company Act Release No. 25870, *supra* note, 68 FR at 170.

[31] *See* Item 401 of Regulation S–K [17 CFR 229.401] (requiring background information about directors and officers); Section 406/407 Adopting Release, *supra* note (adopting Item 406 of Regulation S–K, which requires disclosure with respect to codes of ethics applicable to a registrant's principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions, and Item 401(h) of Regulation S–K, which requires disclosure of whether a company has at least one audit committee financial expert serving on its audit committee, and if so, the name of the expert and whether the expert is independent of management).

[32] Paragraph 3 of certification exhibit in Item 10(b) of Form N–CSR.

[33] Rule 10b–5 under the Exchange Act [17 CFR 240.10b–5] provides that: ''It shall be unlawful for any person, directly or indirectly, * * * to make any untrue statement of a material fact or to omit to state a material fact necessary in order to make the statements made, in the light of the circumstances under which they were made, not misleading * * *''

[34] Instruction 102P3 of Form N–SAR; Instruction to Item 133 of Form N–SAR.

A UIT is an unmanaged, fixed portfolio of securities that has no corporate management structure, and generally is not required to transmit reports to shareholders containing its financial statements. *See* Section 4(2) of the Investment Company Act [15 U.S.C. 80a–4(2)] (defining UIT). SBICs are management investment companies that are licensed as SBICs under the Small Business Investment Act of 1958. *See* General Instruction A of Form N–5 [17 CFR 239.24; 17 CFR 274.5] (describing SBIC).

[35] UITs report the following information on Form N–SAR: (i) Identifying information (Items 1–6); (ii) the names and addresses of the trust's depositors, sponsors, trustees, principal underwriters, and independent accountants (Items 111–115); (iii) whether the trust is part of a family of investment companies or an insurance company separate account (Items 116–117); (iv) the following numbers: Number of series, dollar amounts of deposits and prior series units, sales charges aggregated for all series, values of and income from various types of securities and expenses aggregated for all series (Items 118–127, 131); (v) information regarding insurance and guarantees (Items 128–130); and (vi) a list of any pre-1972 Investment Company Act file numbers (Item 132). SBICs report the following information on Form N–SAR: (i) Identifying information (Items 1–6); (ii) the names and addresses of the SBIC's advisers, transfer agents, independent accountants, and custodian (Items 89–92); (iii) whether the adviser has clients other than investment companies (Item 93); (iv) whether the SBIC is part of a family of investment companies (Item 94); (v) information on the sales, repurchase and redemptions of the SBIC's securities (Item 95); (vi) securities of the SBIC registered on an exchange (Item 96); (vii) certain financial information, including income, expenses, assets, liabilities, and shareholders' equity (Items 97–101); (viii) exhibits (Item 102); (ix) information on subsidiaries (Items 103–104); and (x) information on fidelity bonds and officers and directors insurance (Items 105–110).

have therefore concluded that requiring UITs and SBICs to certify their reports on Form N–SAR does not produce any meaningful benefit to investors.

While certification of Form N–SAR will no longer be required, UITs and SBICs will continue to file Form N–SAR under both the Exchange Act and the Investment Company Act.[36] UITs and SBICs generally are not required to transmit reports to shareholders containing their financial statements, and UITs and SBICs will not be required to file certified shareholder reports under the Exchange Act.[37] We do not believe that it would be appropriate to remove UITs and SBICs from Exchange Act reporting status by making Form N–SAR an Investment Company Act-only form.

4. Disclosure Controls and Procedures

We are adopting, with modifications to address commenters' concerns, new rule 30a–3, which requires registered management investment companies to maintain, and regularly evaluate the effectiveness of, controls and procedures designed to ensure that the information required in filings on Form N–CSR is recorded, processed, summarized, and reported on a timely basis.[38] Investment companies filing reports under Section 13(a) or 15(d) of the Exchange Act are currently required to maintain disclosure controls and procedures with respect to Exchange Act reports.[39] Rule 30a–3 applies this requirement uniformly to all registered management investment companies, regardless of whether they are subject to Section 13(a) or 15(d) of the Exchange Act.[40] We believe that registered management investment companies filing Form N–CSR should maintain effective disclosure controls and procedures, regardless of whether they fall within the periodic reporting requirements of the Exchange Act. We are also amending the definition of ''disclosure controls and procedures'' in rule 30a–2(c) to make clear that such controls and procedures apply to registered management investment companies regardless of whether they are subject to Section 13(a) or 15(d) of the Exchange Act, and that they do not apply to SBICs and UITs filing Exchange Act reports on Form N–SAR that are not required to be certified.[41]

We are also adopting, as proposed, the requirement of rule 30a–3(b) that a registered management investment company, under the supervision and with the participation of the principal executive and financial officers, conduct an evaluation of its disclosure controls and procedures within the 90-day period prior to the filing date of each Form N–CSR requiring certification under Investment Company Act rule 30a–2.[42] We expect that this evaluation will be carried out in a manner that will form the basis for the certification required by Section 302 of the Sarbanes-Oxley Act regarding disclosure controls and procedures required by Investment Company Act rule 30a–2(b)(4).[43]

As proposed, rule 30a–3 would have extended the requirement to maintain and evaluate disclosure controls and procedures to filings under the Securities Act of 1933 (''Securities Act'') and the Investment Company Act.[44] Commenters argued that this extension would impose a larger burden on investment companies than on operating companies, which are only required to maintain disclosure controls and procedures with respect to their Exchange Act reports. Commenters pointed out that under the rule, as proposed, investment companies would have to establish and maintain, and conduct evaluations of the effectiveness of, disclosure controls and procedures on at least a semi-annual basis, with respect to all of the updates of their registration statements, as well as with respect to other filings required under the Securities Act and the Investment Company Act, including advertisements and sales literature.[45] According to commenters, these periodic evaluations would add substantially to the workload of fund officers, but would not result in a discernible benefit to fund shareholders or further the intent of the Sarbanes-Oxley Act.

Section 302 of the Sarbanes-Oxley Act does not require evaluations of disclosure controls and procedures with respect to non-Exchange Act filings, and we have determined that it would not be appropriate to extend this requirement to Securities Act and Investment Company Act filings at this time. We are concerned that the evaluation process could be unduly burdensome, relative to its benefits, when applied to these other filings. Therefore, we are limiting the requirement to maintain and evaluate disclosure controls and procedures to Form N–CSR, the Exchange Act document that will be subject to the Sarbanes-Oxley Act certification requirements.

We wish to emphasize that effective disclosure controls and procedures are essential for an investment company to meet its disclosure obligations under all of the securities laws, including the Securities Act and the Investment Company Act. Our limitation of the definition of disclosure controls and procedures to Form N–CSR in the rules we adopt today in no way diminishes the importance of disclosure controls and procedures designed to ensure that the information required in other filings made by an investment company, including prospectuses and prospectus amendments, advertisements and sales literature, and Form N–SAR, is recorded, processed, summarized, and reported on a timely basis. Our determination to limit the scope of disclosure controls and procedures in these rules rests on our concern that the burdens of the specific evaluation

[36] Rules 30a–1, 30b1–1, and 30d–1 under the Investment Company Act [17 CFR 270.30a–1; 17 CFR 270.30b1–1; 17 CFR 270.30d–1]; 17 CFR 249.330; 17 CFR 274.101; General Instruction A to Form N–SAR.

[37] Rules 30b2–1(a) and 30d–1 under the Investment Company Act [17 CFR 270.30b2–1(a); 17 CFR 270.30d–1] and General Instruction A to Form N–CSR [17 CFR 249.331; 17 CFR 274.128]. SBICs are not required under rule 30e–1(a) [17 CFR 270.30e–1(a)] to transmit reports to shareholders containing their financial statements, because Form N–5 [17 CFR 239.24; 17 CFR 274.5], the registration form for SBICs, does not prescribe requirements for reports to shareholders by SBICs.

[38] 17 CFR 270.30a–3. SBICs will not be required to maintain disclosure controls and procedures as required by rule 30a-3 because they do not file reports on Form N–CSR. *See supra* note 37.

[39] Rules 13a–15 and 15d–15 under the Exchange Act [17 CFR 240.13a–15; 17 CFR 15d–15].

[40] *See supra* note 2 (description of Exchange Act reporting requirements).

[41] Rule 30a–2(c) under the Investment Company Act [17 CFR 270.30a–2(c)]. We are also adopting conforming amendments to rules 13a–15 and 15d–15 under the Exchange Act [17 CFR 240.13a–15; 17 CFR 240.15d–15] to exclude SBICs and UITs from the requirements to maintain disclosure controls and procedures under those rules.

[42] 17 CFR 270.30a–3(b).

[43] We recognize that, in the case of a series fund or family of investment companies, the disclosure controls and procedures for each fund in the series or family may be the same. Therefore, for purposes of Rule 30a–2(b)(4)(ii) and (iii), a single evaluation of the effectiveness of the disclosure controls and procedures for the series or family could be used in multiple certifications for the funds in the series or family, as long as the evaluation has been performed within 90 days of the date of the report on Form N–CSR.

[44] Form N–CSR Proposing Release, *supra* note, 67 FR at 57306 (proposed rules 30a–2(c) and 30a–3 under the Investment Company Act).

[45] Section 24(b) of the Investment Company Act [15 U.S.C. 80a–24(b)] requires investment companies to file ''any advertisement, pamphlet, circular, form letter, or other sales literature'' with the Commission. Rule 24b–3 under the Investment Company Act [17 CFR 270.24b–3] permits investment companies to satisfy this requirement by filing sales literature with the National Association of Securities Dealers, Inc. (''NASD'') or another national securities association registered under Section 15A of the Exchange Act [15 U.S.C. 78o]. Rule 497(a)(1) under the Securities Act [17 CFR 230.497(a)(1)] requires an investment company advertisement pursuant to rule 482 under the Securities Act [17 CFR 230.482] to be filed with the Commission, and rule 497(i) under the Securities Act [17 CFR 230.497(i)] permits a rule 482 advertisement to be considered filed with the Commission if it is filed with the NASD or another national securities association registered under Section 15A of the Exchange Act.

process mandated by the rules may outweigh its benefits when extended to these other filings.

5. Extension of Time for Filing Form N–CSR

We are also adopting amendments to require an investment company to file a Form 12b–25 if it will not be able to file a report on Form N–CSR in a timely manner.[46] Filing of a Form 12b–25 would provide the investment company with an automatic extension of time to file Form N–CSR of up to 15 calendar days following the prescribed due date. Form 12b–25 currently may be used for reports on Form N–SAR, and we note that the form will continue to be available to all filers on Form N–SAR, including registered management investment companies filing exclusively under the Investment Company Act.

B. Section 406 of the Sarbanes-Oxley Act—Code of Ethics

We are adopting, with modifications to address commenters' concerns, our proposed amendments that implement Section 406 of the Sarbanes-Oxley Act with respect to registered management investment companies. These requirements are similar to those we recently adopted for operating companies, and we direct investment companies to that release for information concerning these requirements.[47] The amendments we are adopting will require a registered management investment company to:

- Disclose annually whether the investment company has adopted a code of ethics that applies to the investment company's principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions, regardless of whether these individuals are employed by the investment company or a third party;[48]
- If the investment company has not adopted a code of ethics, explain why it has not done so;[49]
- Describe briefly the nature of any amendment to, or waiver from a provision of, the investment company's code of ethics in its report on Form N–CSR or Form N–SAR, as applicable. In the alternative, the investment company may disclose this information on its Internet website within five business days following the date of the amendment or waiver, if the investment company has disclosed in its most recently filed report on Form N–CSR or Form N–SAR its intention to provide disclosure in this manner and its Internet address, it makes the information available on its website for a 12-month period, and it retains the information for a period of not less than six years following the end of the fiscal year in which the amendment or waiver occurred.[50]

The rules, as adopted, reflect modifications that are similar to those we recently made to the proposed code of ethics disclosure requirements for operating companies, for the reasons described in the release adopting these disclosure requirements for operating companies. These modifications include:

- Elimination of the component of the definition of a code of ethics requiring the code to promote the avoidance of conflicts of interest, including disclosure to an appropriate person or persons identified in the code of any material transaction or relationship that reasonably could be expected to give rise to such a conflict;[51]
- Addition of an instruction to indicate that a company may have separate codes of ethics for different types of officers and that the provisions of the company's code of ethics that address the elements listed in the definition and apply to those officers may be part of a broader code that addresses additional issues and applies to additional persons;[52]
- Allowing a company to choose among three alternative methods of making their ethics codes publicly available, including:

(i) Filing a copy of the code as an exhibit to its annual report on Form N–CSR or Form N–SAR;

(ii) Posting the text of the code on the company's Internet website and disclosing, in its most recent report on Form N–CSR or Form N–SAR, its Internet address and the fact that it has posted the code of ethics on its Internet website; or

(iii) Providing an undertaking in the company's most recent report on Form N–CSR or Form N–SAR to provide a copy of the code to any person without charge upon request, and explaining the manner in which such a request may be made;[53]

- Extension of the deadline for disclosing any amendments to, or waivers from, the company's code of ethics on its Internet website from two business days to five business days after the amendment or waiver;[54]
- Clarification that only amendments to, and waivers from, a company's code relating to specified elements of the code and specified officers must be disclosed;[55]
- Addition of a definition of the terms ''waiver'' and ''implicit waiver';[56] and
- Clarification that a company does not need to disclose technical, administrative, or other non-substantive amendments to its code of ethics.[57]

These disclosure requirements will apply to all registered management investment companies, regardless of whether they are required to file reports pursuant to Section 13(a) or 15(d) of the Exchange Act. Management investment companies other than SBICs will provide the required disclosure in Item 2 of Form N–CSR, and SBICs will provide the required disclosure as an exhibit to Form N–SAR.[58]

Several commenters suggested that the code of ethics requirements should not apply to any registered investment companies. These commenters argued that the proposed amendments were unnecessary and potentially duplicative, noting that investment companies are already required to disclose whether they have a code of

[46] Rule 12b–25(a) and (b)(2)(ii) under the Exchange Act [17 CFR 240.12b–25(a) and (b)(2)(ii)] and Exchange Act Form 12b–25 [17 CFR 249.322].

[47] *See* Section II.B., ''Code of Ethics,'' in Section 406/407 Adopting Release, *supra* note 8.

[48] Item 2(a) of Form N–CSR; Instruction 102P3(a)(1) of Form N–SAR.

[49] *Id.*

[50] Items 2(c), 2(d), and 2(e), and Instruction 3 to Item 2, of Form N–CSR; Instructions 102P3(a)(3), (a)(4), (a)(5), and (a)(9) of Form N–SAR.

[51] Item 2(b) of Form N–CSR; Instruction 102P3(a)(2) of Form N–SAR; Section II.B.2.c., ''Final Definition of 'Code of Ethics,' '' in Section 406/407 Adopting Release, *supra* note.

[52] Instruction 1 to Item 2 of Form N–CSR; Instruction 102P3(a)(7) of Form N–SAR; Section II.B.2.c., ''Final Definition of 'Code of Ethics,' '' in Section 406/407 Adopting Release, *supra* note 8.

[53] Item 2(f) of Form N–CSR; Instruction 102P3(a)(6) of Form N–SAR; Section II.B.3, ''Filing of Ethics Code as an Exhibit,'' in Section 406/407 Adopting Release, *supra* note 8. Because Forms N–CSR and N–SAR are filed semi-annually, unlike Forms 10–K and 10–KSB for operating companies, our rules require disclosure of the intention to provide Internet disclosure of the code of ethics, or the undertaking to provide a copy of the code of ethics to any person upon written request, in the investment company's most recently filed semi-annual report on Form N–CSR or N–SAR.

[54] Instruction 3 to Item 2 of Form N–CSR; Instruction 102P3(a)(9) of Form N–SAR; Section II.B.5, ''Form 8–K or Internet Disclosure Regarding Changes to, or Waivers from, the Code of Ethics,'' in Section 406/407 Adopting Release, *supra* note 8.

[55] Items 2(c) and 2(d) of Form N–CSR; Instructions 102P3(a)(3) and (a)(4) of Form N–SAR; Section II.B.5, ''Form 8–K or Internet Disclosure Regarding Changes to, or Waivers from, the Code of Ethics,'' in Section 406/407 Adopting Release, *supra* note.

[56] Instruction 5 to Item 2 of Form N–CSR; Instruction 102P3(a)(11) of Form N–SAR; Section II.B.5, ''Form 8–K or Internet Disclosure Regarding Changes to, or Waivers from, the Code of Ethics,'' in Section 406/407 Adopting Release, *supra* note 8.

[57] Instruction 4 to Item 2 of Form N–CSR; Instruction 102P3(a)(10) of Form N–SAR; ''Form 8–K or Internet Disclosure Regarding Changes to, or Waivers from, the Code of Ethics,'' in Section 406/407 Adopting Release, *supra* note 8.

[58] Item 2 of Form N–CSR; Instruction 102P3(a) of Form N–SAR.

ethics pursuant to rule 17j–1 under the Investment Company Act, and that in any event, investment companies are highly regulated under the Investment Company Act, which addresses the underlying ethical concerns substantively rather than simply through disclosure.[59]

We continue to believe, however, that the rule should apply with equal force to investment companies and operating companies, and we note that the Sarbanes-Oxley Act does not distinguish between them with respect to the code of ethics requirements. We recognize that rule 17j–1 currently requires investment companies, and their investment advisers and principal underwriters, to adopt codes of ethics designed to prevent fraud resulting from personal trading in securities by portfolio managers and other employees. The amendments we are adopting today, however, will address a broader range of conduct, including disclosure provided in filings with the Commission; compliance with governmental laws, rules, and regulations; and ethical conduct generally, including the ethical handling of actual or apparent conflicts of interest.[60]

The rules we are adopting will require disclosure of an investment company's code of ethics that applies to its principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions, regardless of whether these individuals are employed by the investment company or a third party.[61] Our proposed rules would also have required disclosure of certain codes of ethics of an investment company's investment adviser and principal underwriter that apply to the adviser's and underwriter's principal executive officer and senior financial officers.[62]

We are persuaded by commenters that including codes of ethics of the investment adviser and principal underwriter goes beyond the intended scope of Section 406. In large financial services organizations, the principal executive officer and senior financial officers may have little to do with the operations or financial reporting of the investment company, but are instead responsible principally for the adviser's or underwriter's own operations and financial reporting.

In addition, we have determined to exclude UITs from the code of ethics disclosure requirements. Because UITs are unmanaged, passive investment companies, they typically do not have principal executive officers, principal financial officers, principal accounting officers or controllers, or persons performing similar functions. In light of the fact that we have limited the rules we are adopting to these persons, we believe that it is appropriate to exclude UITs from the disclosure requirements. We note that we have provided a similar exclusion to issuers of asset-backed securities.[63]

C. Section 407 of the Sarbanes-Oxley Act—Audit Committee Financial Experts

We are adopting, with modifications to address commenters' concerns, our proposals that implement Section 407 of the Sarbanes-Oxley Act with respect to registered management investment companies. These requirements are similar to those that we recently adopted for operating companies, and we direct investment companies to that release for guidance concerning these requirements.[64] Under the provisions that we are adopting, a registered management investment company must disclose annually that its board of directors has determined that the company either: (i) Has at least one ''audit committee financial expert'' serving on its audit committee, and if so, the name of the expert and whether the expert is ''independent'; or (ii) does not have an audit committee financial expert serving on its audit committee. An investment company disclosing that it does not have an audit committee financial expert must explain why it does not have such an expert.[65]

The rules, as adopted, reflect modifications that are similar to those that we recently made to the proposed financial expert disclosure requirements for operating companies, for the reasons described in the release adopting these disclosure requirements for operating companies. These modifications include:

- Use of the term ''audit committee financial expert'' rather than ''financial expert;''[66]
- Modification of the proposals that would have required disclosure of the number and names of audit committee financial experts serving on a company's audit committee to more closely track the language used in Section 407 of the Sarbanes-Oxley Act, and to require a company to disclose that its board of directors has determined that the company either has at least one audit committee financial expert serving on its audit committee or does not have an audit committee financial expert serving on its audit committee;[67]
- Modification of the proposals to permit, but not require, an investment company to disclose that it has more than one audit committee financial expert on its audit committee. Therefore, once an investment company's board determines that a particular audit committee member qualifies as an audit committee financial expert, it may, but is not required to, determine whether additional audit committee members also qualify as experts. Every investment company subject to the audit committee disclosure requirements would, however, have to determine whether or not it has at least one audit committee financial expert; a company will not satisfy the new disclosure requirements by stating that it has decided not to make a determination or by simply disclosing the qualifications of all of its audit committee members. Furthermore, if the company's board determines that at least one of the audit committee members qualifies as an expert, the company must accurately disclose this fact. It will not be appropriate for a company to disclose that it does not have an audit committee financial expert if its board has determined that

[59] 17 CFR 270.17j–1.

[60] General Instruction D to Form N–CSR permits a registered management investment company to incorporate its code of ethics by reference from another document, such as its registration statement. *See* Item 23(p) of Form N–1A; Item 24.2.r of Form N–2; Item 28(b)(17) of Form N–3 (requiring codes of ethics required by rule 17j–1 to be filed as exhibits to registration statements).

[61] Item 2 of Form N–CSR; Instruction 102P3(a) of Form N–SAR.

[62] Section 406/407 Proposing Release, *supra* note, 67 FR at 66217.

[63] *See* Instruction 3 to Item 406 of Regulation S–K [17 CFR 229.406]; Section II.D., ''Asset-Backed Issuers,'' in Section 406/407 Adopting Release, *supra* note 8.

[64] *See* Section II.A, ''Audit Committee Financial Experts,'' in Section 406/407 Adopting Release, *supra* note 8.

[65] Registered management investment companies other than SBICs will be required to provide the audit committee financial expert disclosure in Item 3 of Form N–CSR. SBICs will be required to provide this disclosure in an exhibit to Form N–SAR, pursuant to Instruction 102P3(b) of Form N–SAR (SBICs).

[66] Item 3 of Form N–CSR; Instruction 102P3(b) of Form N–SAR; Section II.A.1, ''Title of the Expert,'' in Section 406/407 Adopting Release, *supra* note 8. Throughout this release, we refer to both ''audit committee financial experts'' and ''financial experts'' as appropriate in a particular context. For example, when discussing statutory provisions, we refer to ''financial experts.'' For purposes of the discussions in this release, the meanings of these terms are identical.

[67] Item 3(a)(1) of Form N–CSR; Instruction 102P3(b)(1) of Form N–SAR; Section II.A.2, ''Disclosure of the Number and Names of Audit Committee Financial Experts,'' in Section 406/407 Adopting Release, *supra* note 8.

such an expert serves on the audit committee;[68]

• Reorganization of the components of the definition of audit committee financial expert to make it easier to read and to emphasize, by including them in the first part of the definition, the attributes that an audit committee financial expert must possess;[69]

• Revision of the second attribute to state that the audit committee financial expert must have the ability to assess the general application of generally accepted accounting principles in connection with the accounting for estimates, accruals, and reserves, rather than stating that the expert must have experience applying these principles;[70]

• Broadening of the third attribute by requiring an audit committee financial expert to have experience ''preparing, auditing, analyzing, or evaluating'' financial statements that present a breadth and level of complexity of accounting issues that are generally comparable to the breadth and complexity of issues that can reasonably be expected to be raised by the registrant's financial statements, or experience actively supervising a person who prepares, audits, analyzes or evaluates financial statements;[71]

• Modification of the fourth attribute to require understanding of, rather than experience with, internal controls and procedures for financial reporting;[72]

• Modification of the definition to state that a person must have acquired the five necessary attributes through any one or more of the following: (i) Education and experience as a principal financial officer, principal accounting officer, controller, public accountant, or auditor or experience in one or more positions that involve the performance of similar functions; (ii) experience actively supervising a principal financial officer, principal accounting officer, controller, public accountant, auditor, or person performing similar functions; (iii) experience overseeing or assessing the performance of companies or public accountants with respect to the preparation, auditing, or evaluation of financial statements; or (iv) other relevant experience.[73]

• Elimination of the requirement that an audit committee financial expert must have gained the relevant expertise with a company that was required to file reports pursuant to Section 13(a) or 15(d) of the Exchange Act;[74]

• Addition of a requirement that if a person qualifies as an audit committee financial expert by virtue of possessing ''other relevant experience,'' the company's disclosure briefly list that person's experience;[75]

• Elimination of the list of factors that a company's board of directors should consider in evaluating the education and experience of an audit committee financial expert candidate;[76] and

• Addition of a safe harbor in the audit committee disclosure requirements.[77]

We wish to emphasize that, as with an operating company, the board of an investment company must ensure that it names an audit committee financial expert who embodies the highest standards of personal and professional integrity. In this regard, a board should consider any disciplinary actions to which a potential expert is, or has been, subject in determining whether that person would be a suitable audit committee financial expert.[78]

The disclosure requirements that we are adopting will apply to all registered management investment companies, regardless of whether they are required to file reports under Section 13(a) or 15(d) of the Exchange Act. Several commenters objected to our proposal to require a registered management investment company to provide disclosure about audit committee financial experts serving on its audit committee. They argued that investment companies should be excluded entirely from any disclosure requirement relating to audit committee financial experts, because the nature of investment company accounting is such that investment company audit committees rarely are required to apply complex accounting principles. These commenters stated that the preparation of investment company financial statements is straightforward and does not present the types of circumstances that require the exercise of judgment, such as selection of accounting policies, that preparation of the financial statements of operating companies would.

We continue to believe, however, that the rule should apply with equal force to investment companies and operating companies, and we note that the Sarbanes-Oxley Act does not distinguish between them with respect to the financial expert disclosure requirements. In addition, while investment company financial statements may, in many cases, be simpler than those of some operating companies, the underlying financial systems, reporting mechanisms, and internal controls are sufficiently complex that an investment company's audit committee would benefit from having one or more members who meet the definition of audit committee financial expert. Finally, we note that the modifications that we have made to the definition of an audit committee financial expert should address the concerns of commenters that the definition was too narrowly drawn to apply in the context of investment companies. The commenters argued, in particular, that the second, third, and fourth required attributes were too restrictive, and that experience as a public accountant or auditor, or principal financial officer, controller, or public accounting officer of a company should not be the exclusive means for acquiring the attributes. As described above, we have made changes that are responsive to these concerns.

[68] Instruction 2 to Item 3(a) of Form N–CSR; Instruction 102P3(b)(5) of Form N–SAR; Section II.A.2, ''Disclosure of the Number and Names of Audit Committee Financial Experts,'' in Section 406/407 Adopting Release, *supra* note.

[69] Items 3(b) and 3(c) of Form N–CSR; Instructions 102P3(b)(6) and (b)(7) of Form N–SAR; Section II.A.4.d., ''Discussion of Significant Modifications to the Proposed Definition of ''Financial Expert,''' in Section 406/407 Adopting Release, *supra* note 8.

[70] Item 3(b)(2) of Form N–CSR; Instruction 102P3(b)(6)(ii) of Form N–SAR; Section II.A.4.d.(ii), ''Discussion of Significant Modifications to the Proposed Definition of ''Financial Expert,''' in Section 406/407 Adopting Release, *supra* note.

[71] Item 3(b)(3) of Form N–CSR; Instruction 102P3(b)(6)(iii) of Form N–SAR; Section II.A.4.d., ''Discussion of Significant Modifications to the Proposed Definition of ''Financial Expert,''' in Section 406/407 Adopting Release, *supra* note 8. By active supervision, we do not simply mean that a traditional hierarchical reporting relationship exists between supervisor and those being supervised. Rather, we mean that a person engaged in active supervision addresses, albeit at a supervisory level, the same general types of issues regarding preparation, auditing, analysis, or evaluation of financial statements as those addressed by the person or persons being supervised.

[72] Item 3(b)(4) of Form N–CSR; Instruction 102P3(b)(6)(iv) of Form N–SAR; Section II.A.4.d., ''Discussion of Significant Modifications to the Proposed Definition of ''Financial Expert,''' in Section 406/407 Adopting Release, *supra* note 8.

[73] Item 3(c) of Form N–CSR; Instruction 102P3(b)(7) of Form N–SAR; Section II.A.4.d., ''Discussion of Significant Modifications to the Proposed Definition of ''Financial Expert,''' in Section 406/407 Adopting Release, *supra* note 8.

[74] Item 3(c) of Form N–CSR; Instruction 102P3(b)(7) of Form N–SAR; Section II.A.4.d., ''Discussion of Significant Modifications to the Proposed Definition of ''Financial Expert,''' in Section 406/407 Adopting Release, *supra* note 8.

[75] Instruction to Item 3 of Form N–CSR; Instruction 102P3(b)(9) of Form N–SAR.

[76] Section II.A.4.d., ''Discussion of Significant Modifications to the Proposed Definition of ''Financial Expert,''' in Section 406/407 Adopting Release, *supra* note 8.

[77] Item 3(d) of Form N–CSR; Instruction 102P3(b)(8) of Form N–SAR; Section II.A.5, ''Safe Harbor from Liability for Audit Committee Financial Experts,'' in Section 406/407 Adopting Release, *supra* note 8.

[78] Section II.A.4.d., ''Discussion of Significant Modifications to the Proposed Definition of ''Financial Expert,''' in Section 406/407 Adopting Release, *supra* note 8.

We are adopting, substantially as proposed, a test for whether an audit committee financial expert may be considered to be ''independent'' that differs from the test we have adopted for operating companies. The definition of ''independence'' adopted for operating companies refers to the definition of ''independent'' used in Item 7(d)(3)(iv) of Schedule 14A, which generally is not applicable to investment companies.[79] Under the rules we are adopting, in order to be considered ''independent,'' a member of an audit committee of a registered management investment company may not, other than in his or her capacity as a member of the audit committee, the board of directors, or any other board committee: (i) Accept directly or indirectly any consulting, advisory, or other compensatory fee from the issuer; or (ii) be an ''interested person'' of the investment company, as defined in Section 2(a)(19) of the Investment Company Act.[80]

III. Transition Provisions and Compliance Dates

Except as provided in the following sentence, the effective date of the rules, rule and form amendments, and Form N–CSR is March 1, 2003. The effective date of the removal of the certification requirement from Form N–SAR for registered management investment companies other than SBICs is May 1, 2003.

A registered management investment company other than an SBIC that has a fiscal annual or semi-annual period ending on or before March 31, 2003, may choose either to file Form N–CSR or to continue to comply with the certification requirements of Form N–SAR. A registered management investment company that elects to file Form N–CSR for a fiscal annual or semi-annual period ending on or before March 31, 2003, is not required to comply with paragraphs (b)(4), (5), and (6) of Investment Company Act Rule 30a-2, Item 9(a) of Form N–CSR, or paragraph (b) of Exchange Act Rules 13a-15 and 15d-15 and Investment Company Act Rule 30a-3 with respect to that Form N–CSR. A registered management investment company that elects to certify Form N–SAR for a fiscal annual or semi-annual period ending on or before March 31, 2003, must file its report to shareholders for that period as currently required. This transition is designed so that each such registered management investment company other than an SBIC will be required to provide a certification of its financial statements and financial information, while providing the flexibility to each company to determine whether to certify Form N–SAR or Form N–CSR during the transition period and sufficient time to establish and evaluate disclosure controls and procedures for Form N–CSR. A registered management investment company other than an SBIC that has a fiscal annual or semi-annual period ending on or after April 1, 2003, is required to file Form N–CSR for that period. Beginning immediately, a unit investment trust or an SBIC may omit the certification from Form N–SAR.

Registered management investment companies must comply with the code of ethics disclosure requirements promulgated under Section 406 of the Sarbanes-Oxley Act in their annual reports on Form N–CSR or N–SAR for fiscal years ending on or after July 15, 2003. They also must comply with the requirements regarding disclosure of amendments to, and waivers from, their ethics codes on or after the date on which they file their first annual report on Form N–CSR or N–SAR in which disclosure of their code of ethics is required. Registered management investment companies similarly must comply with the audit committee financial expert disclosure requirements promulgated under Section 407 of the Sarbanes-Oxley Act in their annual reports on Form N–CSR or N–SAR for fiscal years ending on or after July 15, 2003.

IV. Paperwork Reduction Act

The new rules and rule and form amendments contain ''collection of information'' requirements within the meaning of the Paperwork Reduction Act of 1995 (''PRA'').[81] We published notice requesting comment on the collection of information requirements in the release proposing Form N–CSR,[82] submitted these requirements to the Office of Management and Budget (''OMB'') for review in accordance with the PRA,[83] and received approval by OMB for this collection of information. In addition, we published notice requesting comment on the collection of information requirements in the proposing release implementing Sections 406 and 407 of the Sarbanes-Oxley Act[84] and submitted these requirements to OMB for review. This request is pending before OMB.

The titles for the collection of information are ''Form N–CSR under the Investment Company Act of 1940 and Securities Exchange Act of 1934, Certified Shareholder Report;'' ''Form N–SAR under the Investment Company Act of 1940, Semi-Annual Report for Registered Investment Companies;'' and ''Form 12b–25 under the Securities Exchange Act of 1934, Notification of Late Filing.''

Form N–SAR (OMB Control No. 3235–0330) under the Exchange Act and the Investment Company Act [17 CFR 249.330; 17 CFR 274.101] is used by registered investment companies to file periodic reports with the Commission. Form N–CSR (OMB Control No. 3235–0570) under the Exchange Act and the Investment Company Act [17 CFR 249.331; 17 CFR 274.128] will be used by registered management investment companies to file certified shareholder reports. Form 12b–25 (OMB Control No. 3235–0058) under the Exchange Act [17 CFR 249.322] provides notice to the Commission and the marketplace that a company will be unable to file a required report in a timely manner.

Compliance with the new rules and rule and form amendments is mandatory and the information provided will not be kept confidential. Under our rules for retention of manual signatures, registered investment companies have to maintain the certifications for five years.[85] An agency may not conduct or sponsor, and a person is not required to respond to, an information collection unless it displays a currently valid OMB control number.

A. Summary of New Rules

On August 28, 2002, the Commission implemented the certification requirement of Section 302 of the Sarbanes-Oxley Act with respect to registered investment companies by adopting new rule 30a–2 under the Investment Company Act and the Sarbanes-Oxley Act.[86] Rule 30a–2 requires a registered investment company that files periodic reports under Section 13(a) or 15(d) of the Exchange Act, *i.e.*, Form N–SAR, to include the certification specified by Section 302 in those periodic reports.

In a companion release, we also proposed to require registered management investment companies to file certified shareholder reports with the Commission on new Form N–CSR

[79] *See* Item 7(d)(3)(vii) of Schedule 14A [17 CFR 240.14a-101] (providing that a registered investment company, other than a closed-end investment company, need not provide the information required by Item 7(d)(3) about its audit committee).

[80] Item 3(a)(2) of Form N–CSR; Instruction 102P3(b)(2) of Form N–SAR.

[81] 44 U.S.C 3501 *et seq.*

[82] Form N–CSR Proposing Release, *supra* note 5.

[83] 44 U.S.C. 3507(d) and 5 CFR 1320.11.

[84] Investment Company Act Release No. 25775 (Oct. 22, 2002) [67 FR 66208 (Oct. 30, 2002)].

[85] *See* Rule 302(b) of Regulation S–T [17 CFR 232.302(b)].

[86] Investment Company Act Release No. 25722 (Aug. 28, 2002) [67 FR 57276 (Sept. 9, 2002)].

and to designate these certified shareholder reports as reports that are required under Sections 13(a) and 15(d) of the Exchange Act and Section 30 of the Investment Company Act.[87] As we noted in that release, we believe that the certification requirement of Section 302 of the Sarbanes-Oxley Act was intended to improve the quality of the disclosure that a company provides regarding its financial condition in its reports to investors.[88] For registered management investment companies, the required reports to shareholders, rather than reports on Form N–SAR, are the primary vehicle for providing financial information to investors. We believe that the information in these reports to shareholders should be certified, and we are adopting amendments to our forms and rules to require this certification.

We are adopting an amendment to rule 30b2–1 under the Investment Company Act, which will require a registered management investment company to file a report with the Commission on new Form N–CSR containing (i) a copy of any required shareholder report, (ii) additional information regarding disclosure controls and procedures, and (iii) the certification required by the Sarbanes-Oxley Act.[89] New rule 30d–1 designates certified shareholder reports on Form N–CSR as periodic reports under Section 13(a) or 15(d) of the Exchange Act.[90] New rule 30a–3 requires all registered management investment companies to maintain, and regularly evaluate the effectiveness of, disclosure controls and procedures designed to ensure that the information required in filings under the Exchange Act is recorded, processed, summarized, and reported on a timely basis. We are also amending the definition of ''disclosure controls and procedures'' in rule 30a–2(c) to make clear that such controls and procedures apply to all registered management investment companies regardless of whether they are required to file reports on Form N–CSR under the Exchange Act, and that they do not apply to SBICs and UITs filing Exchange Act reports on Form N–SAR.[91] Amendments to Exchange Act rules 13a–15 and 15d–15 will exclude SBICs and UITs from the requirements to maintain disclosure controls and procedures for purposes of the evaluation conducted as part of the required certification.[92] We are also removing the requirement that Form N–SAR be certified by a registered investment company's principal executive and financial officers. This shifts the information collection burden relating to the certification specified by Section 302 of the Sarbanes-Oxley Act, for registered management investment companies, from Form N–SAR to Form N–CSR.

Finally, we are requiring registered management investment companies to include new disclosures on Form N–CSR or Form N–SAR, as appropriate, in order to implement the requirements of Sections 406 and 407 of the Sarbanes-Oxley Act of 2002. First, the rules require a management investment company to disclose whether it has at least one ''audit committee financial expert'' serving on its audit committee, and if so, the name of the expert and whether the expert is independent of management. A management investment company that does not have an audit committee financial expert must disclose this fact and explain why it has no such expert. Second, the rules require a management investment company to disclose whether it has adopted a code of ethics that applies to the company's principal executive officer and senior financial officers, or persons performing similar functions, regardless of whether they are employed by the management investment company or a third party. A management investment company disclosing that it has not adopted such a code must disclose this fact and explain why it has not done so. A management investment company also will be required to disclose amendments to, and waivers from, the code of ethics relating to any of those officers.

All of these new rules and rule amendments are part of the collection of information of new Form N–CSR or Form N–SAR (in the case of SBICs) because Form N–CSR contains the requirement that each registered management investment company filing reports on this form has to certify the contents of the report, and Form N–CSR and Form N–SAR contain the requirement that management investment companies must provide the appropriate audit committee financial expert and code of ethics disclosures.

We are amending our rules and forms to provide that, for registered management investment companies other than small business investment companies, Form N–SAR will be filed under the Investment Company Act only and not the Exchange Act.[93] Also, we have amended Form N–SAR to eliminate the requirement that UITs and SBICs certify their reports on Form N–SAR.[94] We are also adopting amendments to require an investment company to file a Form 12b-25 if it will not be able to file a report on Form N–CSR in a timely manner.[95]

B. Reporting and Cost Burden Estimates

Certification of Form N–CSR

The reporting burden associated with the certification requirement requires the principal executive and financial officer to review and analyze each periodic report to be filed by an investment company in order to make the required certification. In the release proposing Form N–CSR, we estimated a total of five burden hours per respondent for the certification and asked for comment on this estimate.[96] We received three comment letters specifically discussing our estimate of the burden for filing and certifying Form

[87] *See* Form N–CSR Proposing Release, *supra* note 5.

A management investment company is an investment company other than a unit investment trust or face-amount certificate company. *See* Section 4 of the Investment Company Act [15 U.S.C. 80a–4]. Management investment companies typically issue shares representing an undivided proportionate interest in a changing pool of securities, and include open-end and closed-end companies. *See* T. Lemke, G. Lins, A. Smith III, Regulation of Investment Companies, Vol. I, ch. 4, § 4.04, at 4–5 (2002).

[88] Form N–CSR Proposing Release, *supra* note 5, 67 FR at 57299.

[89] Rule 30b2–1(a) under the Investment Company Act [17 CFR 270.30b2–1(a)]; Items 1, 9, and 10(b). In addition, we are amending rule 30a–2 under the Investment Company Act [17 CFR 270.30a–2] to require Form N–CSR to include the certification required by Section 302 of the Sarbanes-Oxley Act.

[90] We are also adopting a technical conforming amendment that would delete the language in current rule 30a–1 [17 CFR 270.30a–1] stating that a registered management investment company required to file an annual report pursuant to Section 13(a) or 15(d) of the Exchange Act and Section 30(a) of the Investment Company Act shall be deemed to have satisfied its requirement to file an annual report by the filing of semi-annual reports on Form N–SAR. The amendments rename rule 30a–1 in order to specify that it relates to annual reports by registered unit investment trusts, and rename rule 30b1–1 [17 CFR 270.30b1–1] in order to specify that it relates to semi-annual reports of registered management investment companies.

[91] Rule 30a–2(c) under the Investment Company Act [17 CFR 270.30a–2].

[92] 17 CFR 240.13a–15(a); 17 CFR 240.15d–15(a).

[93] *See* Rule 30b1–1 under the Investment Company Act [17 CFR 270.30b1–1]; and General Instruction A to Form N–SAR [17 CFR 274.101]. In addition, we are adopting technical conforming amendments to rule 30b1–3 [17 CFR 270.30b1–3] to remove the reference to Form N–SAR.

[94] Instruction 102P3 of Form N–SAR; Instruction to Item 133 of Form N–SAR.

[95] Rule 12b-25(a) and (b)(2)(ii) under the Exchange Act [17 CFR 240.12b-25(a) and (b)(2)(ii)] and Exchange Act Form 12b-25 [17 CFR 249.322]. There is no collection of information for the amendments to rule 12b-25 because they are attributed to Form 12b-25.

[96] This estimate is based on the estimate of the burden of certification with respect to operating companies. *See* Investment Company Act Release No. 25722, *supra* note, 67 FR at 57284 (estimating PRA burden of certification of Forms 10–K, 10–KSB, 10–Q, 10–QSB, 20–F, and 40–F at five hours per form).

N–CSR. Two commenters claimed that our estimate was too low, because it did not reflect the fact that investment companies often have multiple portfolios. We note that our estimate already takes into account that many registered management investment companies have multiple portfolios. Our estimate of the hour burden required for operating companies to certify their reporting forms, such as Form 10–K, is similar to our estimate of the burden for investment companies.[97] While reports on Form N–CSR will contain financial statements for multiple portfolios, investment company financial statements are generally much simpler than operating company financial statements, and operating company reporting forms, such as Form 10–K, contain much information (*i.e.*, Management's Discussion and Analysis) that Form N–CSR will not contain. Based on the comments, however, we have revised our estimate, to estimate that the certification requirement required by Section 302 of the Sarbanes-Oxley Act will result in an increase of five burden hours per registrant per filing and an additional 0.5 hours per additional portfolio in connection with the certification of annual and semi-annual reports on Form N–CSR.[98]

Audit Committee Financial Expert

The amendments will increase the burden of completing Form N–CSR and Form N–SAR by requiring a management investment company to disclose whether it has at least one ''audit committee financial expert'' serving on its audit committee, and if so, the name of the expert and whether the expert is independent of management. A management investment company that does not have an audit committee financial expert must disclose this fact and explain why it has no such expert. In the release proposing these amendments, we estimated that the disclosure regarding audit committee financial experts would increase the annual burden of completing Form N–CSR or Form N–SAR by 0.5 hours per registered management investment company. We received no comments on this estimate. We believe the additional burden of these amendments would be limited, because they will not require any investment company to add an ''audit committee financial expert'' to its board. We estimate that the disclosure requirements regarding audit committee financial experts will result in an incremental increase of 0.5 burden hours per registrant per year in connection with preparing each annual report on Form N–CSR or Form N–SAR.[99] Management investment companies (other than SBICs) will have to provide this disclosure on Form N–CSR; SBICs will have to provide this disclosure on Form N–SAR.

Codes of Ethics

The amendments will require a registered management investment company to disclose whether it has adopted a written code of ethics for its principal executive officer, principal financial officer, principal accounting officer or controller, or persons serving similar functions, and file the code as an exhibit to Form N–CSR or Form N–SAR. An investment company disclosing that it has not adopted such a code must disclose this fact and explain why it has not done so. In the release proposing these amendments, we estimated that the disclosure regarding code of ethics would increase the annual burden by 0.5 hours per registered management investment company. We believe that the additional burden of these amendments would be limited, because they will not require any company to adopt such a code of ethics. Management should be readily able to determine whether or not its company has adopted a code of ethics. In certain cases, the required disclosure would require minimal analysis regarding why the company does not have a code. In addition, in the first year, registrants must file a copy of the code with the Commission. We estimate that the disclosure requirements regarding codes of ethics will also result in an incremental increase of 0.5 burden hours per registrant in connection with each annual report on Form N–CSR or Form N–SAR.[100] Management investment companies (other than SBICs) will have to make this disclosure on Form N–CSR; SBICs will have to make this disclosure on Form N–SAR.

Form N–SAR

The amendments remove the certification requirement from Form N–SAR and shift the burden of this requirement, for PRA purposes, to Form N–CSR. We estimate that about 4,500 registrants, including 3,702 management investment companies (including 2 SBICs), and 798 UITs, currently file reports on Form N–SAR. Based on an increase of 2 burden hours relating to audit committee financial experts and codes of ethics disclosure [101] and a decrease of 41,010 burden hours relating to the removal of the certification of Form N–SAR,[102] we estimate that, in the aggregate, all respondents will have an incremental decrease of 41,008 burden hours associated with Form N–SAR to comply with the new rules and rule and form amendments.

Form N–CSR

We estimate that about 3,700 registrants will file Form N–CSR. Based on Commission experience with reporting forms in general and other related rules, we estimate that approximately 75% of the added burden hours will be expended by internal staff for internal review and the remaining 25% will be for outside legal costs associated with reviewing the new disclosures at a cost of $300 per hour.[103] Based on the burden hour estimate for the certification of Form N–CSR, the disclosure related to an audit committee financial expert, and the disclosure related to the code of ethics, we estimate that, in the aggregate, all respondents will incur an incremental increase of

[97] Investment Company Act Release No. 25722, *supra* note, 67 FR at 57284 (estimating PRA burden of certification of Forms 10–K, 10–KSB, 10–Q, 10–QSB, 20–F, and 40–F at five hours per form).

[98] Currently, the estimated total burden for the certification requirement of Form N–CSR is 37,000 hours, reflecting an estimate of 3,700 management investment companies filing twice a year and an estimate of five hours per filing. In response to comments, we are increasing this estimate by 6,150 hours to reflect the additional burden for certification of multiple portfolios. We calculate 6,150 hours as follows: We estimate that there are 9,850 total portfolios of registered management investment companies. This reflects 6,150 additional series (*i.e.*, series beyond the first series or the 3,700 series already accounted for in the burden estimate) of multiple series funds filing twice a year and 0.5 hours per additional series per filing. Based on our experience with reporting forms in general, we estimate that the incremental burden hours of reviewing financial statements for other series will be relatively limited because many series may be able to use the same certification process for many of the items (*i.e.*, disclosure controls and procedures). This new requirement will result in a new total of 43,150 burden hours for the certification requirement of Form N–CSR.

[99] We estimate the total new burden for this disclosure requirement to be 1,851 hours. ((0.5 hours × 3,700 management investment companies other than SBICs) + (0.5 hours × 2 SBICs) = 1,851 hours).

[100] We estimate the total new burden for this disclosure requirement to be 1,851 hours. (0.5 hours × 3,700 management investment companies other than SBICs) + (0.5 hours × 2 SBICs) = 1,851 hours.

[101] This estimate includes 1 hour for the audit committee financial expert disclosure (0.5 hours x 2 SBICs) and 1 hour for the code of ethics disclosure (0.5 hours × 2 SBICs).

[102] (3,702 management companies (including SBICs) × 10 hours annually) + (798 UITs × 5 hours annually) = 41,010 hours.

[103] These percentages are based on consultations with several issuers, law firms and other persons who regularly assist issuers in preparing and filing reports with the Commission. We have used an estimated hourly rate of $300.00 to determine the estimated cost to issuers of having the required disclosures reviewed by outside counsel. We arrived at this hourly rate estimate based on consultations with several private law firms.

35,139 burden hours [104] and $3,513,900 in outside legal costs [105] to comply with the new rules and rule and form amendments.

Form 12b–25

Form 12b–25 provides notice to the Commission and the marketplace that registrants will be unable to file a required report in a timely manner. If certain conditions are met, the registrant will be granted an automatic filing extension. The proposed amendments would permit investment companies to use Form 12b–25 for the purpose of obtaining extensions with respect to filing Form N–CSR. We estimate that an average of 168 investment companies per year use Form 12b–25 to obtain extensions of time for filing Form N–SAR spending, on average, approximately 2.5 hours completing the form. We estimate that the same number of investment companies, though not necessarily the same specific investment companies, will also use Form 12b–25 to obtain extensions of filing Form N–CSR annually, resulting in an incremental increase of 420 burden hours [106] to comply with the new rules and form and form and rule amendments.

V. Cost-Benefit Analysis

The Commission is sensitive to the costs and benefits imposed by its rules. Our rules and rule and form amendments more fully implement Section 302 of the Sarbanes-Oxley Act by requiring a registered management investment company, other than a small business investment company (''SBIC''), to file certified shareholder reports with the Commission on Form N–CSR containing (i) a copy of any required report to shareholders, (ii) additional information regarding disclosure controls and procedures, and (iii) the certification required by Section 302 of the Sarbanes-Oxley Act. These amendments also will designate certified shareholder reports on Form N–CSR, filed by management investment companies, as periodic reports filed with the Commission under the Exchange Act. Therefore, these amendments will require the certification of each management investment company's principal executive and financial officer to be included in its certified shareholder reports on Form N–CSR. We also are amending the instructions to Form N–SAR, the semi-annual reporting form for registered investment companies, to remove the certification requirement from the form and designate it as an Investment Company Act only filing for registered management investment companies other than SBICs. Further, we are amending Form 12b–25 to permit investment companies to use Form 12b–25 for the purpose of obtaining extensions with respect to filing Form N–CSR. In addition, the rules will require all registered management investment companies, other than SBICs, to maintain, and regularly evaluate the effectiveness of, disclosure controls and procedures designed to ensure that the information required in their filings on Form N–CSR is recorded, processed, summarized, and reported on a timely basis.

Finally, we are requiring registered management investment companies to include new disclosures on Form N–CSR or Form N–SAR, as appropriate, in order to implement the requirements of Sections 406 and 407 of the Sarbanes-Oxley Act of 2002. First, the rules require a management investment company to disclose whether it has at least one ''audit committee financial expert'' serving on its audit committee, and if so, the name of the expert and whether the expert is independent of management. A management investment company that does not have an audit committee financial expert must disclose this fact and explain why it has no such expert. Second, the rules require a management investment company to disclose whether it has adopted a code of ethics that applies to the company's principal executive officer and senior financial officers, or persons performing similar functions, regardless of whether they are employed by the management investment company or any third party. A management investment company disclosing that it has not adopted such a code must disclose this fact and explain why it has not done so. A management investment company also will be required to disclose amendments to, and waivers from, the code of ethics relating to any of those officers.

We received one comment letter specifically addressing this Section. The commenter urged the Commission to review its cost-benefit analysis with a view not only to the new rules but to the increased costs, such as legal and accounting fees, imposed on smaller investment companies associated with other recently adopted rules, such as anti-money laundering procedures. The purpose of this cost-benefit analysis is to focus on the costs associated only with the adoption of the rules requiring the filing of Form N–CSR. The costs associated with other recently adopted rules imposed on smaller investment companies should be discussed in the cost-benefit sections of those specific rulemakings.

A. Benefits

Certification of Form N–CSR

In adopting these new rules and rule and form amendments, we intend to more fully implement the intent of Section 302 of the Sarbanes-Oxley Act, by improving the quality of the disclosure that an investment company provides about its financial condition in its periodic reports to investors. Section 302 of the Sarbanes-Oxley Act requires the principal executive and financial officers of an issuer to certify the information contained in the issuer's quarterly or annual reports filed under Section 13(a) or 15(d) of the Exchange Act. Currently, Form N–SAR is the reporting form for registered investment companies that satisfies the filing requirement under Section 13(a) or 15(d) of the Exchange Act. Form N–SAR does not contain financial statements and is a regulatory compliance form that is not delivered to investors. Thus, the amendments will remove the certification requirement from Form N–SAR, a form that does not contain financial statements, and will impose the certification requirement on Form N–CSR, a form that contains financial statements. Requiring a registered investment company's principal executive and financial officers to file certified shareholder reports on Form N–CSR will require these officers to certify, in part, that the financial statements and other financial information contained in the report fairly present in all material respects the financial condition, results of operations, changes in net assets, and cash flows (if the financial statements are required to include a statement of cash flows) of the registered investment company.

The rules should help to ensure that registered investment companies maintain sufficient disclosure controls and procedures to provide reasonable assurance to investors that registered investment companies can record, process, summarize, and report on a timely basis information that is required on Form N–CSR, including information

[104] 43,150 hours for certification + 1,851 hours for audit committee financial expert disclosure + 1,851 hours for code of ethics disclosure = 46,852 hours x .75 = 35,139 hours.

[105] 43,150 hours for certification + 1,851 hours for audit committee financial expert disclosure + 1,851 hours for code of ethics disclosure = 46,852 hours × .25 for outside counsel × $300 per hour = $3,513,900.

[106] 168 registered investment companies × 2.5 hours = 420 burden hours.

contained in reports to shareholders.[107] To the extent that registered investment companies do not maintain adequate procedures, the rules should lead to the development, or enhancement and modernization, of these procedures. Further, the certification requirement in our rules will require an investment company under the supervision of its management to conduct an evaluation of these disclosure controls and procedures within the 90-day period prior to the filing date of each report requiring certification. This will help to ensure that registered investment companies devote adequate resources and attention to the maintenance of their reporting systems. Additionally, the required evaluation will help to ensure the continuous, orderly, and timely flow of information within the registered investment company and, ultimately, to investors.

By emphasizing the importance of the role of senior officers in the reporting process, the new rules and rule and form amendments will help to enhance investor confidence in the quality of the disclosure in registered investment companies' reports to shareholders. This, in turn, will help to encourage investor confidence in these investment companies. Even though the certification is consistent with the current obligation of officers and directors of a mutual fund not to make statements that are materially misleading, we believe that investors may benefit from the certification because the certifying officers provide additional assurance to investors that the reports that they file under the Exchange Act meet this standard. We requested comment on these benefits, but received none.

Audit Committee Financial Expert

A management investment company must disclose whether it has at least one ''audit committee financial expert'' serving on its audit committee, and if so, the name of the expert and whether the expert is independent of management. A management investment company that does not have an audit committee financial expert must disclose this fact and explain why it has no such expert. We believe that investors will benefit from this disclosure by being able to consider it when reviewing the disclosure currently required about the background and affiliations of the directors of the investment company. Investors will also benefit to the extent that having an audit committee financial expert on an audit committee of a company increases their confidence in the company. The modifications we are making to our proposal will not reduce the level of required expertise and thus will not mitigate the benefits to investor confidence of requiring this disclosure. We requested comment on these benefits, but received none.

Codes of Ethics

The requirement that investment companies file copies of their codes of ethics will allow investors to better understand the ethical principles that guide executives of companies in which they invest. Investors will also benefit to the extent that having disclosure of a code of ethics of a company increases their confidence in the company. We requested comment on these benefits, but received none.

B. Costs

While the new rules and rule and form amendments may lead to some additional costs for registered investment companies, we believe that these costs should be limited.

Certification of Form N–CSR

These amendments will require each registered management investment company's principal executive and financial officer to certify the information contained in its certified shareholder reports on Form N–CSR. In order to provide the required certification, each principal executive and financial officer will need to review these reports. We believe that these officers already review these reports, so there should be no additional burden imposed on these companies. To the extent that these officers would need to spend additional time critically reviewing the overall context of the disclosure provided in these reports, the company would incur costs which are difficult for us to quantify.

We believe that most registered management investment companies already maintain some form of disclosure controls and procedures for identifying and processing the information needed to satisfy their disclosure obligations to their shareholders. The amendments do not dictate that registered investment companies follow any particular procedure. Alternatively, we could have required specific controls and procedures for all investment companies. By allowing management investment companies to determine what procedures are necessary to meet the obligations of the new rules, the Commission is mitigating the costs associated with compliance. Some registered management investment companies may need to institute appropriate procedures while others may need to enhance existing informal or ad hoc procedures. These incremental costs are difficult to quantify. We do not have data to quantify the cost of implementing, or upgrading and strengthening existing, internal reporting procedures.

The requirement in the certification that disclosure controls and procedures be evaluated within 90 days of the filing of a report may result in costs for registered management investment companies. Many registered management investment companies may already regularly monitor and evaluate their procedures. However, the size and scope of these internal systems are likely to vary among registered management investment companies, and it is difficult to provide an accurate cost estimate.

Audit Committee Financial Experts

The added burden associated with the requirements to name the audit committee financial expert and disclose whether the audit committee financial expert is independent should be minimal. We have added a safe harbor provision to clarify that we do not intend to increase or decrease the current level of liability of audit committee members, or the audit committee member determined to be the expert, by requiring the disclosure as to whether an audit committee financial expert serves on the audit committee. We do not think that the requirement to name the audit committee financial expert should affect the expert's potential liability as an audit committee member. We requested comment on these costs, but received none.

Codes of Ethics

We also note that we are adopting rules that require a registered management investment company to provide disclosure of any codes of ethics applicable to its principal executive officer and senior financial officers, regardless of whether they are employees of the registrant or a third party and provide this disclosure on Form N–CSR or Form N–SAR (in the case of SBICs). This additional disclosure may impose certain costs such as retrieval, printing and copying costs. However, this information should be readily available to the board of directors and management of the investment company. Therefore, we estimate the additional costs to investment companies in complying with these provisions will be limited.

[107] *See* new rule 30a–3 under the Investment Company Act [17 CFR 270.30a–3].

We requested comment on these costs, but received none.

We note that we have modified our proposed rules to provide two alternatives to the code of ethics filing requirement. An investment company may either post its code of ethics on its website if it discloses that it intends to do so in its report on Form N–CSR or N–SAR, or undertake in its report on Form N–CSR or N–SAR to provide investors with a copy of its code of ethics upon request. These alternatives should allow registrants to choose the most cost-efficient method to meet the new requirements.

We believe that the additional audit committee financial expert and code of ethics requirements are necessary to implement the purposes of the Sarbanes-Oxley Act and will impose minimal additional burden on companies. For example, we expect that investment companies will incur added costs to disclose the name of the audit committee financial expert, to disclose whether that person is independent and to file or otherwise make available copies of their codes of ethics to investors. Investment companies electing to disclose their codes of ethics, and changes in and waivers from their codes of ethics, via their websites in lieu of publicly filing such disclosure on Form N–CSR or N–SAR must disclose this election in their reports on Form N–CSR or N–SAR. Such costs do not include the costs imposed on investment companies by the Sarbanes-Oxley Act itself. Rather, they reflect the costs of our requirements beyond the requirements of the Sarbanes-Oxley Act.

Total Cost Calculations

For purposes of the PRA,[108] with respect to Form N–SAR, we further estimate that the removal of the certification requirement will remove an incremental 41,010 hours from the current total burden hours or $6,151,500[109] and the disclosure of the code of ethics and audit committee financial experts will add an incremental 2 burden hours to the current total burden hours or $259.[110]

With respect to Form N–CSR, all respondents will incur an incremental increase of 35,139 burden hours[111] or $5,152,782[112] and $3,513,900 in outside legal costs[113] to comply with the amendments. The current total burden hours of Form 12b–25 will incrementally increase by 420 hours or $15,468[114] to comply with the amendments.

VI. Consideration of Burden on Competition; Promotion of Efficiency, Competition, and Capital Formation

Section 23(a)(2) of the Exchange Act requires us, when adopting rules under the Exchange Act, to consider the impact that any new rule would have on competition. Section 23(a)(2) also prohibits us from adopting any rule that would impose a burden on competition not necessary or appropriate in furtherance of the purposes of the Exchange Act.[115] In addition, Section 2(c) of the Investment Company Act,[116] Section 2(b) of the Securities Act[117] and Section 3(f) of the Exchange Act[118] require the Commission, when engaging in rulemaking that requires it to consider or determine whether an action is necessary or appropriate in the public interest, to consider, in addition to the protection of investors, whether the action will promote efficiency, competition, and capital formation. We received no comments relating to this specific section.

The new rules and rule and form amendments are intended to more fully implement the intent of Section 302 of the Sarbanes-Oxley Act that we adopt rules requiring the principal executive and financial officers of investment companies to certify the accuracy of their periodic reports filed pursuant to Section 13(a) or 15(d) of the Exchange Act. Also, the amendments are intended, in part, to increase transparency regarding the competence of the audit committee and the application of codes of ethics to a company's principal executive officer and senior financial officers. We believe that the amendments will benefit investors by providing them with greater confidence in the accuracy and completeness of the disclosure contained in the annual and semi-annual reports that they receive from management investment companies, including the financial statements. However, the magnitude of the effect of the amendments on efficiency, competition, and capital formation is difficult to quantify, particularly given that most management investment companies currently are required to comply with the certification requirements in recently adopted amendments to Form N–SAR, which we are removing as part of the amendments we are adopting today.

VII. Final Regulatory Flexibility Analysis

This Final Regulatory Flexibility Analysis (''Analysis'') has been prepared in accordance with 5 U.S.C. 604, and relates to the Commission's rules and rule and form amendments under the Exchange Act and the Investment Company Act that will require registered management investment companies to file certified shareholder reports on Form N–CSR with the Commission, will designate these certified reports as reports that are required under Sections 13(a) and 15(d) of the Exchange Act, and will implement Sections 406 and 407 of the Sarbanes-Oxley Act. Initial Regulatory Flexibility Analyses (''IRFAs''), which were prepared in accordance with 5 U.S.C. 603, were published in the release proposing Form N–CSR and in the release proposing rules to implement Sections 406 and 407 of the Sarbanes-Oxley Act.

The rule amendments require each registered management investment company's principal executive and financial officers to certify the information contained in these reports in the manner specified by Section 302

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[108] See Section IV above.

[109] 41,010 hours × $150 = $6,151,500. The estimate cost savings is derived from the estimated reduction in burden hours, and an estimated hourly wage rate for principal executive officers of $150.00. The hourly wage rates for principal executive and financial officers are not published. We arrived at $150.00 based on other hourly wage rates published and consultations with individuals who are familiar with the hourly wage rates. This wage rate includes 35% for overhead. *See* Securities Industry Association, *Report on Management & Professional Earnings in the Securities Industry 2001* (Oct. 2001).

[110] 2 hours × $129.81 = $259. The hourly wage rate of $129.81 is based on published hourly wage rates for the deputy general counsel. This wage rate includes 35% for overhead. *See* Securities Industry Association, *Report on Management & Professional Earnings in the Securities Industry 2001* (Oct. 2001).

[111] 43,150 hours for certification + 1,851 hours for audit committee financial expert disclosure + 1,851 hours for code of ethics disclosure = 46,852 hours × .75 = 35,139 hours.

[112] 35,139 hours × $146.64 = $5,152,782. This estimated wage rate of $146.64 is a blended rate, based on published hourly wage rates for a deputy general counsel outside of New York City ($129.81) and our estimated wage rate for principal executive and financial officers ($150.00). We estimate that principal executive and financial officers would spend 5 hours certifying the annual reports on Form N–CSR and a deputy general counsel would spend 1 hour completing the code of ethics and audit committee financial expert disclosures. This yields a weighted wage rate of $146.64 (($129.81 × 1/6) + ($150.00 × 5/6)) = $146.64. This weighted wage rate includes 35% for overhead. *See* Securities Industry Association, *Report on Management & Professional Earnings in the Securities Industry 2001* (Oct. 2001).

[113] 43,150 hours for certification + 1,851 hours for audit committee financial expert disclosure + 1,851 hours for code of ethics disclosure = 46,852 hours × .25 of outside counsel × $300 per hour = $3,513,900.

[114] 420 hours × $36.83 = $15,468. We estimate that an attorney with an hourly wage rate of $36.83 completes Form 12b–25. This wage rate includes 35% for overhead. *See* Securities Industry Association, *Report on Management & Professional Earnings in the Securities Industry 2001* (Oct. 2001).

[115] 15 U.S.C. 78w(a)(2).

[116] 15 U.S.C. 80a–2(c).

[117] 15 U.S.C. 77b(b).

[118] 15 U.S.C. 78c(f).

of the Sarbanes-Oxley Act of 2002. In addition, we are providing that, for registered management investment companies other than small business investment companies, Form N–SAR will be filed under the Investment Company Act of 1940 only and not the Securities Exchange Act of 1934. We are also removing the requirement that Form N–SAR be certified by a registered investment company's principal executive and financial officers. Furthermore, we are adopting a new rule to require every registered management investment company, other than small business investment companies, to maintain disclosure controls and procedures designed to ensure that the information required in reports on Form N–CSR is recorded, processed, summarized, and reported on a timely basis. Finally, we are requiring registered management investment companies to include new disclosures on Form N–CSR or Form N–SAR, as appropriate, in order to implement the requirements of Sections 406 and 407 of the Sarbanes-Oxley Act of 2002. First, the rules require a management investment company to disclose whether it has at least one ''audit committee financial expert'' serving on its audit committee, and if so, the name of the expert and whether the expert is independent of management. A management investment company that does not have an audit committee financial expert must disclose this fact and explain why it has no such expert. Second, the rules require a management investment company to disclose whether it has adopted a code of ethics that applies to the company's principal executive officer and senior financial officers, or persons performing similar functions, regardless of whether they are employed by the management investment company or a third party. A management investment company disclosing that it has not adopted such a code must disclose this fact and explain why it has not done so. A management investment company also will be required to disclose amendments to, and waivers from, the code of ethics relating to any of those officers.

A. Need for, and Objectives of, Amendments

The purpose of the new rules and rule and form amendments is to more fully implement the intent of Section 302 of the Sarbanes-Oxley Act that we adopt rules requiring the officers of investment companies to certify the accuracy of their periodic reports filed pursuant to Section 13(a) or 15(d) of the Exchange Act.

The amendments will require registered management investment companies to file with the Commission certified shareholder reports on Form N–CSR, and will designate these reports as filings which satisfy the reporting requirements of Sections 13(a) and 15(d) of the Exchange Act for management investment companies. We believe that by requiring the certification required by Section 302 of the Sarbanes-Oxley Act to be included in a management investment company's certified shareholder report on Form N–CSR, which contains financial statements, we are more fully implementing the intent of Section 302, which is to improve the quality of the disclosure that companies provide about their financial condition in their shareholder reports. In addition, we are adopting new disclosure requirements required to comply with Sections 406 and 407 of the Sarbanes-Oxley Act.

B. Significant Issues Raised by Public Comment

In both the IRFA for the release proposing Form N–CSR and the IRFA for the release proposing to implement Sections 406 and 407 of the Sarbanes-Oxley Act, we requested comment on any aspect of the IRFAs, including the number of small entities that would be affected by the proposal, the nature of the impact, how to quantify the numbers of small entities that would be affected, and how to quantify the impact of the proposals. We received one comment letter concerning the IRFA for the release proposing Form N–CSR. The commenter raised a concern that more flexible alternatives should have been considered for small investment companies (such as not mandating Form N–CSR or new reporting requirements at all) because a small amount of fraud is committed by such investment companies. We note that Congress' mandate for the Commission to require the certification specified by Section 302 of the Sarbanes-Oxley Act does not distinguish between small and large investment companies. Further, our disclosure rules generally do not distinguish between small and large investment companies. While we have the discretion to require that only larger investment companies file new Form N–CSR, it would not be appropriate to provide investors in larger investment companies with greater confidence in the accuracy and completeness of the disclosure contained in the annual and semi-annual reports that they receive from their investment companies, but not investors in small investment companies.

C. Small Entities Subject to the Rule

The new rules and rule and form amendments will affect registered investment companies that are small entities. For purposes of the Regulatory Flexibility Act (''RFA''), an investment company is a small entity if it, together with other investment companies in the same group of related investment companies, has net assets of $50 million or less as of the end of its most recent fiscal year.[119] We estimate that there are approximately 205 investment companies together with other investment companies in the same group of related investment companies that have net assets of $50 million or less as of the end of its most recent fiscal year.[120]

D. Reporting, Recordkeeping, and Other Compliance Requirements

The new rules and rule and form amendments will require management investment companies to file certified shareholder reports on Form N–CSR, containing (i) a copy of any required shareholder report, (ii) additional information regarding disclosure controls and procedures, and (iii) the certification required by Section 302 of the Sarbanes-Oxley Act. The form of the certification will parallel the form of the certification we adopted on Form N–SAR, and on Forms 10–K and 10–Q. The certification will require the management investment company's principal executive and financial officers to state, in part, that, based on their knowledge, the information in the certified shareholder report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made not misleading with respect to the period covered by the report, and that the financial statements, and other financial information included in the report, fairly present the financial condition, results of operations, changes in net assets, and cash flows (if the financial statements are required to include a statement of cash flows) of the registrant. The certification also will require the signing officers to certify that they have established and maintained disclosure controls and procedures to ensure that material

[119] 17 CFR 270.0–10.

[120] This estimate is based on figures compiled by the Commission staff regarding investment companies registered on Form N–1A, Form N–2, and Form N–3. In determining whether an insurance company separate account is a small entity for purposes of the Regulatory Flexibility Act, the assets of insurance company separate accounts are aggregated with the assets of their sponsoring insurance companies. Investment Company Act rule 0–10(b) [17 CFR 270.0–10(b)].

information relating to the registrant is made known to senior management, and also to certify that they have evaluated these procedures within 90 days of the filing date of the report. The amendments may increase the costs associated with compliance with investment companies' reporting obligations. However, this cost increase is expected to be limited, because most management investment companies are currently required to provide a similar certification with respect to their reports on Form N–SAR.

In addition, the amendments will require registered management investment companies to disclose information regarding whether an audit committee financial expert serves on the investment company's audit committee and whether the investment company has adopted a code of ethics that applies to the investment company's principal executive officer and senior financial officers. All registered management investment companies, including those that are not required to file reports pursuant to Section 13(a) or 15(d) of the Exchange Act, will be subject to these amendments. Because the disclosure requirements of these amendments will be new, management investment companies may need to hire outside counsel or other third parties to prepare the new disclosure. We expect that reporting information in response to these new disclosure items will increase costs incurred by small entities because the new disclosure items will require these entities to compile and report more information. For purposes of the PRA and our cost-benefit analysis,[121] with respect to Form N–SAR, we further estimate that the removal of the certification requirement will remove an incremental 41,010 hours from the current total burden hours, equivalent to a cost of $6,151,500§ [122] and the disclosure of the code of ethics and audit committee financial experts will add an incremental 2 burden hours to the current total burden hours, equivalent to a cost of $259.[123] With respect to Form N–CSR, all respondents will incur an incremental increase of 35,139 burden hours,[124] equivalent to internal costs of $5,152,782§ [125] and $3,513,900 in outside legal costs [126] to comply with the amendments. The current total burden hours of Form 12b-25 will incrementally increase by 420 hours or $15,468 [127] as a result of the amendments.

E. Agency Action to Minimize Effect on Small Entities

As required by Section 603 of the RFA, and with respect to Sections 302, 406, and 407 of the Sarbanes-Oxley Act, the Commission has considered the following alternatives to minimize the economic impact of the proposed rules and rule amendments on small entities: (i) The establishment of differing compliance or reporting requirements that take into account the resources available to small entities; (ii) the clarification, consolidation, or simplification of compliance and reporting requirements under the proposed amendments for small entities; and (iii) an exemption from coverage of the proposed amendments, or any part thereof, for small entities.

The rules we are adopting are intended to more fully implement the intent of Section 302 of the Sarbanes-Oxley Act, and should help ensure that information about an investment company's business and financial condition, specifically its financial statements, is adequately reviewed by an investment company's senior executives, thereby enhancing investor confidence in the quality of its disclosure. In addition, the rules we are adopting implement Sections 406 and 407 of the Sarbanes-Oxley Act by requiring disclosure with respect to codes of ethics and audit committee financial experts to provide investors better understanding of the ethical principles and background and affiliations of the executives and directors of the investment company.

The Commission believes at the present time that special compliance or reporting requirements for small entities, or an exemption from coverage for small entities, would not be appropriate or consistent with investor protection. The designation of certified shareholder reports on Form N–CSR as reporting forms that must contain the certification required by Section 302 of the Sarbanes-Oxley Act is intended to improve investor confidence in the quality of an investment company's disclosure to investors in its shareholder reports, particularly the financial statements contained in these reports. We believe it is important that the benefits resulting from the certification of shareholder reports as required by the new rules be provided to investors in all management investment companies, not just investors in management investment companies that are not considered small entities. The Commission also notes that Section 302 of the Sarbanes-Oxley Act does not distinguish between small entities and other investment companies. Similarly, Sections 406 and 407 of the Sarbanes-Oxley Act do not distinguish between small entities and other investment companies.

We believe that different compliance or reporting requirements or timetables for small entities would interfere with achieving the primary goal of increasing transparency of corporate activities and internal procedures. We generally believe that an exemption for small entities from coverage of the new rules is not appropriate and is inconsistent with the policies underlying the Sarbanes-Oxley Act. We also think that the disclosure requirements relating to the audit committee financial experts and codes of ethics are clear and straightforward. In addition, we are not aware of any way to clarify or simplify compliance for small entities.

VIII. Statutory Authority

The rules and rule and form amendments contained in this release are being adopted pursuant to Sections 10(b), 13, 15(d), 23(a), and 36 of the Exchange Act [15 U.S.C. 78j(b), 78m, 78o(d), 78w(a), and 78mm], Sections 6(c), 8, 24(a), 30, and 38 of the Investment Company Act [15 U.S.C. 80a–6(c), 80a–8, 80a–24(a), 80a–29, and 80a–37], and Sections 3(a), 302, 406, and 407 of the Sarbanes–Oxley Act of 2002 [Pub. L. 107–204, 116 Stat. 745].

List of Subjects

17 CFR Parts 240 and 249

Reporting and recordkeeping requirements, Securities.

17 CFR Parts 270 and 274

Investment companies, Reporting and recordkeeping requirements, Securities.

Text of Amendments

In accordance with the foregoing, Title 17, Chapter II, of the Code of Federal Regulations is amended as follows:

[121] *See* Sections IV and V above.

[122] 41,010 hours × $150 = $6,151,500. *See supra* note 109 (explaining the wage rate).

[123] 2 hours × $129.81 = $259. *See supra* note (explaining the wage rate).

[124] 43,150 hours for certification + 1,851 hours for audit committee financial expert disclosure + 1,851 hours for code of ethics disclosure = 46,852 hours × .75 = 35,139 hours.

[125] 35,139 hours × $146.64 = $5,152,782. *See supra* note 112 (explaining the wage rate).

[126] 43,150 hours for certification + 1,851 hours for audit committee financial expert disclosure + 1,851 hours for code of ethics disclosure = 46,852 hours × .25 of outside counsel × $300 per hour = $3,513,900.

[127] 420 hours × $36.83 = $15,468. *See supra* note 114 (explaining the wage rate).

PART 240—GENERAL RULES AND REGULATIONS, SECURITIES EXCHANGE ACT OF 1934

1. The authority citation for Part 240 is amended by adding the specific authority for ''Section 240.12b–25'' in numerical order to read as follows:

Authority: 15 U.S.C. 77c, 77d, 77g, 77j, 77s, 77z–2, 77z–3, 77eee, 77ggg, 77nnn, 77sss, 77ttt, 78c, 78d, 78e, 78f, 78g, 78i, 78j, 78j–1, 78k, 78k–1, 78*l*, 78m, 78n, 78o, 78p, 78q, 78s, 78u–5, 78w, 78x, 78*ll*, 78mm, 79q, 79t, 80a–20, 80a–23, 80a–29, 80a–37, 80b–3, 80b–4 and 80b–11, unless otherwise noted.

* * * * *

Section 240.12b–25 is also issued under 15 U.S.C. 80a–8, 80a–24(a), 80a–29, and 80a–37.

* * * * *

2. Section 240.12b–25 is amended by revising the section heading and paragraphs (a) and (b)(2)(ii) to read as follows:

§ 240.12b–25 Notification of inability to timely file all or any required portion of a Form 10–K, 10–KSB, 20–F, 11–K, N–SAR, N–CSR, 10–Q or 10–QSB.

(a) If all or any required portion of an annual or transition report on Form 10–K, 10–KSB, 20–F or 11–K (17 CFR 249.310, 249.310b, 249.220f or 249.311), or a quarterly or transition report on Form 10–Q or 10–QSB (17 CFR 249.308a or 249.308b) required to be filed pursuant to sections 13 or 15(d) of the Act (15 U.S.C. 78m or 78o(d)) and rules thereunder, or if all or any required portion of a semi-annual, annual or transition report on Form N–CSR (17 CFR 249.331; 17 CFR 274.128) or Form N–SAR (17 CFR 249.330; 17 CFR 274.101) required to be filed pursuant to sections 13 or 15(d) of the Act or section 30 of the Investment Company Act of 1940 (15 U.S.C. 80a–29) and the rules thereunder, is not filed within the time period prescribed for such report, the registrant, no later than one business day after the due date for such report, shall file a Form 12b–25 (17 CFR 249.322) with the Commission which shall contain disclosure of its inability to file the report timely and the reasons therefor in reasonable detail.

(b) * * *

(2) * * *

(ii) The subject annual report, semi-annual report or transition report on Form 10–K, 10–KSB, 20–F, 11–K, N–SAR, or N–CSR, or portion thereof, will be filed no later than the fifteenth calendar day following the prescribed due date; or the subject quarterly report or transition report on Form 10–Q or 10–QSB, or portion thereof, will be filed no later than the fifth calendar day following the prescribed due date; and

* * * * *

3. Section 240.13a–15 is amended by revising paragraph (a) to read as follows:

§ 240.13a–15 Issuer's disclosure controls and procedures related to preparation of required reports.

(a) Every issuer that has a class of securities registered pursuant to section 12 of the Act (15 U.S.C. 78*l*), other than an Asset-Backed Issuer (as defined in § 240.13a–14(g) of this chapter), a small business investment company registered on Form N–5 (§§ 239.24 and 274.5 of this chapter), or a unit investment trust as defined by Section 4(2) of the Investment Company Act of 1940 (15 U.S.C. 80a–4(2)), must maintain disclosure controls and procedures (as defined in § 240.13a–14(c) of this chapter).

* * * * *

4. Section 240.15d–15 is amended by revising paragraph (a) to read as follows:

§ 240.15d–15 Issuer's disclosure controls and procedures related to preparation of required reports.

(a) Every issuer that files reports under section 15(d) of the Act (15 U.S.C. 78o(d)), other than an Asset-Backed Issuer (as defined in § 240.13a–14(g) of this chapter), a small business investment company registered on Form N–5 (§§ 239.24 and 274.5 of this chapter), or a unit investment trust as defined by Section 4(2) of the Investment Company Act of 1940 (15 U.S.C. 80a–4(2)), must maintain disclosure controls and procedures (as defined in § 240.15d–14(c) of this chapter).

* * * * *

PART 249—FORMS, SECURITIES EXCHANGE ACT OF 1934

5. The authority citation for Part 249 is amended by adding the following citations in numerical order to read as follows:

Authority: 15 U.S.C. 78a, *et seq.*, unless otherwise noted.

* * * * *

Section 249.330 is also issued under secs. 3(a), 406, and 407, Pub. L. No. 107–204, 116 Stat. 745.

Section 249.331 is also issued under secs. 3(a), 302, 406, and 407, Pub. L. 107–204, 116 Stat. 745.

6. Section 249.322 is amended by revising paragraph (a) to read as follows:

§ 249.322 Form 12b–25—Notification of late filing.

(a) This form shall be filed pursuant to § 240.12b–25 of this chapter by issuers who are unable to file timely all or any required portion of an annual or transition report on Form 10–K and Form 10–KSB, 20–F, or 11–K (§§ 249.310, 249.310b, 249.220f or 249.311) or a quarterly or transition report on Form 10–Q and Form 10–QSB (§§ 249.308a and 249.308b) pursuant to section 13 or 15(d) of the Act (15 U.S.C. 78m or 78o(d)) or a semi-annual, annual, or transition report on Form N–SAR (§§ 249.330; 274.101) or Form N–CSR (§§ 249.331; 274.128) pursuant to section 13 or 15(d) of the Act or section 30 of the Investment Company Act of 1940 (15 U.S.C. 80a–29). The filing shall consist of a signed original and three conformed copies, and shall be filed with the Commission at Washington, DC 20549, no later than one business day after the due date for the periodic report in question. Copies of this form may be obtained from ''Publications,'' Securities and Exchange Commission, 450 5th Street, NW., Washington, DC 20549 and at our Web site at *http://www.sec.gov.*

* * * * *

7. Form 12b–25 (referenced in § 249.322) is amended by:

a. Revising the preamble;

b. Revising paragraph (b) of Part II; and

c. Revising Part III to read as follows:

Note: The text of Form 12b–25 does not, and this amendment will not, appear in the Code of Federal Regulations.

Form 12b–25

Notification of Late Filing

(Check One): __ Form 10–K __ Form 20–F __ Form 11–K __ Form 10–Q __ Form N–SAR __ Form N–CSR

* * * * *

Part II—Rules 12b–25(b) and (c)

* * * * *

(b) The subject annual report, semi-annual report, transition report on Form 10–K, Form 20–F, Form 11–K, Form N–SAR or Form N–CSR, or portion thereof, will be filed on or before the fifteenth calendar day following the prescribed due date; or the subject quarterly report or transition report on Form 10–Q, or portion thereof, will be filed on or before the fifth calendar day following the prescribed due date; and

* * * * *

Part III—Narrative

State below in reasonable detail why Forms 10–K, 20–F, 11–K, 10–Q, N–SAR, N–CSR, or the transition report or portion thereof, could not be filed within the prescribed time period.

* * * * *

8. Section 249.330 is revised to read as follows:

§ 249.330 Form N–SAR, annual and semi-annual report of certain registered investment companies.

This form shall be used by registered unit investment trusts and small business investment companies for semi-annual or annual reports to be filed pursuant to § 270.30a–1 or § 270.30b1–1 of this chapter in satisfaction of the requirement of section 30(a) of the Investment Company Act of 1940 that every registered investment company must file annually with the Commission such information, documents, and reports as investment companies having securities registered on a national securities exchange are required to file annually pursuant to section 13(a) of the Securities Exchange Act of 1934 (15 U.S.C. 78m) and the rules and regulations thereunder.

9. Section 249.331 is added to read as follows:

§ 249.331 Form N–CSR, certified shareholder report.

This form shall be used by registered management investment companies to file reports pursuant to § 270.30b2–1(a) of this chapter not later than 10 days after the transmission to stockholders of any report that is required to be transmitted to stockholders under § 270.30e–1 of this chapter.

PART 270—RULES AND REGULATIONS, INVESTMENT COMPANY ACT OF 1940

10. The authority citation for Part 270 is amended by revising the general authority citation and the specific authority for ''Section 270.30a–2'' and adding the following citations in numerical order to read as follows:

Authority: 15 U.S.C. 80a–1 *et seq.*, 80a–34(d), 80a–37, and 80a–39, unless otherwise noted.

* * * * *

Section 270.30a–1 is also issued under 15 U.S.C. 78m, 78o(d), 80a–8, and 80a–29.

Section 270.30a–2 is also issued under 15 U.S.C. 78m, 78o(d), 80a–8, and 80a–29, and secs. 3(a) and 302, Pub. L. 107–204, 116 Stat. 745.

Section 270.30a–3 is also issued under 15 U.S.C. 78m, 78o(d), 80a–8, and 80a–29, and secs. 3(a) and 302, Pub. L. 107–204, 116 Stat. 745.

Section 270.30b1–1 is also issued under 15 U.S.C. 78m, 78o(d), 80a–8, and 80a–29.

Section 270.30b2–1 is also issued under 15 U.S.C. 78m, 78o(d), 80a–8, and 80a–29, and secs. 3(a) and 302, Pub. L. 107–204, 116 Stat. 745.

Section 270.30d–1 is also issued under 15 U.S.C. 78m, 78o(d), 80a–8, and 80a–29, and secs. 3(a) and 302, Pub. L. 107–204, 116 Stat. 745.

* * * * *

11. Section 270.8b–15 is amended by adding a sentence at the end of the section to read as follows:

§ 270.8b–15 Amendments.

* * * An amendment to any report required to include the certification as specified in § 270.30a–2 must provide a new certification by each principal executive officer and principal financial officer of the registrant.

12. Section 270.30a–1 is revised to read as follows:

§ 270.30a–1 Annual reports for unit investment trusts.

Every registered unit investment trust shall file an annual report on Form N–SAR with respect to each calendar year not more than sixty calendar days after the close of each year. A registered unit investment trust that has filed a registration statement with the Commission registering its securities for the first time under the Securities Act of 1933 is relieved of this reporting obligation with respect to any reporting period or portion thereof prior to the date on which that registration statement becomes effective or is withdrawn.

13. Section 270.30a–2 is revised by:

a. Revising the section heading; and

b. Revising paragraphs (a) and (c) to read as follows:

§ 270.30a–2 Certification of Form N–CSR.

(a) Each report filed on Form N–CSR (§§ 249.331 and 274.128 of this chapter) by a registered management investment company must include a certification containing the information set forth in paragraph (b) of this section in the form specified in the report. Each principal executive officer or officers and principal financial officer or officers of the investment company, or persons performing similar functions, at the time of filing of the report must sign the certification.

* * * * *

(c) For purposes of this section and § 270.30a–3, the term ''disclosure controls and procedures'' means controls and other procedures of a registered management investment company that are designed to ensure that information required to be disclosed by the investment company on Form N–CSR is recorded, processed, summarized, and reported within the time periods specified in the Commission's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by an investment company in the reports that it files or submits on Form N–CSR is accumulated and communicated to the investment company's management, including its principal executive officer or officers and principal financial officer or officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure.

* * * * *

14. Section 270.30a–3 is added to read as follows:

§ 270.30a–3 Disclosure controls and procedures related to preparation of required filings.

(a) Every registered management investment company, other than a small business investment company registered on Form N–5 (§§ 239.24 and 274.5 of this chapter), must maintain disclosure controls and procedures (as defined in § 270.30a–2(c)).

(b) Within the 90-day period prior to the filing date of each report requiring certification under § 270.30a–2, an evaluation must be carried out under the supervision, and with the participation of, the registered management investment company's management, including the registered management investment company's principal executive officer or officers and principal financial officer or officers, or persons performing similar functions, of the effectiveness of the design and operation of the registered management investment company's disclosure controls and procedures.

15. Section 270.30b1–1 is revised to read as follows:

§ 270.30b1–1 Semi-annual report for registered management investment companies.

Every registered management investment company shall file a semi-annual report on Form N–SAR (§ 274.101 of this chapter) not more than sixty calendar days after the close of each fiscal year and fiscal second quarter. A registered management investment company that has filed a registration statement with the Commission registering its securities for the first time under the Securities Act of 1933 is relieved of this reporting obligation with respect to any reporting period or portion thereof prior to the date on which that registration statement becomes effective or is withdrawn.

16. Section 270.30b1–3 is revised to read as follows:

§ 270.30b1–3 Transition reports.

Every registered management investment company filing reports on Form N–SAR that changes its fiscal year end shall file a report on Form N–SAR not more than 60 calendar days after the later of either the close of the transition period or the date of the determination to change the fiscal year end which report shall not cover a period longer than six months.

17. Section 270.30b2–1 is revised to read as follows:

§ 270.30b2–1 Filing of reports to stockholders.

(a) Every registered management investment company shall file a report on Form N–CSR (§§ 249.331 and 274.128 of this chapter) not later than 10 days after the transmission to stockholders of any report that is required to be transmitted to stockholders under § 270.30e–1.

(b) A registered investment company shall file with the Commission a copy of every periodic or interim report or similar communication containing financial statements that is transmitted by or on behalf of such registered investment company to any class of such company's security holders and that is not required to be filed with the Commission under paragraph (a) of this section. The filing shall be made not later than 10 days after the transmission to security holders.

18. Section 270.30d–1 is added to read as follows:

§ 270.30d–1 Designation of periodic reports under the Securities Exchange Act of 1934.

A registered management investment company, other than a small business investment company registered on Form N–5 (§§ 239.24 and 274.5 of this chapter), that is required to file annual and quarterly reports pursuant to section 13(a) or 15(d) of the Securities Exchange Act of 1934 (15 U.S.C. 78m(a) or 78o(d)) shall satisfy its requirement to file such reports by the filing, in accordance with the rules and procedures specified therefor, of reports on Form N–CSR (§§ 249.331 and 274.128 of this chapter). A registered unit investment trust or a small business investment company registered on Form N–5 that is required to file annual and quarterly reports pursuant to section 13(a) or 15(d) of the Securities Exchange Act of 1934 shall satisfy its requirement to file such reports by the filing, in accordance with the rules and procedures specified therefor, of reports on Form N–SAR (§§ 249.330 and 274.101 of this chapter).

PART 274—FORMS PRESCRIBED UNDER THE INVESTMENT COMPANY ACT OF 1940

19. The authority citation for Part 274 is revised to read as follows:

Authority: 15 U.S.C. 77f, 77g, 77h, 77j, 77s, 78c(b), 78l, 78m, 78n, 78o(d), 80a–8, 80a–24, 80a–26, and 80a–29, unless otherwise noted.

Section 274.101 is also issued under secs. 3(a), 406, and 407, Pub. L. 107–204, 116 Stat. 745.

Section 274.128 is also issued under secs. 3(a), 302, 406, and 407, Pub. L. 107–204, 116 Stat. 745.

20. Section 274.101 is revised to read as follows:

§ 274.101 Form N–SAR, semi-annual report of registered investment companies.

This form shall be used by registered management investment companies for semi-annual or annual reports to be filed pursuant to rule 30b1–1 (17 CFR 270.30b1–1) and by registered unit investment trusts for annual reports to be filed pursuant to rule 30a–1 (17 CFR 270.30a–1).

21. Form N–SAR (referenced in §§ 249.330 and 274.101) is amended by:

a. Revising the reference ''133'' in item 6 to read ''132'';

b. Removing item 133;

c. Revising the first, fifth, and sixth paragraphs of General Instruction A;

d. Removing the reference ''and item 133'' at the end of paragraph (1) of General Instruction D;

e. Removing paragraph (5) of General Instruction G;

f. Revising the Instruction to sub-item 77Q3 in Instructions to Specific Items;

g. Revising the Instruction to sub-item 102P3 in Instructions to Specific Items;

h. Removing the Instruction to Item 133 in Instructions to Specific Items; and

i. Revising the reference ''133'' in the Signature Page section in Instructions to Specific Items to read ''132''.

These additions and revisions read as follows:

Note: The text of Form N–SAR does not, and this amendment will not, appear in the Code of Federal Regulations.

Form N–SAR

* * * * *

General Instructions

A. Rule as to Use of Form N–SAR

Form N–SAR is a reporting form that is to be used for semi-annual and annual reports by all registered investment companies that have filed a registration statement which has become effective pursuant to the Securities Act of 1933 (''1933 Act'') with the exception of face amount certificate companies. Face amount certificate companies should continue to file periodic reports pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 (''1934 Act''). Registered management investment companies, other than small business investment companies, are required to file semi-annual and annual reports on Form N–SAR under the Investment Company Act of 1940 (the ''Act'') and rule 30b1–1 (17 CFR 270.30b1–1) under the Act. Registered small business investment companies are required to file semi-annual and annual reports under the Act and rule 30b1–1 (17 CFR 270.30b1–1) under the Act, and, if applicable, Section 13 or 15(d) of the 1934 Act. Registered unit investment trusts (''UITs'') are required to file annual reports on Form N–SAR under the Act and rule 30a–1 (17 CFR 270.30a–1) under the Act, and, if applicable, Section 13 or 15(d) of the 1934 Act.

* * * * *

Unit investment trusts: The fourth section of the form, which contains items 111 through 132, is to be completed only by all UITs. Each UIT is required to complete appropriate items in this section once a year for the 12-month period ending December 31 and to include information for all of its series.

Under Section 30 of the Act, Sections 13 and 15(d) of the 1934 Act, and the rules and regulations thereunder, the Commission is authorized to solicit the information required by Form N–SAR from registered investment companies. Disclosure of the information specified on Form N–SAR is mandatory. Information supplied on Form N–SAR will be included routinely in the public files of the Commission and will be available for inspection by any interested persons.

* * * * *

Instructions to Specific Items

* * * * *

Sub-Item 77Q3

Furnish any other information required to be included as an exhibit pursuant to such rules and regulations as the Commission may prescribe.

* * * * *

Sub-Item 102P3

(a)(1)Disclose whether, as of the end of the period covered by the report, the registrant has adopted a code of ethics that applies to the registrant's principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing

similar functions, regardless of whether these individuals are employed by the registrant or a third party. If the registrant has not adopted such a code of ethics, explain why it has not done so. The information required by this paragraph (a)(1) is only required in an annual report on this Form N–SAR.

(2) For purposes of this Instruction 102P3(a), the term ''code of ethics'' means written standards that are reasonably designed to deter wrongdoing and to promote:

(i) Honest and ethical conduct, including the ethical handling of actual or apparent conflicts of interest between personal and professional relationships;

(ii) Full, fair, accurate, timely, and understandable disclosure in reports and documents that a registrant files with, or submits to, the Commission and in other public communications made by the registrant;

(iii) Compliance with applicable governmental laws, rules, and regulations;

(iv) The prompt internal reporting of violations of the code to an appropriate person or persons identified in the code; and

(v) Accountability for adherence to the code.

(3) The registrant must briefly describe the nature of any amendment, during the period covered by the report, to a provision of its code of ethics that applies to the registrant's principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions, regardless of whether these individuals are employed by the registrant or a third party, and that relates to any element of the code of ethics definition enumerated in paragraph (a)(2) of this Instruction 102P3. The registrant must file a copy of any such amendment as an exhibit to this report on Form N–SAR, unless the registrant has elected to satisfy paragraph (a)(6) of this Instruction 102P3 by posting its code of ethics on its website pursuant to paragraph (a)(6)(ii) of this Instruction 102P3, or by undertaking to provide its code of ethics to any person without charge, upon request, pursuant to paragraph (a)(6)(iii) of this Instruction 102P3.

(4) If the registrant has, during the period covered by the report, granted a waiver, including an implicit waiver, from a provision of the code of ethics to the registrant's principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions, regardless of whether these individuals are employed by the registrant or a third party, that relates to one or more of the items set forth in paragraph (a)(2) of this Instruction 102P3, the registrant must briefly describe the nature of the waiver, the name of the person to whom the waiver was granted, and the date of the waiver.

(5) If the registrant intends to satisfy the disclosure requirement under paragraph (a)(3) or (4) of this Instruction 102P3 regarding an amendment to, or a waiver from, a provision of its code of ethics that applies to the registrant's principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions and that relates to any element of the code of ethics definition enumerated in paragraph (a)(2) of this Instruction 102P3 by posting such information on its Internet website, disclose the registrant's Internet address and such intention.

(6) The registrant must:

(i) File with the Commission a copy of its code of ethics that applies to the registrant's principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions, as an exhibit to its annual report on this Form N–SAR;

(ii) Post the text of such code of ethics on its Internet website and disclose, in its most recent report on this Form N–SAR, its Internet address and the fact that it has posted such code of ethics on its Internet website; or

(iii) Undertake in its most recent report on this Form N–SAR to provide to any person without charge, upon request, a copy of such code of ethics and explain the manner in which such request may be made.

(7) A registrant may have separate codes of ethics for different types of officers. Furthermore, a ''code of ethics'' within the meaning of paragraph (a)(2) of this Instruction 102P3 may be a portion of a broader document that addresses additional topics or that applies to more persons than those specified in paragraph (a)(1). In satisfying the requirements of paragraph (a)(6), a registrant need only file, post, or provide the portions of a broader document that constitutes a ''code of ethics'' as defined in paragraph (a)(2) and that apply to the persons specified in paragraph (a)(1).

(8) If a registrant elects to satisfy paragraph (a)(6) of this Instruction 102P3 by posting its code of ethics on its website pursuant to paragraph (a)(6)(ii), the code of ethics must remain accessible on its website for as long as the registrant remains subject to the requirements of this Instruction 102P3 and chooses to comply with this Instruction 102P3 by posting its code on its website pursuant to paragraph (a)(6)(ii).

(9) The registrant does not need to provide any information pursuant to paragraphs (a)(3) and (4) of this Instruction 102P3 if it discloses the required information on its Internet website within five business days following the date of the amendment or waiver and the registrant has disclosed in its most recently filed report on this Form N–SAR its Internet address and intention to provide disclosure in this manner. If the amendment or waiver occurs on a Saturday, Sunday, or holiday on which the Commission is not open for business, then the five business day period shall begin to run on and include the first business day thereafter. If the registrant elects to disclose this information through its website, such information must remain available on the website for at least a 12-month period. The registrant must retain the information for a period of not less than six years following the end of the fiscal year in which the amendment or waiver occurred. Upon request, the registrant must furnish to the Commission or its staff a copy of any or all information retained pursuant to this requirement.

(10) The registrant does not need to disclose technical, administrative, or other non-substantive amendments to its code of ethics.

(11) For purposes of this Instruction 102P3(a):

(i) The term ''waiver'' means the approval by the registrant of a material departure from a provision of the code of ethics; and

(ii) The term ''implicit waiver'' means the registrant's failure to take action within a reasonable period of time regarding a material departure from a provision of the code of ethics that has been made known to an executive officer, as defined in rule 3b–7 under the 1934 Act (17 CFR 240.3b–7), of the registrant.

(b)(1) Disclose that the registrant's board of directors has determined that the registrant either:

(i) Has at least one audit committee financial expert serving on its audit committee; or

(ii) Does not have an audit committee financial expert serving on its audit committee.

(2) If the registrant provides the disclosure required by paragraph (b)(1)(i) of this Instruction 102P3, it must disclose the name of the audit committee financial expert and whether that person is ''independent.'' In order to be considered ''independent'' for purposes of this Instruction 102P3(b), a member of an audit committee may not,

other than in his or her capacity as a member of the audit committee, the board of directors, or any other board committee:

(i) Accept directly or indirectly any consulting, advisory, or other compensatory fee from the issuer; or

(ii) Be an ''interested person'' of the investment company as defined in Section 2(a)(19) of the Act (15 U.S.C. 80a–2(a)(19)).

(3) If the registrant provides the disclosure required by paragraph (b)(1)(ii) of this Instruction 102P3, it must explain why it does not have an audit committee financial expert.

(4) The information required by paragraphs (b)(1) ''–(3) of this Instruction 102P3 is only required in an annual report on Form N–SAR.

(5) If the registrant's board of directors has determined that the registrant has more than one audit committee financial expert serving on its audit committee, the registrant may, but is not required to, disclose the names of those additional persons. A registrant choosing to identify such persons must indicate whether they are independent pursuant to paragraph (b)(2) of this Instruction 102P3.

(6) For purposes of this Instruction 102P3, an ''audit committee financial expert'' means a person who has the following attributes:

(i) An understanding of generally accepted accounting principles and financial statements;

(ii) The ability to assess the general application of such principles in connection with the accounting for estimates, accruals, and reserves;

(iii) Experience preparing, auditing, analyzing, or evaluating financial statements that present a breadth and level of complexity of accounting issues that are generally comparable to the breadth and complexity of issues that can reasonably be expected to be raised by the registrant's financial statements, or experience actively supervising one or more persons engaged in such activities;

(iv) An understanding of internal controls and procedures for financial reporting; and

(v) An understanding of audit committee functions.

(7) A person shall have acquired such attributes through:

(i) Education and experience as a principal financial officer, principal accounting officer, controller, public accountant, or auditor or experience in one or more positions that involve the performance of similar functions;

(ii) Experience actively supervising a principal financial officer, principal accounting officer, controller, public accountant, auditor, or person performing similar functions;

(iii) Experience overseeing or assessing the performance of companies or public accountants with respect to the preparation, auditing, or evaluation of financial statements; or

(iv) Other relevant experience.

(8)(i) A person who is determined to be an audit committee financial expert will not be deemed an ''expert'' for any purpose, including without limitation for purposes of Section 11 of the 1933 Act (15 U.S.C. 77k), as a result of being designated or identified as an audit committee financial expert pursuant to this Instruction 102P3(b).

(ii) The designation or identification of a person as an audit committee financial expert pursuant to this Instruction 102P3(b) does not impose on such person any duties, obligations, or liability that are greater than the duties, obligations, and liability imposed on such person as a member of the audit committee and board of directors in the absence of such designation or identification.

(iii) The designation or identification of a person as an audit committee financial expert pursuant to this Instruction 102P3(b) does not affect the duties, obligations, or liability of any other member of the audit committee or board of directors.

(9) If a person qualifies as an audit committee financial expert by means of having held a position described in paragraph (b)(7)(iv) of this Instruction 102P3, the registrant shall provide a brief listing of that person's relevant experience.

(c) Furnish any other information required to be included as an exhibit pursuant to such rules and regulations as the Commission may prescribe.

* * * * *

22. Section 274.128 and Form N–CSR (referenced in §§ 249.331 and 274.128) are added to read as follows:

§ 274.128 Form N–CSR, certified shareholder report.

This form shall be used by registered management investment companies to file reports pursuant to § 270.30b2–1(a) of this chapter not later than 10 days after the transmission to stockholders of any report that is required to be transmitted to stockholders under § 270.30e–1 of this chapter.

* * * * *

Note: The text of Form N–CSR does not, and this amendment will not, appear in the *Code of Federal Regulations.*

FORM N–CSR

Certified Shareholder Report of Registered Management Investment Companies

Investment Company Act file number __

_____

(Exact name of registrant as specified in charter)

_____

(Address of principal executive offices) (Zip code)

_____

(Name and address of agent for service)

Registrant's telephone number, including area code: _____

Date of fiscal year end: _____

Date of reporting period: _____

Form N–CSR is to be used by management investment companies to file reports with the Commission not later than 10 days after the transmission to stockholders of any report that is required to be transmitted to stockholders under Rule 30e–1 under the Investment Company Act of 1940 (17 CFR 270.30e–1). The Commission may use the information provided on Form N–CSR in its regulatory, disclosure review, inspection, and policymaking roles.

A registrant is required to disclose the information specified by Form N–CSR, and the Commission will make this information public. A registrant is not required to respond to the collection of information contained in Form N–CSR unless the Form displays a currently valid Office of Management and Budget (''OMB'') control number. Please direct comments concerning the accuracy of the information collection burden estimate and any suggestions for reducing the burden to Secretary, Securities and Exchange Commission, 450 Fifth Street, NW, Washington, DC 20549–0609. The OMB has reviewed this collection of information under the clearance requirements of 44 U.S.C. 3507.

General Instructions

A. Rule as to Use of Form N–CSR

Form N–CSR is a combined reporting form that is to be used for reports of registered management investment companies under Section 30(b)(2) of the Investment Company Act of 1940 (the ''Act'') and Section 13(a) or 15(d) of the Securities Exchange Act of 1934 (the ''Exchange Act''), filed pursuant to Rule 30b2–1(a) under the Act (17 CFR 270.30b2–1(a)). A report on this Form shall be filed within 10 days after the transmission to stockholders of any annual or semi-annual report that is required to be transmitted to

stockholders pursuant to Rule 30e–1 under the Act (17 CFR 270.30e–1).

B. Application of General Rules and Regulations

The General Rules and Regulations under the Act and the Exchange Act contain certain general requirements that are applicable to reporting on any form under those Acts. These general requirements should be carefully read and observed in the preparation and filing of reports on this form, except that any provision in the form or in these instructions shall be controlling.

C. Preparation of Report

1. This Form is not to be used as a blank form to be filled in, but only as a guide in preparing the report in accordance with Rules 8b–11 (17 CFR 270.8b–11) and 8b–12 (17 CFR 270.8b–12) under the Act and Rules 12b–11 (17 CFR 240.12b–11) and 12b–12 (17 CFR 240.12b–12) under the Exchange Act. The Commission does not furnish blank copies of this Form to be filled in for filing.

2. These general instructions are not to be filed with the report.

3. Attention is directed to Rule 12b–20 under the Exchange Act (17 CFR 240.12b–20), which states: ''In addition to the information expressly required to be included in a statement or report, there shall be added such further material information, if any, as may be necessary to make the required statements, in the light of the circumstances under which they are made not misleading.''

D. Incorporation by Reference

A registrant may incorporate by reference information required by Item 10(a), but no other Items of the Form shall be answered by incorporating any information by reference. All incorporation by reference must comply with the requirements of this Form and the following rules on incorporation by reference: Rule 10(d) of Regulation S–K under the Securities Act of 1933 (17 CFR 229.10(d)) (general rules on incorporation by reference, which, among other things, prohibit, unless specifically required by this Form, incorporating by reference a document that includes incorporation by reference to another document, and limits incorporation to documents filed within the last 5 years, with certain exceptions); Rule 303 of Regulation S–T (17 CFR 232.303) (specific requirements for electronically filed documents); Rules 12b–23 and 12b–32 under the Exchange Act (17 CFR 240.12b–23 and 240.12b–32) (additional rules on incorporation by reference for reports filed pursuant to Sections 13 and 15(d) of the Exchange Act); and Rules 0–4, 8b–23, and 8b–32 under the Act (17 CFR 270.0–4, 270.8b–23, and 270.8b–32) (additional rules on incorporation by reference for investment companies).

E. Definitions

Unless the context clearly indicates the contrary, terms used in this Form N–CSR have meanings as defined in the Act and the rules and regulations thereunder. Unless otherwise indicated, all references in the Form to statutory sections or to rules are sections of the Act and the rules and regulations thereunder.

F. Signature and Filing of Report

1. If the report is filed in paper pursuant to a hardship exemption from electronic filing (see Item 201 *et seq*. of Regulation S–T (17 CFR 232.201 *et seq*.)), eight complete copies of the report shall be filed with the Commission. At least one complete copy of the report shall be filed with each exchange on which any class of securities of the registrant is registered. At least one complete copy of the report filed with the Commission and one such copy filed with each exchange must be manually signed. Copies not manually signed must bear typed or printed signatures.

2. (a) The report must be signed by the registrant, and on behalf of the registrant by its principal executive officer or officers (who also must provide the certification required by Rule 30a–2 under the Act (17 CFR 270.30a–2) exactly as specified in this Form) and its principal financial officer or officers (who also must provide the certification required by Rule 30a–2 under the Act (17 CFR 270.30a–2) exactly as specified in this Form).

(b) The name of each person who signs the report shall be typed or printed beneath his or her signature. Any person who occupies more than one of the specified positions shall indicate each capacity in which he or she signs the report. Attention is directed to Rule 12b–11 under the Exchange Act (17 CFR 240.12b–11) and Rule 8b–11 under the Act (17 CFR 270.8b–11) concerning manual signatures and signatures pursuant to powers of attorney.

Item 1. Reports to Stockholders

Include a copy of the report transmitted to stockholders pursuant to Rule 30e–1 under the Act (17 CFR 270.30e–1).

Item 2. Code of Ethics

(a) Disclose whether, as of the end of the period covered by the report, the registrant has adopted a code of ethics that applies to the registrant's principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions, regardless of whether these individuals are employed by the registrant or a third party. If the registrant has not adopted such a code of ethics, explain why it has not done so.

Instruction to paragraph (a).

The information required by this Item is only required in an annual report on this Form N–CSR.

(b) For purposes of this Item, the term ''code of ethics'' means written standards that are reasonably designed to deter wrongdoing and to promote:

(1) Honest and ethical conduct, including the ethical handling of actual or apparent conflicts of interest between personal and professional relationships;

(2) Full, fair, accurate, timely, and understandable disclosure in reports and documents that a registrant files with, or submits to, the Commission and in other public communications made by the registrant;

(3) Compliance with applicable governmental laws, rules, and regulations;

(4) The prompt internal reporting of violations of the code to an appropriate person or persons identified in the code; and

(5) Accountability for adherence to the code.

(c) The registrant must briefly describe the nature of any amendment, during the period covered by the report, to a provision of its code of ethics that applies to the registrant's principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions, regardless of whether these individuals are employed by the registrant or a third party, and that relates to any element of the code of ethics definition enumerated in paragraph (b) of this Item. The registrant must file a copy of any such amendment as an exhibit pursuant to Item 10(a), unless the registrant has elected to satisfy paragraph (f) of this Item by posting its code of ethics on its website pursuant to paragraph (f)(2) of this Item, or by undertaking to provide its code of ethics to any person without charge, upon request, pursuant to paragraph (f)(3) of this Item.

(d) If the registrant has, during the period covered by the report, granted a waiver, including an implicit waiver,

from a provision of the code of ethics to the registrant's principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions, regardless of whether these individuals are employed by the registrant or a third party, that relates to one or more of the items set forth in paragraph (b) of this Item, the registrant must briefly describe the nature of the waiver, the name of the person to whom the waiver was granted, and the date of the waiver.

(e) If the registrant intends to satisfy the disclosure requirement under paragraph (c) or (d) of this Item regarding an amendment to, or a waiver from, a provision of its code of ethics that applies to the registrant's principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions and that relates to any element of the code of ethics definition enumerated in paragraph (b) of this Item by posting such information on its Internet website, disclose the registrant's Internet address and such intention.

(f) The registrant must:

(1) File with the Commission, pursuant to Item 10(a), a copy of its code of ethics that applies to the registrant's principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions, as an exhibit to its annual report on this Form N–CSR;

(2) Post the text of such code of ethics on its Internet website and disclose, in its most recent report on this Form N–CSR, its Internet address and the fact that it has posted such code of ethics on its Internet website; or

(3) Undertake in its most recent report on this Form N–CSR to provide to any person without charge, upon request, a copy of such code of ethics and explain the manner in which such request may be made.

Instructions to Item 2.

1. A registrant may have separate codes of ethics for different types of officers. Furthermore, a ''code of ethics'' within the meaning of paragraph (b) of this Item may be a portion of a broader document that addresses additional topics or that applies to more persons than those specified in paragraph (a). In satisfying the requirements of paragraph (f), a registrant need only file, post, or provide the portions of a broader document that constitutes a ''code of ethics'' as defined in paragraph (b) and that apply to the persons specified in paragraph (a).

2. If a registrant elects to satisfy paragraph (f) of this Item by posting its code of ethics on its website pursuant to paragraph (f)(2), the code of ethics must remain accessible on its website for as long as the registrant remains subject to the requirements of this Item and chooses to comply with this Item by posting its code on its website pursuant to paragraph (f)(2).

3. The registrant does not need to provide any information pursuant to paragraphs (c) and (d) of this Item if it discloses the required information on its Internet website within five business days following the date of the amendment or waiver and the registrant has disclosed in its most recently filed report on this Form N–CSR its Internet address and intention to provide disclosure in this manner. If the amendment or waiver occurs on a Saturday, Sunday, or holiday on which the Commission is not open for business, then the five business day period shall begin to run on and include the first business day thereafter. If the registrant elects to disclose this information through its website, such information must remain available on the website for at least a 12-month period. The registrant must retain the information for a period of not less than six years following the end of the fiscal year in which the amendment or waiver occurred. Upon request, the registrant must furnish to the Commission or its staff a copy of any or all information retained pursuant to this requirement.

4. The registrant does not need to disclose technical, administrative, or other non-substantive amendments to its code of ethics.

5. For purposes of this Item:

(a) The term ''waiver'' means the approval by the registrant of a material departure from a provision of the code of ethics; and

(b) The term ''implicit waiver'' means the registrant's failure to take action within a reasonable period of time regarding a material departure from a provision of the code of ethics that has been made known to an executive officer, as defined in Rule 3b–7 under the Exchange Act (17 CFR 240.3b–7), of the registrant.

Item 3. Audit Committee Financial Expert

(a)(1) Disclose that the registrant's board of directors has determined that the registrant either:

(i) Has at least one audit committee financial expert serving on its audit committee; or

(ii) Does not have an audit committee financial expert serving on its audit committee.

(2) If the registrant provides the disclosure required by paragraph (a)(1)(i) of this Item, it must disclose the name of the audit committee financial expert and whether that person is ''independent.'' In order to be considered ''independent'' for purposes of this Item, a member of an audit committee may not, other than in his or her capacity as a member of the audit committee, the board of directors, or any other board committee:

(i) Accept directly or indirectly any consulting, advisory, or other compensatory fee from the issuer; or

(ii) Be an ''interested person'' of the investment company as defined in Section 2(a)(19) of the Act (15 U.S.C. 80a–2(a)(19)).

(3) If the registrant provides the disclosure required by paragraph (a)(1)(ii) of this Item, it must explain why it does not have an audit committee financial expert.

Instructions to paragraph (a).

1. The information required by this Item is only required in an annual report on Form N–CSR.

2. If the registrant's board of directors has determined that the registrant has more than one audit committee financial expert serving on its audit committee, the registrant may, but is not required to, disclose the names of those additional persons. A registrant choosing to identify such persons must indicate whether they are independent pursuant to paragraph (a)(2) of this Item.

(b) For purposes of this Item, an ''audit committee financial expert'' means a person who has the following attributes:

(1) An understanding of generally accepted accounting principles and financial statements;

(2) The ability to assess the general application of such principles in connection with the accounting for estimates, accruals, and reserves;

(3) Experience preparing, auditing, analyzing, or evaluating financial statements that present a breadth and level of complexity of accounting issues that are generally comparable to the breadth and complexity of issues that can reasonably be expected to be raised by the registrant's financial statements, or experience actively supervising one or more persons engaged in such activities;

(4) An understanding of internal controls and procedures for financial reporting; and

(5) An understanding of audit committee functions.

(c) A person shall have acquired such attributes through:

(1) Education and experience as a principal financial officer, principal

accounting officer, controller, public accountant, or auditor or experience in one or more positions that involve the performance of similar functions;

(2) Experience actively supervising a principal financial officer, principal accounting officer, controller, public accountant, auditor, or person performing similar functions;

(3) Experience overseeing or assessing the performance of companies or public accountants with respect to the preparation, auditing, or evaluation of financial statements; or

(4) Other relevant experience.

(d)(1) A person who is determined to be an audit committee financial expert will not be deemed an ''expert'' for any purpose, including without limitation for purposes of Section 11 of the Securities Act of 1933 (15 U.S.C. 77k), as a result of being designated or identified as an audit committee financial expert pursuant to this Item.

(2) The designation or identification of a person as an audit committee financial expert pursuant to this Item does not impose on such person any duties, obligations, or liability that are greater than the duties, obligations, and liability imposed on such person as a member of the audit committee and board of directors in the absence of such designation or identification.

(3) The designation or identification of a person as an audit committee financial expert pursuant to this Item does not affect the duties, obligations, or liability of any other member of the audit committee or board of directors.

Instruction to Item 3.

If a person qualifies as an audit committee financial expert by means of having held a position described in paragraph (c)(4) of this Item, the registrant shall provide a brief listing of that person's relevant experience.

Items 4–8. [Reserved]

Item 9. Controls and Procedures

(a) Disclose the conclusions of the registrant's principal executive officer or officers and principal financial officer or officers, or persons performing similar functions, about the effectiveness of the registrant's disclosure controls and procedures (as defined in Rule 30a–2(c) under the Act (17 CFR 270.30a–2(c))) based on their evaluation of these controls and procedures as of a date within 90 days of the filing date of the report that includes the disclosure required by this paragraph.

(b) Disclose whether or not there were significant changes in the registrant's internal controls or in other factors that could significantly affect these controls subsequent to the date of their evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Item 10. Exhibits

File the exhibits listed below as part of this Form. Letter or number the exhibits in the sequence indicated.

(a) Any code of ethics, or amendment thereto, that is the subject of the disclosure required by Item 2, to the extent that the registrant intends to satisfy the Item 2 requirements through filing of an exhibit.

(b) A separate certification for each principal executive officer and principal financial officer of the registrant as required by Rule 30a–2 under the Act (17 CFR 270.30a–2) in the exact form set forth below:

Certifications

I, [identify the certifying individual], certify that:

1. I have reviewed this report on Form N–CSR of [identify registrant];

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations, changes in net assets, and cash flows (if the financial statements are required to include a statement of cash flows) of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Rule 30a–2(c) under the Investment Company Act of 1940) for the registrant and have:

(a) Designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this report (the ''Evaluation Date''); and

(c) presented in this report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;

5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize, and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and

(b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and

6. The registrant's other certifying officers and I have indicated in this report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: _____

_____

[Signature] [Title]

Signatures

[See General Instruction F]

Pursuant to the requirements of the Securities Exchange Act of 1934 and the Investment Company Act of 1940, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

(Registrant) _____

By (Signature and Title)* _____

Date _____

Pursuant to the requirements of the Securities Exchange Act of 1934 and the Investment Company Act of 1940, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

By (Signature and Title)* _____

Date _____

By (Signature and Title)* _____

_____

Date

* Print the name and title of each signing officer under his or her signature.

Dated: January 27, 2003.

By the Commission.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 03–2254 Filed 1–31–03; 8:45 am]

BILLING CODE 8010–01–P

Federal Register

Monday,
February 3, 2003

Part III

Department of Labor

Office of the Secretary

Delegation of Authority and Assignment of Responsibilities to the Employee Benefits Security Administration; Notice

DEPARTMENT OF LABOR

Office of the Secretary

[Secretary's Order 1–2003]

Delegation of Authority and Assignment of Responsibilities to the Employee Benefits Security Administration

1. *Purpose.* To delegate authority and assign responsibilities for the administration of the Department of Labor's responsibilities under the Employee Retirement Income Security Act of 1974 (ERISA), the Welfare and Pension Plans Disclosure Act (WPPDA) and the Federal Employees' Retirement System Act of 1986 (FERSA), and to change the name of the Office of the Assistant Secretary for Pension and Welfare Benefits and the Pension and Welfare Benefits Administration (PWBA).

2. *Authority and Directives Affected.* This Order is issued pursuant to 5 U.S.C. 301; 29 U.S.C. 551, *et seq.*; and 5 U.S.C. 5315. This order supersedes Secretary's Order 1–87, 52 FR 13139 (Apr. 21, 1987), and the memoranda to Meredith Miller, on Oct. 28, 1998, 63 FR 59339 (Nov. 3, 1998), and on Dec. 16, 1998, 63 FR 71506 (Dec. 28, 1998).

3. *Background.* ERISA places responsibility in the Department of Labor for the administration of a comprehensive program to protect the interests of participants and beneficiaries of private sector employee benefit plans.

Secretary's Order 1–87 delegated authority for this program to the Pension and Welfare Benefits Administration (PWBA), which was headed by the Assistant Secretary for Pension and Welfare Benefits who reported to the Secretary of Labor.

FERSA requires the Department of Labor to, among other things, administer and enforce the fiduciary responsibility, prohibited transaction, and bonding provisions of FERSA. Secretary's Order 1–87 also delegated these responsibilities to PWBA.

In more recent years, statutes such as the Health Insurance Portability and Accountability Act of 1996 (HIPAA), the Newborns' and Mothers' Health Protection Act of 1996, the Mental Health Parity Act of 1996, the Women's Health and Cancer Rights Act of 1998 and the Child Support Performance and Incentive Act of 1998 amended ERISA. Pursuant to Secretary's Order 1–87, PWBA has carried out the Department's additional responsibilities under these Acts.

Changing the agency's name to the Employee Benefits Security Administration (EBSA) will more clearly communicate the agency's mission of protecting private sector employee benefits. Restating the delegations contained in Secretary's Order 1–87, and including an additional delegation regarding claims of governmental privileges, previously published separately, will provide a single source for questions regarding the Assistant Secretary's current authority and responsibility.

4. *Re-Designation of the Assistant Secretary for Pension and Welfare Benefits and the Pension and Welfare Benefits Administration.* a. The title and position of Assistant Secretary for Pension and Welfare Benefits is re-designated Assistant Secretary for Employee Benefits Security. The Office of the Assistant Secretary for Pension and Welfare Benefits is re-designated the Office of the Assistant Secretary for Employee Benefits Security, and

b. The Pension and Welfare Benefits Administration is re-designated as the Employee Benefits Security Administration.

c. All offices, subdivisions and positions within the Department of Labor deriving their names in whole, or in part, from the Office of the Assistant Secretary for Pension and Welfare Benefits or the Pension and Welfare Benefits Administration shall accomplish an appropriate change of name pursuant to this order.

d. All employees of the Office of the Assistant Secretary for Pension and Welfare Benefits and the Pension and Welfare Benefits Administration are re-designated employees of the Office of the Assistant Secretary for Employee Benefits Security or the Employee Benefits Security Administration, respectively.

e. All programs, activities, functions, and responsibilities delegated to the Office of the Assistant Secretary for Pension and Welfare Benefits or the Pension and Welfare Benefits Administration are re-designated programs, activities, functions and responsibilities of the Office of the Assistant Secretary for Employee Benefits Security or the Employee Benefits Security Administration, respectively.

f. All currently effective delegations made by the Assistant Secretary for Pension and Welfare Benefits to employees of the Pension and Welfare Benefits Administration are deemed delegations by the Assistant Secretary for Employee Benefits Security to employees of the Employee Benefits Security Administration.

g. Other agencies within the Department of Labor shall make any appropriate re-designation in conformity with the spirit and purpose of this order.

5. *Delegation of Authority and Assignment of Responsibilities.* a. Except as hereinafter provided, the Assistant Secretary for Employee Benefits Security is delegated the authority (including the authority to re-delegate) and assigned the responsibilities of the Secretary of Labor:

(1) Under the following statutes, including any amendments:

(i) The Employee Retirement Income Security Act of 1974, as amended, except for subtitle C of title III and title IV (29 U.S.C. 1001–1232);

(ii) The Welfare and Pension Plans Disclosure Act of 1958, as amended Pub. L. 85–836, 72 Stat. 997; Pub. L. 86–624, 74 Stat. 417; Pub. L. 87–420, 76 Stat. 35.

(iii) The Federal Employees' Retirement System Act of 1986 (5 U.S.C. 8401–8479); and

(iv) As directed by the Secretary, such additional Federal acts similar to or related to those listed in paragraphs (i) through (iii), above, that from time to time may assign additional authority or responsibilities to the Secretary.

(2) To request information the Internal Revenue Service (IRS) possesses for use in connection with the administration of title I of ERISA of 1974.

(3) To invoke all appropriate governmental privileges, arising from the functions of the Employee Benefits Security Administration, following his/her personal consideration of the matter and in accordance with the following guidelines:

(i) Generally Applicable Guidelines. The Assistant Secretary may not re-delegate the authority to invoke a privilege. The privilege may be asserted only with respect to specifically described information and only where the Assistant Secretary determines the privilege is applicable. In asserting a privilege, the Assistant Secretary shall articulate in writing specific reasons for preserving the confidentiality of the information.

(ii) Informant's Privilege (to protect from disclosure the identity of any person who has provided information to the Employee Benefits Security Administration in cases arising under the statutory provisions listed in paragraph 5.a.(1) of this order that are delegated or assigned to the Employee Benefits Security Administration). To assert this privilege, the Assistant Secretary must first determine that disclosure of the privileged matter may: (A) Interfere with the Employee Benefits Security Administration's enforcement

of a particular statute for which it exercises investigative or enforcement authority; (B) adversely affect persons who have provided information to the Employee Benefits Security Administration; or (C) deter other persons from reporting violations of the statute.

(iii) Deliberative Process Privilege (to withhold information which may disclose pre-decisional intra-agency or inter-agency deliberations in cases arising under the statutory provisions listed in paragraph 5.a.(1) of this order including: The analysis and evaluation of facts; written summaries of factual evidence; and recommendations, opinions, or advice on legal or policy matters). To assert this privilege, the Assistant Secretary must first determine that: (A) The information is not purely factual and does not concern recommendations that the department expressly adopted or incorporated by reference in its ultimate decision; (B) the information was generated prior to and in contemplation of a decision by a part of the Department; and (C) disclosure of the information would have an inhibiting effect on the Department's decision-making processes.

(iv) Privilege for Investigative Files compiled for law enforcement purposes (to withhold information which may reveal the Employee Benefits Security Administration's confidential investigative techniques and procedures). To assert this privilege, the Assistant Secretary must first determine that disclosure of the privileged matter may have an adverse impact upon the Employee Benefits Security Administration's enforcement of the statutory provisions listed in paragraph 5.a.(1) of this order, by: (A) Disclosing investigative techniques and methodologies; (B) deterring persons from providing information to the Employee Benefits Security Administration; (C) prematurely revealing the facts of the Department's case; or (D) disclosing the identities of persons who have provided information under an express or implied promise of confidentiality.

(v) Prior to filing a formal claim of privilege, the Assistant Secretary shall personally review the information sought to be withheld, including all the documents sought to be withheld (or, in cases where the volume of information is so large all of it cannot be personally reviewed in a reasonable time, an adequate and representative sample of such information) and a description or summary of the litigation in which the disclosure is sought.

(vi) The Assistant Secretary may comply with any additional requirements imposed by local court rules or precedent in asserting a governmental privilege.

(vii) In asserting a governmental privilege, the Assistant Secretary may ask the Solicitor of Labor or the Solicitor's representative to prepare and file any necessary legal papers or documents.

b. The Solicitor of Labor is responsible for providing legal advice and assistance to all officials of the Department relating to the administration of the statutes listed in paragraph 5.a.(1) of this order, for bringing appropriate legal actions on behalf of the Secretary, and representing the Secretary in all civil proceedings. The Solicitor of Labor is also authorized to request information the IRS possesses for use in connection with the administration of title I of ERISA.

c. The Inspector General is authorized to request information the IRS possesses for use in connection with the administration of title I of ERISA.

6. *Reservation of Authority.* a. The submission of reports and recommendations to the President and the Congress concerning the administration of the statutes listed in paragraph 5.a.(1) of this order and responsibilities under subtitle C of title III of ERISA are reserved to the Secretary. The Pension Benefit Guaranty Corporation carries out responsibilities under title IV of ERISA.

b. This Secretary's Order does not affect the authorities and responsibilities of the Office of Inspector General under the Inspector General Act of 1978, as amended, or under Secretary's Order 2–90 (January 31, 1990).

7. *Effective Date.* This order is effective upon the date of publication in the **Federal Register**.

Dated: January 23, 2003.

Elaine L. Chao,

Secretary of Labor.

[FR Doc. 03–2163 Filed 1–31–03; 8:45 am]

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Federal Register

Monday,

February 3, 2003

Part IV

Department of Health and Human Services

Food and Drug Administration

21 CFR Part 1

Registration of Food Facilities and Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002; Proposed Rules

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1

[Docket No. 02N–0276]

RIN 0910–AC40

Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Food and Drug Administration (FDA) is proposing a regulation that would require domestic and foreign facilities that manufacture, process, pack, or hold food for human or animal consumption in the United States to register with FDA by December 12, 2003. The proposed regulation would implement the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act), which requires domestic and foreign facilities to register with FDA by December 12, 2003, even in the absence of final regulations. Registration is one of several tools that will enable FDA to act quickly in responding to a threatened or actual terrorist attack on the U.S. food supply by giving FDA information about all facilities that manufacture, process, pack, or hold food for consumption in the United States. In the event of an outbreak of food-borne illness, such information will help FDA and other authorities determine the source and cause of the event. In addition, the registration information will enable FDA to notify quickly the facilities that might be impacted by the outbreak.

DATES: Submit written or electronic comments by April 4, 2003. Written comments on the information collection provisions should be submitted by March 5, 2003.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments. Submit written comments on the information collection provisions to the Office of Information and Regulatory Affairs, the Office of Management and Budget (OMB), New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Stuart Shapiro, Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Leslye M. Fraser, Center for Food Safety and Applied Nutrition (HFS–4), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–2378.

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I. Background and Legal Authority

The events of September 11, 2001, highlighted the need to enhance the security of the U.S. food supply. Congress responded by passing the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (''the Bioterrorism Act'') (Public Law 107–188), which was signed into law on June 12, 2002. The Bioterrorism Act includes a provision in title III (Protecting Safety and Security of Food and Drug Supply), Subtitle A—Protection of Food Supply, section 305, which requires the Secretary of Health and Human Services (the Secretary) to develop regulations mandating domestic and foreign facilities that manufacture, process, pack, or hold food for human or animal consumption in the United States to register with FDA by December 12, 2003. The provision creates section 415 and amends sections 301 and 801 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 331 *et seq.*).

The major components of section 305 of the Bioterrorism Act are as follows:

- The owner, operator, or agent in charge of a facility is responsible for submitting the registration form to FDA;
- The registration form must include the name and address of each facility at which, and all trade names under which, the registrant conducts business. Foreign facilities also must include the name of the U.S. agent for the facility;
- FDA also may require each facility to submit the general food category (as identified under § 170.3 (21 CFR 170.3)) of the food manufactured, processed, packed, or held at the facility, if FDA determines this submission necessary through guidance. FDA plans to issue such guidance;
- Foreign facilities exporting food to the United States are required to register unless the food undergoes further processing or packaging by another facility outside the United States;
- Other facilities excluded from the registration requirement are: farms, restaurants and other retail facilities, nonprofit food establishments in which food is prepared for or served directly to the consumer, and fishing vessels (except those engaged in processing as defined in § 123.3(k) (21 CFR 123.3(k)));
- FDA shall notify the registrant when it has received the registration and assign a unique registration number to each registered facility. This number is not subject to public disclosure under section 552 of title 5, United States Code (the Freedom of Information Act);
- FDA may encourage electronic registration; and
- Registered facilities must notify FDA in a timely manner of changes to their registration information.

In addition to section 305 of the Bioterrorism Act, FDA is relying on sections 701(a) and 701(b) of the act (21 U.S.C. 371(a) and (b)) in issuing this proposed rule. Section 701(a) authorizes the agency to issue regulations for the efficient enforcement of the act, while

section 701(b) of the act authorizes FDA and the Department of Treasury to jointly prescribe regulations for the efficient enforcement of section 801 of the act.

II. Preliminary Stakeholder Comments

On July 17, 2002, FDA sent a letter to members of the public interested in food issues outlining the four provisions in title III of the Bioterrorism Act that require FDA to issue regulations in an expedited time period, and FDA's plans for implementing them (see http://www.cfsan.fda.gov/~dms/sec-ltr.html). In the letter, FDA invited stakeholders to submit comments to FDA by August 30, 2002, for FDA's consideration as it developed this proposed rule. FDA also held several meetings with representatives of industry, consumer groups, other Federal agencies, and foreign embassies after sending out the July 17, 2002, letter, in order to solicit stakeholder comments. In response to these solicitations, FDA received numerous comments regarding section 305 of the Bioterrorism Act.

FDA has considered all the comments received by August 30, 2002. FDA will consider all comments received thus far along with the comments we receive during the public comment period on this proposed rule as we develop the final rule. Some of the significant comments FDA received on or before August 30, 2002, include:

- Defining farm to include typical post-harvesting operations, if all food is grown on the farm;
- Including food product categories in a format that satisfies both the requirements of the Bioterrorism Act and stakeholder concerns;
- Allowing facilities that handle most or all of the food categories listed to check ''most/all'' food product categories instead of requiring them to check every product category handled by the facility;
- Maintaining flexibility regarding qualifications for a U.S. agent;
- Including dates the facility is in operation, if its business is seasonal;
- Defining ''facility'' to include multiple buildings on a single site, or buildings within the same general physical location;
- Allowing a corporate headquarters or other central management to submit registrations for multiple facilities;
- Providing for both electronic and paper registration;
- Providing registration numbers instantaneously, if registration is done electronically;
- Requiring only trade names of facilities, as opposed to brand names of products the facility produces;
- Defining ''food'' consistent with the act's definition;
- Including a model of what the electronic registration screen would look like;
- Defining ''timely updates'' to mean within 30 calendar days of changes to information on the registration form; and
- Requiring facilities that begin to manufacture, process, pack, or hold food for consumption in the United States on or after December 12, 2003, to register before they begin such activities.

III. The Proposed Regulation

This proposed rule implements the food facility registration requirements in section 305 of the Bioterrorism Act. Together with the proposed rules implementing section 307 (prior notice), section 306 (recordkeeping), and section 303 (administrative detention) of the Bioterrorism Act, registration of food facilities will enable FDA to act quickly in responding to a threatened or actual bioterrorist attack on the U.S. food supply or to other food-related emergencies. Registration will provide FDA with information about facilities that manufacture, process, pack, or hold food for consumption in the United States. In the event of an outbreak of food-borne illness, such information will help FDA and other authorities determine the source and cause of the event. In addition, the registration information will enable FDA to notify quickly the facilities that might be impacted by the outbreak.

In establishing and implementing this proposed rule, FDA will comply fully with its international trade obligations, including the applicable World Trade Organization (WTO) agreements and the North American Free Trade Agreement (NAFTA). For example, FDA believes this proposed rule is not more trade-restrictive than necessary to meet the objectives of the Bioterrorism Act. FDA has endeavored to make the registration process as simple as possible for both domestic and foreign facilities.

A. Highlights of Proposed Rule

The key features of this proposed rule are as follows:

- Owners, operators, or agents in charge of facilities engaged in manufacturing, processing, packing, or holding food for consumption in the United States must register the facility with FDA;
- Facilities covered under this rule must be registered by December 12, 2003;
- Domestic facilities must register with FDA, whether or not food from the facility enters interstate commerce;
- A foreign facility may designate its U.S. agent as its agent in charge for purposes of registering the foreign facility;
- Foreign facilities are exempt from registering if food from these facilities undergoes further processing or packaging by another facility outside the United States. The facility is not exempted from registration if the processing or packaging activities of the subsequent facility are limited to the affixing of a label to a package or other de minimis activity. The facility that conducts the de minimis activity also must register.
- The following facilities are also exempt from registering: Farms; retail facilities; restaurants; nonprofit food facilities in which food is prepared for, or served directly to, the consumer; fishing vessels not engaged in processing, as defined in § 123.3(k); and facilities regulated exclusively, throughout the entire facility, by the U.S. Department of Agriculture (USDA) under the Federal Meat Inspection Act (21 U.S.C. 601 *et seq.*), the Poultry Products Inspection Act (21 U.S.C. 451 *et seq.*), or the Egg Products Inspection Act (21 U.S.C. 1031 *et seq.*);
- FDA strongly encourages electronic registration, which will be quicker and more convenient for both facilities and FDA than registration by mail.

B. General Provisions

1. Who Must Register Under This Subpart? (Proposed § 1.225)

As required by the Bioterrorism Act, the proposed rule applies to facilities engaged in the manufacturing/processing, packing, or holding of food for human or animal consumption in the United States. The proposed rule applies to both domestic and foreign food facilities. Individual homes are not subject to the regulation if the food that is manufactured/processed, packed, or held in the home does not enter commerce.

FDA is proposing in § 1.225(b) to require all domestic facilities that manufacture/process, pack, or hold food to register, whether or not the food from the facility enters interstate commerce. The Bioterrorism Act provides that ''any facility engaged in manufacturing, processing, packing, or holding food for consumption in the United States'' must register and defines ''domestic facility'' as ''a facility located in any of the States or Territories.'' Therefore, FDA tentatively concludes that the statute requires all domestic facilities to

register, whether or not they engage in interstate commerce. Moreover, having a central database of all domestic facilities producing food would greatly assist FDA in limiting the effects of a food-related emergency covering several States. Nonetheless, because FDA recognizes that this is an important and controversial issue, the agency is seeking comment on whether the agency has authority to exempt domestic facilities engaged only in intrastate commerce from the registration requirement and, if so, whether FDA should use that authority. FDA also seeks comment on how many intrastate facilities are not covered by one of the exemptions from the registration requirement (e.g., the farm or retail exemption). Finally, FDA invites recommendations on what screening questions the agency could ask to enable the owner, operator, or agent in charge of a facility to easily determine whether the facility is an interstate or intrastate facility.

For both domestic and foreign facilities, FDA is proposing in § 1.225(a) and (b) that the owner, operator, or agent in charge, register the facility. FDA is also proposing in § 1.225(c) that the U.S. agent may register a foreign facility if the foreign facility has designated the U.S. agent as its agent in charge. If a foreign facility wants to designate its U.S. agent as its agent in charge for purposes of registering, FDA recommends that the facility and U.S. agent enter into a written agreement authorizing the U.S. agent to register the facility and specifying the U.S. agent's other responsibilities. There are other roles in the course of business that an agent in charge may fill. A formal written agreement between the facility and its U.S. agent would provide clarity for both. Because the proposed rule would require the U.S. agent to reside or maintain a place of business in the United States, allowing the U.S. agent to register the foreign facility will give foreign facilities reliable access to electronic registration that some facilities might not otherwise have. For example, within the United States, Internet access is readily available to members of the public at many local libraries and certain places of business (e.g., photocopying centers).

This process will allow a foreign facility to be registered much more quickly than requesting a paper registration form from FDA by mail, waiting to receive the registration form in the mail from FDA, completing the registration form and sending it to FDA by mail, waiting for FDA to enter the information manually into the electronic registration database—which could take several weeks to several months depending on the number of paper registrations FDA has received previously—and awaiting a response from FDA by mail that contains the confirmation of registration and the facility's registration number.

2. Who is Exempt From This Subpart? (Proposed § 1.226)

In § 1.226, FDA is proposing to exempt several types of facilities from the registration requirement. First, as noted previously, FDA is proposing in § 1.226(a) to exclude foreign facilities, ''if food from these facilities undergoes further manufacturing/processing (including packaging) by another foreign facility outside the United States.'' In other words, foreign facilities involved in the initial stages of manufacturing/processing food are not required to register if another facility further manufactures/processes or packs the food produced at that facility outside the United States.

This exemption would not apply to facilities if the ''further manufacturing/processing'' at the subsequent facility is of a de minimis nature, such as adding labeling to a package or adding plastic rings to the outside of beverage bottles to hold them together. The facility conducting the de minimis activity would also be required to register. This proposal is based on FDA's tentative conclusion that the statute's exclusion of labeling and ''similar activity of a de minimis nature'' from the definition of ''further processing and packaging'' applies only for purposes of the definition of ''foreign facility.'' FDA tentatively concludes that this limitation does not apply to the term ''processing'' as used elsewhere in the registration provision of the Bioterrorism Act. Accordingly, facilities that label food or engage in similar activities would be required to register as processors. FDA requests comment on this interpretation of the Bioterrorism Act.

The following are examples of which foreign facilities would be subject to, or exempt from, the registration requirement, based on the activities they perform:

(1) A foreign facility would be required to register if it prepares a finished food and places it into packages suitable for sale and distribution in the United States.

(2) A foreign facility distributing food to food processors outside the United States for further manufacturing/processing before the food is exported for consumption in the United States would not be required to register, unless the further manufacturing/processing entails adding labeling or other de minimis activity. If the further manufacturing/processing is of a de minimis nature, both the facility conducting the de minimis activity and the facility immediately prior to it would be required to register.

(3) The last foreign facility that manufactures/processes an article of food before it is exported to the United States would be required to register, even if the food subsequently is held or stored at a different facility outside of the United States. FDA is proposing to require these manufacturers/processors to register because the Bioterrorism Act exempts a foreign facility from registering only if another facility subsequently processes or packages the food.

(4) Facilities located outside the United States that take possession, custody or control of finished foods for holding, packing, and/or storage prior to export to the United States, would be required to register.

Even though the last processors and packagers of food are required to register under the proposed rule, the Bioterrorism Act also requires foreign facilities that pack and/or hold food subsequent to the processing and packaging process to register with FDA. Requiring registration of foreign facilities that conduct a significant activity with respect to the food, starting with the last manufacturer/processor involved, and ending with the last facility before the food is shipped to the United States, is consistent with the Bioterrorism Act, and ensures that FDA has contact information for foreign facilities whose operations would be expected to affect food exported for consumption in the United States. This requirement achieves a balance between protecting the U.S. food supply, and not unduly burdening foreign facilities.

Consistent with the Bioterrorism Act, FDA also is proposing in § 1.226(g) to exempt certain fishing vessels from the registration requirement. These vessels include ''those that not only harvest and transport fish but also engage in practices such as heading, eviscerating, or freezing intended solely to prepare fish for holding on board a harvest vessel.'' However, consistent with the Bioterrorism Act's reference to § 123.3(k), the proposed rule provides that ''those fishing vessels otherwise engaged in processing fish, which for purposes of this section means handling, storing, preparing, heading, eviscerating, shucking, freezing, changing into different market forms, manufacturing, preserving, packing, labeling, dockside unloading, or holding

are subject to all of the regulations in this subpart.''

FDA also is proposing in § 1.226(h) to exempt facilities that are regulated exclusively, throughout the entire facility, by USDA under the Federal Meat Inspection Act (21 U.S.C. 601 *et seq.*), the Poultry Products Inspection Act (21 U.S.C. 451 *et seq.*), or the Egg Products Inspection Act (21 U.S.C. 1031 *et seq.*). Such facilities include meat and poultry slaughterhouses. This section complies with section 315 of the Bioterrorism Act entitled ''Rule of Construction,'' which states that nothing in title III of the Bioterrorism Act, or an amendment made by title III, shall be construed to alter the jurisdiction between USDA and the U.S. Department of Health and Human Services under applicable statutes and regulations.

FDA is proposing in § 1.226 that facilities that are jointly regulated by FDA and USDA will be required to register under this rule because they are under FDA's jurisdiction as well as that of USDA. Examples of facilities jointly regulated by FDA and USDA include slaughter facilities that slaughter cattle and deer, and food processing facilities that process meat and nonmeat products, such as frozen T.V. dinners containing both meat, which is regulated by USDA, and fish, which is regulated by FDA.

As specified in the Bioterrorism Act, FDA also is proposing to exempt several other facilities from the registration requirement. These facilities, which are discussed in the definitions section, include farms (§ 1.226(b)); retail facilities (§ 1.226(c)); restaurants (§ 1.226(d)); and nonprofit food facilities in which food is prepared for, or served directly to, the consumer (§ 1.226(e)).

3. What Definitions Apply to This Subpart? (Proposed § 1.227)

As specified in proposed § 1.227, the following definitions are used throughout the proposed rule:

a. *The act*. The proposed rule (§ 1.227(a)) defines ''the act'' as the Federal Food, Drug, and Cosmetic Act. The proposed rule applies the definitions of terms in section 201 of the act (21 U.S.C. 321) to such terms in the proposed rule.

b. *Calendar day*. FDA is proposing in § 1.227(c)(1) to define ''calendar day'' as every day shown on the calendar. This term includes weekend days.

c. *Facility*. FDA is proposing in § 1.227(c)(2) to define a ''facility'' as ''any establishment, structure, or structures under one management at one general physical location, or, in the case of a mobile facility, traveling to multiple locations, that manufactures/processes, packs, or holds food for consumption in the United States. Individual homes are not facilities if the food that is manufactured/processed, packed, or held in the home does not enter commerce.'' In response to comments that FDA received during its early outreach efforts, FDA is clarifying in the proposed rule that a facility is not limited to one building, but can consist of several contiguous structures.

The definition of ''facility'' also specifies that a facility must be under one management. This means that, for purposes of the proposed rule, a single building may house distinct facilities if they are under separate management. If a facility is under joint management of two or more companies, the joint management arrangement is considered one management.

A mixed-type facility performs activities of a facility that is ordinarily required to register and activities of a facility that is ordinarily exempt, such as a farm or retail facility. In order to determine whether a mixed-type facility must register, FDA will consider whether the activity that would require registration is merely incidental to the activities of an exempt facility. If these activities are merely incidental, the facility need not register. For further clarification, see the discussion of the definitions of ''farm,'' ''retail facility,'' and ''restaurant'' that follow.

i. *Domestic facility*. FDA is proposing in § 1.227(c)(2)(A) to define ''domestic facility'' consistent with the definition of ''State'' in section 201(a)(1) of the act (21 U.S.C. 321(a)(1)). That is, FDA is proposing to define a domestic facility as one that is located in any State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico.

ii. *Foreign facility*. FDA is proposing in § 1.227(c)(2)(ii) to define a foreign facility as a facility other than a domestic facility that manufactures, processes, packs, or holds food for consumption in the United States.

d. *Farm*. FDA is proposing in § 1.227(c)(3) to define ''farm'' in part as ''a facility in one general physical location devoted to the growing of crops for food, the raising of animals for food (including seafood), or both.'' A farm may consist of contiguous parcels of land, ponds located on contiguous parcels of land, or, in the case of netted or penned areas located in large bodies of water, contiguous nets or pens. Some examples of farms include: Apple orchards, hog farms, dairy farms, feedlots, or aquaculture facilities.

The definition of ''farm'' includes: (i) Facilities that pack or hold food, provided that all of the food used in such activities is grown or raised on that farm or is consumed on that farm; and (ii) facilities that manufacture/process food, if all of the food used in such activities is consumed on that farm or another farm under the same ownership. ''Farm'' includes such facilities because they are activities incidental to farming that most farms engage in (e.g., holding and packing of harvested crops). Facilities that engage in manufacturing/processing, packing, or holding of food that is not described in the definition of ''farm'' must register because such activities are not activities that most farms engage in and are thus not included in the definition of ''farm.''

A farm that manufactures/processes, packs, or holds food is not required to register with FDA, if all of the food used in such activities is consumed on that farm or another farm under the same ownership. For example, a farm that manufactures/processes animal feed from ingredients obtained off the farm for consumption by animals on the farm would be exempt because most farms that raise animals engage in this activity.

This definition does not extend to facilities that grow crops and raise animals and also manufacture/process food that is sold for consumption off the facility because such activities are not incidental to farming. For example, a facility that grows oranges and manufactures/processes them into orange juice for sale to a distributor would be required to register as a manufacturing/processing facility.

A facility could meet the definition of ''farm'' if all of the activities on the farm meet the description in § 1.227(c)(3)(i), (c)(3)(ii), or both. For example, one farm could meet the description in § 1.227(c)(3)(i) if all of the food packed or held on the farm was grown on that farm. A second farm could meet the description in § 1.227(c)(3)(ii) if all of the food manufactured/processed on the farm is consumed on that farm, even if some of the food was not grown or raised on the farm (e.g., animal feed processed on the farm using materials obtained off the farm and fed to cattle on that farm).

It should be noted that the proposed retail exemption also may apply to facilities that grow crops and raise animals. Thus, a facility that grows crops and raises animals and that also manufactures/processes, packs, or holds food and sells it directly to consumers would be exempt from registering as a retail facility under § 1.226(e), whether or not the food was all grown or raised on that facility. Similarly, a facility would be exempt as both a farm and a retail facility if it sold crops grown on

the farm to consumers at a roadside stand.

FDA is proposing to require co-op facilities that manufacture/process, pack, or hold food, and that are not subject to the farm exemption, to register with FDA. Co-ops are organizations formed to perform activities, including manufacturing/processing or packing food, for their members. The product of these activities is distributed to the members or the public. A farm that grows wheat for distribution to co-op members would be exempt from registration, but a processing facility owned by the co-op would be required to register if it is not located on the farm and mills the wheat into flour for consumption by co-op members off the farm.

The definition of farm does not include facilities that contract with multiple farmers to grow crops or raise animals. These facilities may manufacture/process feed and distribute it to the contract farmers for feeding to animals being raised on the farm. FDA is proposing that the facilities that manufacture/process feed for the contract farmers would be required to register. The farms that grow the crops or raise the animals would be exempt from the registration requirement.

e. *Food*. FDA is proposing in § 1.227(c)(4) to define ''food'' as it is defined in section 201(f) of the act. That definition is: ''* * * (1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article.'' FDA also is proposing to include some examples of products that are considered food under section 201(f) of the act. These examples include, but are not limited to: Fruits; vegetables; fish; dairy products; eggs; raw agricultural commodities for use as food or components of food; animal feed, including pet food; food and feed ingredients and additives, including substances that migrate into food from food packaging and other articles that contact food; dietary supplements and dietary ingredients; infant formula; beverages, including alcoholic beverages and bottled water; live food animals (such as hogs and elk); bakery goods; snack foods; candy; and canned foods. ''Substances that migrate into food from food packaging'' include immediate food packaging or components of immediate food packaging that are intended for food use. Outer food packaging is not considered a substance that migrates into food.''

f. *Holding*. FDA is proposing in § 1.227(c)(5) to define holding as storage of food. The proposed rule gives examples of holding facilities as including, but not being limited to: Warehouses, cold storage facilities, storage silos, grain elevators, or liquid storage tanks.

g. *Manufacturing/processing*. FDA is proposing in § 1.227(c)(6) to define manufacturing/processing as ''making food from one or more ingredients, or synthesizing, preparing, treating, modifying or manipulating food, including food crops or ingredients.'' Some examples of manufacturing/processing include, but are not limited to: Cutting, peeling, trimming, washing, waxing, eviscerating, rendering, cooking, baking, freezing, cooling, pasteurizing, homogenizing, mixing, formulating, bottling, milling, grinding, extracting juice, distilling, labeling, or packaging. FDA is defining manufacturing and processing together because the meanings of the terms overlap. For example, combining two materials into a finished product, such as macaroni and cheese, could be considered manufacturing, processing, or both. Since both manufacturers and processors are required to register with FDA, FDA does not believe it is necessary to distinguish between manufacturing and processing in the proposed rule.

h. *Nonprofit food facility*. FDA is proposing in § 1.227(c)(7) to define a nonprofit food facility as ''a charitable entity that prepares, serves, or otherwise provides food to the public.'' Examples of these facilities include: food banks, soup kitchens, and nonprofit food delivery services. FDA is proposing that in order to qualify as a nonprofit food facility, the entity must be exempt from paying income tax under the U.S. Internal Revenue Code. This requirement serves to ensure that FDA's definition of a nonprofit facility is consistent with that of other agencies of the U.S. Government.

i. *Packing*. FDA is proposing in § 1.227(c)(8) to define packing as ''placing, putting, or repacking a food into different containers without making any change to the form of the food.'' Facilities engaged in packing of food for consumption in the United States must register under the proposed rule, unless exempt.

j. *Port of entry*. For purposes of the proposed rule, FDA is defining ''port of entry'' as ''the water, air, or land port at which the article of food is imported or offered for import into the United States, i.e., the port where food first arrives in the United States.'' FDA is proposing this definition because the port where the food arrives in the United States may be different than the port where the entry of the article of food is processed for U.S. Customs purposes, i.e., where the article is ''entered.'' Under U.S. Customs Service statutes, products can be imported into one port, then transported to another port under a custodial bond before a consumption entry is filed. For example, food may be imported into the United States from Canada through Buffalo, NY, but not entered for consumption with U.S. Customs until it reaches St. Louis, MO, several days later. In this example, under FDA's proposed definition, the port of entry is Buffalo, NY.

The registration authority in the Bioterrorism Act is intended to give FDA better tools to deter, prepare for, and respond to bioterrorism. Given this purpose, ''port of entry'' must be defined as the port of arrival. Allowing food from a facility that has not registered and that is presented for importation into the United States to be shipped around the country and potentially lost to Government control simply is not consistent with the Bioterrorism Act's stated purpose. FDA believes that its ability to protect U.S. consumers from terrorism or other food-related emergencies will be strongest if food can be examined, and if necessary, held at the point where it first arrives in the United States. FDA requests comment on its proposal to define ''port of entry'' as the port of arrival.

k. *Restaurant*. FDA is proposing in § 1.227(c)(10) to define a restaurant as ''a facility that prepares and sells food directly to consumers for immediate consumption.'' As defined in the rule, some examples of restaurants include, but are not limited to: Cafeterias, lunchrooms, cafes, bistros, fast food establishments, food stands, saloons, taverns, bars, lounges, catering facilities, hospital kitchens, day care kitchens, and nursing home kitchens. See section III.B.3.c of this document for a discussion of mixed-type facilities, which may include restaurants.

Due to possible ambiguity in the term, ''catering facilities'', FDA states in the proposed restaurant definition that facilities that provide food to interstate conveyances, such as airplanes, passenger trains, and cruise ships, rather than directly to consumers, are not restaurants. Facilities that provide food to interstate conveyances are not considered restaurants because they do not serve food directly to consumers for immediate consumption. For example, a facility that provides sandwiches to a passenger train for eventual sale to passengers would not be considered a restaurant. However, the snack bar on the train that sells the sandwiches to consumers would be considered a restaurant. FDA has historically

inspected these facilities that provide food to interstate conveyances and considers them processors, rather than restaurants.

Because the proposed rule also applies to facilities that manufacture/process, pack, or hold food for animal consumption in the United States, by analogy, the term ''restaurants'' also includes pet shelters, kennels, and veterinary facilities in which food is provided to animals.

l. *Retail facility.* In § 1.227(c)(11), the proposed rule defines a retail facility as ''a facility that sells food products directly to consumers only. The term includes, but is not limited to, grocery and convenience stores, vending machine locations, and commissaries. The term includes facilities that not only sell food directly to consumers, but that also manufacture/process food in that facility solely for direct sale to consumers from that same facility.''

The Bioterrorism Act does not limit the retail facility exemption to human food. However, the legislative history to the Bioterrorism Act states that the retail exemption applies to food for ''human'' consumption. Therefore, FDA is taking comments on whether the retail exemption should also be applied to food for animal consumption.

The proposed rule would also require facilities that sell both directly to consumers and to distributors and wholesalers to register. Examples of these facilities are warehouse clubs. Because such facilities do not sell food directly to consumers only, they do not meet the definition of a ''retail facility.''

m. *U.S. agent.* FDA is proposing in § 1.227(c)(12) to define a U.S. agent as ''a person residing or maintaining a place of business in the United States whom a foreign facility designates as its agent.'' This definition is consistent with FDA's drug, biologics, and device registration regulations found in parts 207, 607, and 807 (21 CFR parts 207, 607, and 807), respectively. In order to ensure that the U.S. agent is available to assist FDA in contacting foreign facilities, the proposed definition of U.S. agent also specifies that the U.S. agent ''cannot be in the form of a mailbox, answering machine, or service, or other place where an individual acting as the foreign facility's agent is not physically present.'' FDA also is proposing to have the U.S. agent's responsibilities include acting as a communications link between FDA and the facility, such that FDA will treat representations provided by the U.S. agent to FDA as those of the foreign facility, and will consider information FDA provides to the U.S. agent as the equivalent of providing the same information or documents directly to the foreign food facility. As noted previously, FDA also is proposing to allow the U.S. agent to register on behalf of the foreign facility. FDA recommends that the U.S. agent and facility enter into a written agreement specifying the U.S. agent's responsibilities. The facility does not need to submit a copy of the agreement to FDA as part of its registration. If the foreign agent registers a facility without authorization from the facility, FDA will consider the registration to be a materially false, fictitious, or fraudulent statement to the U.S. Government under 18 U.S.C. 1001.

n. *You or registrant.* FDA is proposing in § 1.227(c)(13) to define ''you'' or ''registrant'' as ''the owner, operator, or agent in charge of a facility that manufactures/processes, packs, or holds food for consumption in the United States.'' FDA is proposing to use ''you'' or ''registrant'' throughout the proposed rule for easier readability.

C. Procedures for Registration of Food Facilities

1. When Must You Register? (Proposed § 1.230)

The Bioterrorism Act requires facilities subject to its requirements to be registered with FDA no later than December 12, 2003. Proposed § 1.230 would require facilities that currently manufacture/process, pack, or hold food for consumption in the United States to be registered by December 12, 2003. FDA is proposing that facilities that begin to manufacture/process, pack, or hold food for consumption in the United States on or after December 12, 2003, must be registered before they begin such activities. This also would apply to facilities engaged in seasonal activities that may not be operating in December, 2003. Before these facilities could begin to manufacture/process, pack, or hold food for consumption in the United States after December 12, 2003 (or resume operations after this date), they must be registered with FDA.

FDA is planning to have both its electronic and paper registration systems operational at least 2 months before the statutory deadline of December 12, 2003. FDA will announce the exact date these systems will be available for registration in the final rule. On or before October 12, 2003, FDA will publish in the **Federal Register** either a final rule setting forth the final registration requirements, or a notice providing an address to which paper registrations should be sent, if either the final rule or the electronic system for accepting registrations has not been completed by that date. Registrations should not be mailed to FDA before publication of that document in the **Federal Register**. Registrations mailed to FDA before the date announced in the **Federal Register** publication will not be accepted.

2. How and Where Do You Register? (Proposed § 1.231)

Although FDA is proposing to allow registration by either electronic or paper means, FDA is planning to devote most of its resources earmarked for registration to building and maintaining an electronic food facility registration system. The majority of facilities, both in the United States and abroad, have access to the Internet, either within their companies or through public libraries, copy centers, schools, or Internet cafes, as well as through a foreign facility's U.S. agent if the facility makes such arrangements. If the U.S. agent does not have Internet access onsite, the agent may register the facility electronically from a local library or other public facility that offers Internet access either free or for a relatively small fee. In this manner, all foreign facilities would be able to obtain an automatic electronic confirmation of registration and the facility's registration number similar to domestic facilities that register electronically.

Registering electronically will benefit both facilities and FDA. FDA will be able to accept electronic registrations from anywhere in the world 24 hours a day, 7 days a week through a link on FDA's Internet Web site. Electronic registration also will enable a facility to be registered more quickly than registering by mail, since obtaining confirmation of registration and the facility's registration number online should be instantaneous once a facility fills in all required fields on the registration screen. In contrast, registration by mail may take several weeks to several months, depending on the efficiency of the mail system and the number of paper registrations that FDA will need to enter manually into the system. Registrations received by mail will be processed in the order in which they are received.

Regarding the electronic Internet-accessible system, the registrant will be able to fill out the entire form online. In order to ensure that the form is filled out completely, the electronic system will not accept a registration submission until all of the mandatory fields are completed. Because FDA intends to allow companies the option of filing registration forms on behalf of one or more of their facilities, FDA will give the registrant the option of completing additional registration forms for other

facilities after the first registration form, and each subsequent registration form, is completed.

FDA is proposing in § 1.231(b) that a registrant may register by mail if none of the means of electronic access mentioned previously are reasonably available. In registering by mail, a registrant also may fill out one or more forms on behalf of one or more facilities. A registrant registering by mail must pick up a copy of the form from FDA headquarters, call FDA at a toll-free number (that will be provided in the final rule) to request a copy of the form, or send FDA a written request for the form. Once the registrant receives the mailed copy of the form, the form must be filled out completely and legibly, and mailed back to FDA at the address provided in the final rule. Once FDA receives the form, an agency employee will check to make sure all mandatory fields are filled out completely and legibly. If the form is not complete or is illegible, it will be returned to the registrant for completion, provided that the registrant's mailing address is legible and valid. If the form is complete and legible, FDA will manually enter the data on the form into the system as soon as practicable, which will depend on the number of other registration forms awaiting manual entry into the system.

The Bioterrorism Act requires FDA to notify the registrant that it has received the facility's registration and to assign the facility a unique registration number. Accordingly, FDA is proposing the following: If a facility registers electronically, FDA will provide the registrant with an automatic electronic confirmation of registration, along with the facility's registration number. This notification will be similar to an automatic electronic receipt many companies provide consumers when they purchase products online (i.e., via the Internet). If the facility registers by mail, FDA will be able to provide the registrant with confirmation of registration and the facility's registration number only after FDA manually enters the registration information into the system. Depending on the number of other paper registrations FDA receives, this entry process could take several weeks to several months. After the registration information is entered into the system, FDA will mail a copy of the information entered to the registrant, along with confirmation of registration and the registration number. If any of the information that was entered into the system is incorrect, the registrant must mail an update to correct the information within 30 calendar days.

For electronic registrations, FDA is proposing in § 1.231 to consider the facility registered when FDA electronically transmits the facility's registration number. If a registration is done by mail, the facility is registered once the data are entered into the registration system and the system generates a registration number. This means that the facility information will be entered into the registration system before the facility receives its registration number, if registration is done by mail. FDA strongly encourages all facilities, both foreign and domestic, to register electronically, as that minimizes the delay in having FDA mail the registrant a form, the registrant returning the completed form to FDA, FDA entering the facility's data manually into the registration system, and FDA subsequently mailing the registration number and receipt of registration to the facility. To the extent possible, all covered facilities should make every effort to register electronically or send in their registration form as far in advance as possible of the date they are intending to import their products into the United States (but not sooner than the announced date) since the Bioterrorism Act requires FDA to hold imported products of any unregistered facility at the U.S. port of entry until the facility is registered with FDA.

The Bioterrorism Act precludes FDA from requiring facilities to register electronically. Given FDA's preference for electronic registration and the ease of electronic registration for both registrants and FDA, FDA is requesting comments regarding what other means FDA should use to encourage electronic registration. FDA also is requesting comments from facilities that believe they will be unable to register electronically, as well as comments regarding data on the number of these facilities.

No registration fee is required for either the electronic or paper registration. FDA is proposing that registrants must submit all registration information in the English language. FDA is proposing to require submissions to be in English in order for FDA to understand the content of submissions and ensure that registration data are entered accurately.

3. What Information is Required in the Registration? (Proposed § 1.232)

FDA is proposing in § 1.232 that registrants must submit to FDA certain information, including: The name, full address, phone number, fax number, and e-mail address of the facility (paragraph (a)); the name and address of the parent company (paragraph (b)), if the facility is a subsidiary of the parent company; emergency contact information, including the contact's name, title, office phone, home phone, cell phone (if available), and e-mail address (if available) (paragraph (c)); all trade names the facility uses (paragraph (d)); and the name, address, phone number, fax number (if available), and e-mail address (if available) of the U.S. agent for foreign facilities (paragraph (f)). FDA is planning to include all of this information in the mandatory section of the registration form. At the end of the form, FDA is planning to provide a statement in which the registrant will certify that the information submitted is true and accurate, and that the individual submitting the registration is authorized by the facility to do so (paragraph (g)). This statement also will require the phone number, e-mail address (if available), and fax number (if available) of the person submitting the registration.

Section 305 of the Bioterrorism Act also states that FDA may require registrants to submit the general food categories of food produced at the facility, if FDA determines through guidance that such information is necessary. FDA plans to issue such guidance, and make it available for comment in accordance with good guidance practices (21 CFR 10.115). The guidance will address FDA's finding that such food categories are necessary. Section 305 of the Bioterrorism Act specifically provides that the food categories to be used are those provided in § 170.3. FDA tentatively concludes that information on the category of food manufactured, processed, packed, or held at each facility that must register is necessary for a quick, accurate, and focused response to a bioterrorist incident or other food-related emergency, because the categories will assist FDA in conducting investigations and surveillance operations in response to such an incident. These categories will also enable FDA to quickly alert facilities potentially affected by such an incident if FDA receives information indicating the type of food affected. For example, if FDA receives information indicating that soft drinks could be affected by a bioterrorist incident or other food related emergency, FDA would be able to alert soft drink manufacturers/processors, packers, and holders about this information. Additionally, the food categories, in conjunction with the prior notification requirements in 21 CFR part 1, subpart I, would aid FDA in verifying that

imported products are correctly identified by where and by when they were produced. For example, if the registration information identifies a facility as producing only dairy products and FDA receives a prior notice purportedly from the facility for the shipment indicating that the facility is shipping nuts, FDA can target that facility for verification based on the discrepancy. FDA believes, however, that information about a facility's food product categories is a key element for both FDA and industry to allow for rapid communications to facilities directly impacted by an actual or potential bioterrorist attack or other food-related emergency. FDA, therefore, is proposing in § 1.232(e) to include on the registration form as a mandatory field the categories from § 170.3. For ease of use, however, the more common categories found in FDA's product code builder at www.fda.gov/search/databases.html will be listed as the main categories on the form, followed by the food product categories in § 170.3 as references for each FDA product code category. For example, the registration form includes coffee and tea as a product category, which includes the products listed in § 170.3(n)(3) and (n)(7). Categories not in § 170.3 will be listed as optional selections.

FDA believes its proposed approach will both permit the agency to collect vital information regarding usable categories of products produced at the facility, and address industry's concern that the food product categories in § 170.3 are unworkable. FDA is interested in receiving comments on whether use of FDA's product code builder categories as the primary selection, with references immediately after each entry to the food product categories in § 170.3 that apply to each selection, addresses the comments' concerns regarding use of the categories in § 170.3, while complying with the requirements of the Bioterrorism Act.

FDA also is proposing to include several other fields that relate directly to the statutory requirements. The first of these is the name, address, phone number, facsimile number (if available), and e-mail address (if available) of the U.S. agent. Because the U.S. agent will act as a communications link between the facility and FDA, it is vital for FDA to have reliable contact information for the U.S. agent.

FDA also is proposing that a mandatory section of the form include, if applicable, the name and address of the parent company, if the facility is owned by a parent corporation. This information is important for FDA in understanding the relationship between a facility and its parent company regardless of the name under which a facility may be operating.

FDA also is proposing to include as a mandatory section the emergency contact information for a facility, which would include an individual's name, title, office phone, home phone, and cell phone (if available). If FDA receives information regarding a potential or actual threat to the nation's food supply, or other food-related emergency, it must be able to get in touch with an individual at each potentially affected facility who could respond immediately to the threat at any hour. The emergency contact person does not have to be physically located at the facility; however he or she must be accessible and able to respond in an emergency. Thus, for example, a parent corporation can list as the emergency contact the name of an individual at headquarters who has overall responsibility for responding to emergencies at any facility owned by the parent company.

FDA is planning to include at the end of the form a statement in which the person submitting the registration information will certify that the information submitted on the form is true and accurate and the person registering the facility is authorized to do so. If a person submits false information on the registration form, or if a person registers a facility without being authorized to do so, that registration will be considered a materially false, fictitious, or fraudulent statement to the U.S. Government under 18 U.S.C. 1001, which subjects the person to criminal penalties. FDA is including this language on the registration submission to deter individuals from either submitting false information, or registering a facility if they are not authorized by the facility to register it. This applies both to individuals who do not have any relationship with the owner, operator, or agent in charge of a facility, and to those who have a connection to the owner, operator, or agent in charge of a facility, such as the U.S. agent, but who do not have authorization from the facility to register on its behalf.

4. What Optional Items Are Included in the Registration Form? (Proposed § 1.233)

FDA also is proposing in § 1.233 to include several optional fields on the registration form. These items are consistent with the statutory directive, and will enable FDA to communicate more quickly with facilities that may be the target of a bioterrorist attack or other food-related emergency. These proposed fields include:

(a) a preferred mailing address, which would allow a facility's corporate headquarters to serve as the primary contact with FDA instead of the facility;

(b) the type(s) of activity conducted at the facility (e.g., manufacturing/processing, packing, or holding), which would allow FDA to target its communications in emergencies to those facilities potentially impacted based on the information FDA receives (e.g., a threat to a type of food product at manufacturing facilities);

(c) food categories not included in § 170.3 (e.g., dietary supplements, infant formula, and food for animal consumption), which would be helpful to FDA for responding to a terrorist incident or other food safety emergency involving these foods;

(d) the type of storage or manufacturing/processing facility, in the event that the facility is solely a warehouse/holding facility and stores multiple types of food;

(e) a food product category of ''most/all food product categories'', if the facility manufactures, processes, packs, or holds foods in most or all of the categories under § 170.3; and

(f) the approximate dates of operation, if the facility's business is seasonal.

FDA encourages all facilities to submit this optional information if it applies to the facility's operations.

5. How and When Do You Update Your Registration Information? (Proposed § 1.234)

FDA is proposing in § 1.234 that the owner, operator, or agent in charge must submit a timely update to FDA via the Internet (or by paper copy if no Internet access) within 30 calendar days of any change to any of the information previously submitted, including, but not limited to, the name of the owner, operator, or agent in charge. FDA is proposing 30 calendar days in order to balance the needs of both industry and FDA. In order for FDA to have accurate information for responding to terrorist threats or other food related emergencies, facilities must submit updates within an expedited timeframe. However, FDA also understands that the need to submit updates may coincide with transitions occurring at the facility in which the facility may not be able to provide updates immediately after such transitions occur. FDA believes that requiring updates within 30 calendar days of changes to the information on the initial registration submission is a reasonable balance between FDA's and industry's interests. FDA requests comments on this 30-day timeframe.

With respect to the content of the update, FDA is proposing that the

update must include any changes to any information the facility previously submitted, including, but not limited to, changes to information regarding food product categories. This information, including these categories, will assist FDA in conducting investigations and surveillance operations in response to a bioterrorist incident. If this information is outdated it will interfere with FDA's ability to quickly ascertain the nature and scope of the problem and to alert affected facilities and prevent further distribution of harmful food. Therefore, for efficient and effective implementation of the Bioterrorism Act, FDA is proposing to require registrants to update previously submitted information in both the mandatory and optional categories, if the registrant originally submitted information in both categories and that information changes. FDA requests comments on this proposed requirement and how it will affect the submission of optional information.

A facility canceling a registration must do so on a separate cancellation form electronically or by mail.

D. Additional Provisions

1. What Other Registration Requirements Apply? (Proposed § 1.240)

In proposed § 1.240, FDA has included a provision reminding registrants that they must comply with all other applicable registration requirements, including those found in part 108 (21 CFR part 108), related to emergency permit control. FDA wants to ensure that registrants subject to the registration regulation being proposed to implement the Bioterrorism Act are aware that this registration does not take the place of that required in part 108, or any other registration requirements.

FDA seeks to minimize the burden of this rule on covered facilities and the submission of duplicative information. FDA is aware that existing registrations required by FDA and other federal agencies ask for information that may be duplicative of some of the information FDA is proposing be submitted under this rule. The Bioterrorism Act requires that certain facilities register with FDA. The Bioterrorism Act also specifies that certain information must be contained in the facilities' registration submissions. FDA seeks comments on whether there are registration requirements under which facilities must submit duplicative information to more than one Federal agency. If so, FDA also seeks comments on whether there is any way, consistent with the requirements and purpose of the Bioterrorism Act, to minimize the duplication of information required to be submitted under these registration requirements. In particular, FDA is interested in comments on whether it has authority, under the Bioterrorism Act or another regulatory mandate, to grant a partial or full exemption from the FDA registration requirement to facilities that have already registered with another Federal agency. If such authority exists, FDA is also interested in whether the goals of the Bioterrorism Act could be met if FDA does not have complete registration information.

2. What Happens if You Fail to Register? (Proposed § 1.241)

As provided in the Bioterrorism Act, two consequences may occur if a facility covered under these regulations fails to register. Failure of either domestic or foreign facilities to register is considered a prohibited act under section 301 of the act (21 U.S.C. 331). Under section 302 of the act (21 U.S.C. 332), the United States can bring a civil action in Federal court to enjoin persons who commit a prohibited act and, under section 303 of the act (21 U.S.C. 333), can bring a criminal action in Federal court to prosecute persons who commit a prohibited act. Under section 305a of the Bioterrorism Act, FDA can seek debarment of any person who has been convicted of a felony relating to importation of food into the United States.

FDA seeks comment on circumstances under which a firm's registration should be considered null and void and on circumstances under which a firm's registration should be revoked. FDA also seeks comment on the process for such determinations.

For foreign facilities that fail to register and attempt to import food into the United States, the Bioterrorism Act requires the food be held at the port of entry unless FDA directs its removal to a secure facility. FDA is proposing in § 1.241(e) that if FDA determines that removal to a secure facility is appropriate (e.g., due to a concern with the security of the article of food or due to space limitations in the port of entry), FDA may direct that the article of food be removed to a bonded warehouse, container freight station, centralized examination station, or another appropriate secure facility that has been approved by FDA. Perishables, however, may not be stored in U.S. Customs Service's bonded warehouses; thus FDA may direct fresh produce or seafood that requires storage to another facility. FDA and the U.S. Customs Service plan to issue guidance for their field offices that will identify locations of secure storage.

In order to minimize confusion about who is responsible for making arrangements if food is held under section 801(l) of the act (21 U.S.C. 381(l)), FDA is proposing in § 1.241(f) that the owner, purchaser, importer, or consignee must arrange for storage of the article of food, in an FDA-designated secure facility and must promptly notify FDA of the location. Any movement of the article to the facility must be accomplished under bond. We note that when section 801(l) of the act requires that food be held, it does not appear to mandate that the Government take actual physical custody of the goods; instead it limits both the movement of the goods and the potential storage locations, thereby making Government oversight straightforward. As described previously, U.S. Customs Service has identified a well-established network of storage facilities that are secure. When these storage facilities are used, charges are borne by the private parties. We thus believe that although Congress intended strict controls over food refused admission under section 801(l) of the act, it did not intend to require FDA or U.S. Customs Service to take custody of or pay for the holding of such food. We seek comment on this issue.

The article of food must be held at the port of entry or in the secure facility until the owner, operator, or agent in charge of the foreign facility has submitted its registration information to FDA, FDA has registered the facility, and FDA has notified the U.S. Customs Service and the person who submitted the registration that the facility is registered and the article of food no longer is subject to a hold under section 801(l)(1) of the act. Notwithstanding section 801(b) of the act, while any article of food is held at its port of entry or in a secure facility under section 801(l) of the act, it may not be delivered to any of its importers, owners, or consignees.

The Bioterrorism Act does not provide specific procedures for the disposition of food under hold under section 801(l) of the act when no subsequent registration is submitted. FDA thus believes that the general requirements of Title 19 of the United States Code and the U.S. Customs implementing regulations that apply to imports for which entry has not been made apply in these circumstances. Under 19 U.S.C. 1448 and 1484, entry of merchandise must be made within the time period prescribed by regulation, which is 15 calendar days after the food arrives in the United States. (See 19 CFR 142.2.) If entry is not made within this timeframe, the carrier or other authorized party is required to

notify U.S. Customs Service and a general order warehouse. Generally, at that point the warehouse must arrange to take and store the food at the expense of the consignee. The disposition of this merchandise is governed by 19 U.S.C. 1491 and the implementing regulations at 19 CFR part 127.

Typically, after 6 months, unentered merchandise is deemed unclaimed and abandoned and can be disposed of by the United States. Before this 6 month period runs, however, such merchandise can be re-exported. FDA and U.S. Customs Service plan to develop additional guidance to explain how the agencies will handle food when it must be placed in general order warehouses due to failure to register.

Even though delivery is not allowed, FDA believes that importers, owners, and consignees of food that has been refused under section 801(l) of the act can make arrangements for food to be held: these arrangements can be made without taking possession of the food. FDA recognizes that food may be shipped in the same container or truck with nonfood items. Since articles that are not food are not subject to these regulations, when mixed or consolidated imported freight contains articles of food that must be held at the port of entry or moved to a secure facility, those articles under hold must be dealt with before the rest of the shipment proceeds.

FDA also is proposing in § 1.241(h) that determination that an article of food is no longer subject to hold under section 801(l) of the act is different than, and may come before, determinations of admissibility under other provisions of the act or other U.S. laws. A determination that an article of food is no longer subject to hold under section 801(l) of the act does not mean that it will be granted admission under other provisions of the act or other U.S. laws.

3. What Does Assignment of a Registration Number Mean? (Proposed § 1.242)

FDA is proposing in § 1.242 to state that assignment of a registration number to a facility means that the facility is registered with FDA. Assignment of a registration number does not in any way denote FDA's approval or endorsement of a facility or its products. Therefore, any representation in food labeling that creates an impression of official approval, endorsement, or apparent safety because a facility that manufactures/processes, packs, or holds the food is registered by FDA would be misleading and would misbrand the food under section 403(a)(1) of the act (21 U.S.C. 343(a)(1)).

4. Is Food Registration Information Available to the Public? (Proposed § 1.243)

The Bioterrorism Act provides that registration information and any information contained therein that would disclose the identity or location of a specific registered facility is not subject to disclosure under 5 U.S.C. 552 (the Freedom of Information Act). This provision does not apply to information obtained by other means or that has previously been disclosed to the public as defined in 21 CFR 20.81. FDA is proposing to codify this provision in § 1.243.

IV. Analysis of Economic Impacts

A. Benefit-Cost Analysis

FDA 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. FDA has determined that this proposed rule is a significant regulatory action as defined by Executive Order 12866.

B. Need for the Regulation

The purpose of this regulation is to ensure FDA has knowledge of all domestic and foreign facilities that manufacture/process, pack, or hold food for consumption in the United States. In the event of an actual or threatened bioterrorist attack on the U.S. food supply or other food-related public health emergency, such information will help FDA and other authorities determine the source and cause of such an event, and allow FDA to communicate with potentially affected facilities. The benefits of this regulation would be realized by accomplishing this purpose, as well as other, related benefits. For example, FDA is developing a regulation, 21 CFR part 1, subpart I, to implement prior notice provisions in section 307 of the Bioterrorism Act. Information provided to FDA in a facility's registration would be helpful in FDA's assessment of whether a shipment may present a threat of serious adverse health consequences or death to humans or animals.

C. Reason for the Regulation

FDA is proposing three regulations that will work in harmony to improve food safety. Food safety is mostly a private good. Establishments have powerful incentives to ensure that the ingredients they purchase are not contaminated and that their production processes are protected from unintentional and intentional contamination. Deliberate (intentional) contamination of food linked to a particular product or facility—particularly if the facility is considered negligent—would be extraordinarily costly to a firm. Indeed, the private incentives to avoid deliberate contamination should be similar to the private incentives for food safety. Deliberate food contamination events nonetheless differ from ordinary outbreaks of foodborne illness in that they are more likely to be low probability events with severe public health consequences.

Although private incentives lead to private efforts to protect against deliberate contamination at the facility level, there are external effects associated with privately produced protection. Private incentives fail to provide the optimal amount of information about the food production and distribution system. Getting food from the farm or sea to the plate involves a complex system of production and distribution. The system works using local knowledge and information; each participant needs to know only as much about the overall system as is necessary for his or her business. Market prices convey most of the information necessary for the ordinary production and distribution of food. In the event of an actual or suspected contamination of the food supply, however, more complete information is needed where it can be centrally used. The suspect food must be traced backward and forward through the distribution chain, both to protect consumers and to find the source and cause of the event.

No individual firm or organization has sufficient financial incentive to establish a central information system relating to food safety for the entire economy. The nation's food processors and importers as a whole would benefit from such a system because it would be easier to uncover and solve problems, but the private costs to create the system

probably would be prohibitive for any single firm or third party organization.

We estimate that an effective system of information would require several hundred thousand participants to gather information and provide it to a central system. The private transactions costs to bring all the participants together voluntarily and get them to agree to create such a system would be extraordinarily high. No single organization could capture additional revenue sufficient to cover the cost. Also, because the provision of information by some participants makes it available for all, there would be a tendency for establishments to try to be free riders in the information system. But the more information and participation in the system, the more effective it is.

Another way of looking at the problem of participation is in terms of marginal private benefits and marginal social benefits. By gathering and providing the information used in a food safety system, an individual establishment receives additional private benefits from enhancing the safety of its own food. In addition, participating in the system increases the effectiveness of the entire information system. In other words, the more establishments participate in the system, the better it works. The individual establishment does not capture this additional social benefit. The marginal private benefit (enhanced safety for individual establishments) is less than the marginal social benefit (the marginal private benefit plus the increased effectiveness of the entire information system). The difference between private and social benefit reduces the incentive for establishments to participate in a voluntary private system.

The events of September 11, 2001, led Congress to conclude that public creation and provision of an information system is necessary. The Bioterrorism Act and its implementing regulations would establish an information system that would allow FDA to have a more integrated picture of the food distribution system. This particular regulation addresses one important aspect of this information system: The need to know what facilities manufacture/process, pack, or hold food for consumption in the United States, what types of food each facility handles, and how each facility can be contacted. However, as stated previously, FDA is proposing three regulations to address these needs, so the costs and benefits of any one regulation will be closely associated with related provisions in other proposed rules. With the regulations in place, the agency would have the additional tools necessary to help prevent and respond to threats to the nation's food supply as well as to other food safety problems.

D. Options

FDA analyzes the costs and benefits of eight regulatory options that address the goal of deterring or containing purposeful or accidental contamination of the U.S. food supply. Option 1 is the status quo and provides the baseline against which all the other options are measured. Option 2 has the most complete coverage of domestic and foreign facilities and required information in the registration. Options 3 through 5 are each less comprehensive than option 2. Options 6 and 7 use a different definition of mixed-type facilities and option 7 permits U.S. agents to register on behalf of the foreign facility they represent. Option 7 is the proposed option. Option 8 is a discussion of the costs and benefits of the Bioterrorism Act's registration provisions becoming requirements without FDA issuing a regulation (statutory default provision).

- Option 1 is to not impose any new regulatory or statutory requirements.
- Option 2 requires the registration of domestic and foreign facilities that manufacture/process, pack, or hold food for consumption in the United States, whether or not food from the facility enters interstate commerce. Farms, fishing vessels, nonprofit food facilities, facilities exclusively regulated by USDA, and retail facilities are exempted from the registration requirement. Mixed-type facilities that perform some activities of a farm or retail facility but that also manufacture/process food for consumption off that facility must register under this option. Foreign facilities are also required to have a U.S. agent to facilitate communication between the foreign facility and FDA.
- Option 3 has the same requirements and coverage as option 2, but excludes facilities that participate only in intrastate commerce. FDA tentatively concludes that this option is not legally viable, as the Bioterrorism Act does not seem to exempt facilities participating only in intrastate commerce.
- Option 4 has the same coverage and requirements as option 2, but excludes all mixed-type facilities, regardless of whether they also manufacture/process food for consumption off the facility or pack or hold food not grown or raised on that facility. As discussed in the following paragraphs, FDA does not believe this option is legally viable.
- Option 5 has the same requirements and coverage as option 2, but does not require that facilities include information about the types of products they manufacture/process, pack, or hold on their registration.
- Option 6 has the same requirements and coverage as option 2, but mixed-type facilities are required to register if they pack or hold food not harvested on that facility or manufacture/process food not for consumption on that facility. However, facilities that manufacture/process food are exempted as retail facilities if they sell the food directly to consumers from that facility.
- Option 7, the proposed option, requires the same coverage of facilities as option 6. Under this option, the U.S. agent can register on behalf of the foreign facility.
- Option 8 is to allow the registration requirement of the Bioterrorism Act to be implemented without issuing a regulation. The Bioterrorism Act requires facilities to register by December 12, 2003, regardless of whether FDA issues a regulation. Due to uncertainty about how this option would be implemented, FDA does not attempt to estimate costs or benefits for this option.

1. Option One: Do Not Require Facilities to Register

Option one is to maintain the status quo, i.e., no statutory or regulatory registration requirement. This option will serve as the baseline against which other options will be measured for assessing costs and benefits. OMB's cost-benefit analysis guidelines recommend discussing requirements that affect the selection of regulatory approaches. These guidelines also recommend analyzing the opportunity cost of legal constraints that prevent the selection of the regulatory action that best satisfies the philosophy and principles of Executive Order 12866.

The Bioterrorism Act requires that FDA implement through regulation registration for food facilities; therefore, this is not a legally viable option.

2. Option Two: Comprehensive Registration of Domestic and Foreign Manufacturers/Processors, Packers, and Holders of Food

Option two requires domestic facilities that manufacture/process, pack, or hold food for consumption in the United States to register with FDA, including facilities engaged in interstate and intrastate commerce. Farms, fishing vessels, nonprofit food facilities, facilities exclusively regulated by USDA, and retail facilities are exempted from the registration requirement. Mixed-type facilities that perform activities of a farm or retail facility but

that also manufacture/process food for consumption off that facility must register under this option. Registration may be electronic or by mail, although FDA strongly encourages all facilities to register electronically. The information required on the registration includes the facility's name, address, parent company name and address (if applicable), emergency contact information, trade names, general food product categories under § 170.3, and certification by the owner, operator, or agent in charge of the facility as to the accuracy of the information and the submitter's authority to register the facility.

Under the Bioterrorism Act, foreign establishments are required to register if they manufacture, process, pack, or hold food for consumption in the United States without the food undergoing further processing or packaging outside the United States. In addition to registering, the Bioterrorism Act requires foreign facilities to have a U.S. agent. The U.S. agent is a person residing in or maintaining a place of business in the United States, who the owner, operator, or agent in charge of a foreign establishment designates as its agent. Only one U.S. agent per foreign establishment is permitted and the U.S. agent must reside or maintain a place of business in the United States. The U.S. agent is responsible for acting as a communications link between FDA and the facility.

a. *Coverage*—i. *Domestic establishments*. Consistent with the Bioterrorism Act, this proposed regulation's legal requirements apply to facilities, as opposed to firms. A firm is composed of facilities under common ownership. As a result, changes in behavior may occur at the firm- or facility-level to comply with this proposed regulation. However, for ease of analysis, FDA will focus on the facility as the unit of analysis. For a count of domestic facilities, FDA used the 2000 County Business Patterns (CBP) (Ref. 1), 1999 Nonemployer Statistics (Ref. 2), the FDA Field Accomplishments and Compliance Tracking System (FACTS) (Ref. 3), and the Census of Agriculture (Ref. 4). The Census Bureau created the 2000 CBP by analyzing data from the Business Register, the Census Bureau's file of all known single and multi-facility companies. These data for single-location firms are obtained by the Census from the Economic Censuses, the Annual Survey of Manufacturers, Current Business Surveys, and administrative records from the Internal Revenue Service, Social Security Administration, and the Bureau of Labor Statistics.

Table 1 of this document provides a count of businesses in the relevant North American Industry Classification (NAICs) codes in the 2000 CBP. There are 103,125 affected facilities in the 2000 CBP under option two. Facilities not included in the CBP are counted in the Nonemployer Statistics, which is also from the Census Bureau (Ref. 2). Nonemployer businesses are companies with no paid employees. The Census Bureau primarily obtains data about nonemployer businesses from annual business income tax returns filed with the Internal Revenue Service. The Nonemployer Statistics dataset is less disaggregated than the CBP dataset. As a result, including entire counts of facilities in some NAICs codes in the Nonemployer Statistics would result in an overestimate of the number of facilities. For example, NAICs code 4931, warehousing and storage, includes warehouses and storage facilities that store nonfood products, and so is too aggregated for this analysis and includes facilities that would not be required to register. To estimate the number of affected warehouses in NAICs 4931, FDA assumed that the percentage of warehouses that are refrigerated and nonrefrigerated warehouses that store farm products is the same for both the 2000 CBP and the 1999 Nonemployer Statistics, and uses this as an adjustment factor for the 1999 Nonemployer Statistics. With this adjustment, there are 68,424 facilities in the relevant NAICs codes in the 1999 Nonemployer Statistics. Table 2 of this document provides a count of businesses in the relevant NAICs codes in the 1999 Nonemployer Statistics. Manufacturers/processors, packers, and holders of substances that migrate into food from food packaging or other articles that contact food do not correspond to any single NAICs code. Tables 3 and 4 of this document provide numbers of facilities in the 2000 CBP and 1999 Nonemployer Statistics, respectively. Broader NAICs codes, such as 322 and 326 that include facilities that deal only in nonfood products have only the number of facilities reported that could reasonably be expected to deal in substances that migrate into food from food packaging or other articles that contact food. For example, stationery manufacturers have been removed from the estimate. The Nonemployer Statistics have more aggregated counts than the 2000 CBP. To get a more accurate count of facilities in the Nonemployer Statistics, the count of facilities in each aggregated NAICs codes is reduced by the percentage of facilities believed to be dealing with substances that migrate into food from packaging in the 2000 CBP. However, this number may be an overestimate as for some NAICs codes, in which it was not clear if the facilities were producing substances for food or nonfood use. For example, plastic forms may be made into food packaging or may be used for other purposes. To further adjust the number of facilities to include only facilities that manufacture/process, pack, or hold substances that migrate into food from food packaging or other articles that contact food, the numbers in each category are adjusted by data reported in The Rauch Guide to the U.S. Packaging Industry (Ref. 5). The Rauch guide reports that the packaging of consumer products accounts for 78 percent of all packaging and that 55 percent of the total used for consumer products is used for food and beverages. This means 43 percent of packaging is used to package food and beverages. To reflect this data, the NAICs categories for end, or near-end use packaging were reduced by 57 percent. NAICs categories for explicit food use, such as kitchen utensils and cutlery were assumed to have 100 percent of facilities manufacturing/processing, packing, or holding food.

Basic chemicals or other components incorporated into packaging may be intended for food or nonfood uses. FDA was unable to determine how many of these components are intended for food use. FDA also was not able to distinguish between manufacturers/processors, packers, or holders of immediate food packaging, which would be considered ''substances that migrate into food from food packaging or other articles that contact food,'' and manufacturers/processors, packers, or holders of outer food packaging, which would not. Therefore, FDA included for purposes of this analysis: (1) Facilities manufacturing/processing, packing, or holding basic chemicals or other components incorporated into packaging for both food and nonfood use, and (2) manufacturers/processors, packers, and holders of both immediate and outer food packaging. Because this approach results in an overestimation of the number of facilities subject to this proposed rule, FDA requests comments on the number of these types of facilities that would be required to register.

Also covered under this proposed rule are slaughterhouses that process FDA regulated meats and renderers. FDA requests comments on the number of these facilities.

The Census data sets do not identify facilities engaged only in intrastate

commerce (Refs. 1 and 2). To be considered a facility engaged only in intrastate commerce, a facility must obtain all its ingredients and sell all its products within a single State. FDA assumes that facilities that participate only in intrastate commerce will be very small and are unlikely to be warehouses or wholesalers. To determine which facilities are in interstate commerce, FDA compared the number of facilities in Census data sets with the number of facilities in the FACTS database. FACTS is a database of facilities regulated by FDA that includes data on operations accomplished by the field (e.g., inspections, investigations, sample collections, sample analyses, etc.) (Ref. 3). FACTS and FDA's Operation and Administration System for Import Support (OASIS) identify firms as workload and nonworkload obligations for FDA. FACTS uses different product categories for facilities than the Census datasets, making a direct comparison of the number of firms within categories with the Census datasets difficult. Table 5 of this document presents a count of facilities in the FACTS database by FDA categories. The FACTS database has some facilities that appear in more than one category, so a single facility may appear more than once in the database. This double counting is not corrected in the count of each type of facility, but is corrected in the total count of facilities. Because the FACTS database gives a count of facilities that FDA inspects, FDA assumes that all facilities in FACTS are in interstate commerce. If we take the total count of facilities from the CBP and Nonemployer Statistics, 171,549, and subtract the count of facilities in FACTS, 71,871, this gives a reasonable estimate of the number of facilities in intrastate commerce 99,678. This calculation is presented in table 6 of this document.

TABLE 1.—COUNT OF FACILITIES IN THE 2000 CBP

NAICs Code	Type of Industry	Number of Facilities
3111	Animal food manufacturing	1,710
3112	Grain and oilseed milling	913
3113	Sugar and confectionery product manufacturing	1,689
3114	Fruit and vegetable preserving and specialty food manufacturing	1,796
3115	Dairy product manufacturing	1,769
3117	Seafood product preparation and packaging	854
3118	Bakeries and tortilla manufacturing	10,644
3119	Other food manufacturing	2,994
3121	Beverage manufacturing	2,748
4224	Grocery and related product wholesale	39,721
4225	Farm product raw material wholesale	9,546
4228	Beer, wine, distilled alcoholic beverage wholesale	4,630
49312	Refrigerated warehousing and storage	945
49313	Farm product warehousing and storage	516
Subtotal		80,475
	Substances that contact food	22,650
Total		103,125

TABLE 2.—COUNT OF FACILITIES IN THE 1999 NONEMPLOYER STATISTICS

NAICs Code	Type of Industry	Number of Facilities
3111	Animal food manufacturing	642
3112	Grain and oilseed milling	287
3113	Sugar and confectionery product manufacturing	1,439
3114	Fruit and vegetable preserving and specialty food manufacturing	2,000
3115	Dairy product manufacturing	594
3117	Seafood product preparation and packaging	693
3118	Bakeries and tortilla manufacturing	6,271
3119	Other food manufacturing	4,725
3121	Beverage manufacturing	1,608
4224	Grocery and related product wholesale	32,050
4225	Farm product raw material wholesale	4,795
4228	Beer, wine, distilled alcoholic beverage wholesale	2,578
4931	Warehousing and storage	964
Subtotal		58,646
	Substances that contact food	9,778
Total		68,424

TABLE 3.—FACILITIES THAT MANUFACTURE/PROCESS, PACK, OR HOLD FOOD CONTACT SUBSTANCES IN THE NONEMPLOYER STATISTICS

NAICs		Total in NAICs	Adjusted by CBP	Percent Used in Food
322	Paper manufacturing	1,621	1,197	43
3251	Basic chemical manufacturing	534	385	100

TABLE 3.—FACILITIES THAT MANUFACTURE/PROCESS, PACK, OR HOLD FOOD CONTACT SUBSTANCES IN THE NONEMPLOYER STATISTICS—Continued

NAICs		Total in NAICs	Adjusted by CBP	Percent Used in Food
3252	Resin, synthetic rubber, artificial and synthetic fibers manufacturing	293	293	100
326	Plastics and rubber products manufacturing	5,528	1,203	43
3271	Clay product and refractory manufacturing	4,452	448	100
3272	Glass and glass product manufacturing	3,463	3,463	43
331	Primary metal manufacturing	3,447	335	100
332	Fabricated metal product manufacturing	33,202	393	100
4226	Chemical and allied products wholesale	5,403	5,403	100
Total				9,778

TABLE 4.—FACILITIES THAT MANUFACTURE/PROCESS, PACK, OR HOLD FOOD CONTACT SUBSTANCES IN THE 2000 CBP

NAICs		Total Number of Facilities	Percent Used in Food
322	Paper manufacturing	4,308	43
32513	Synthetic dye and pigment manufacturing	204	100
32518	Basic inorganic chemical manufacturing	730	100
32519	Basic organic chemical manufacturing	818	100
3252	Resin, synthetic rubber, artificial and synthetic fibers	863	100
326	Plastics and rubber products manufacturing	3,544	43
327112	Vitreous china and other pottery product manufacturing	185	100
3272	Glass and glass product manufacturing	2,340	43
3313	Alumina and aluminum production and processing	613	43
332211	Cutlery and flatware (except precious) manufacturing	166	100
332214	Kitchen utensil, pot and pan manufacturing	72	100
332431	Metal can manufacturing	242	100
332439	Other metal container manufacturing	437	100
4226	Chemical and allied products wholesale	15,293	100
Adjusted total			22,650

TABLE 5.—COUNT OF FACILITIES IN FACTS

Type of Facility	Number of Facilities
Manufacturers	34,437
Repackers/packer	6,204
Warehouses	34,760
Shippers	1,519
Caterers	664
Commissary	705
Subtotal	78,289
Collapsed to account for multiple firms.	71,871

TABLE 6.—NUMBER OF FACILITIES IN INTERSTATE AND INTRASTATE COMMERCE

2000 CBP	103,125
1999 Nonemployer statistics	68,424
Subtotal of facilities in inter and intrastate commerce.	171,549
FACTS (interstate commerce)	-71,871
Facilities only in intrastate commerce.	99,678

ii. *Mixed-type facilities.* Although farms and retail facilities are exempted from registration by the Bioterrorism Act, some mixed-type facilities perform activities of a farm or retail facility and activities of a facility that is required to register. Under this regulatory option, FDA would require mixed-type facilities that manufacture/process food that is not consumed at that facility to register. Examples of manufacturing/processing include canning, freezing, cooking, pasteurization, homogenization, irradiation, milling, grinding, chopping, slicing, cutting, coloring, waxing, shelling of nuts, peeling, labeling, and packaging. Farms that mix feed would be considered mixed-type facilities if they manufacture/process feed at the facility with ingredients obtained from

another source, and the feed is then sold or transferred for final use off-farm.

To estimate the number of mixed-type facilities that grow crops or raise animals and would be subject to the proposed requirements, FDA used the 1997 USDA NASS Census of Agriculture (Ref. 6), and data obtained from various county level Cooperative Extension Service (CES) offices (Ref. 7). The Census of Agriculture provides the total number of farms producing specific commodities. To estimate the number of farms that are mixed-type facilities, FDA used a sample of counties with information from their respective CES offices. CES offices from Clay County, KS; Monterey, Sonoma, Marin, and San Diego counties in CA; Jackson County, WI; Gillespie and San Saba counties in TX; Carol County, MD; and Berks County, PA provide data on the percentage of farms producing specific commodities to be considered mixed-type facilities (Ref. 7). FDA assumes that farms that produce other commodities, including vegetables (nonorganic), other fruits, and wheat, plus feed mixing on poultry and other livestock farms are not mixed-type facilities based on CES interviews (Ref. 7). Table 7 of this document lists the numbers and percent of farms that are mixed-type by commodities. Some commodities that are not processed on mixed-type facilities are not included in the table. The total estimate of affected mixed-type facilities is 25,365. FDA requests comments on these assumptions and estimates.

TABLE 7.—COUNT OF MIXED-TYPE FACILITIES THAT ENGAGE IN FARMING AND THAT WOULD BE REQUIRED TO REGISTER UNDER OPTION 2.

Commodity	Facility Number	Percent Mixed Use	Mixed Use Number
Pig farms (feed mixing)	46,353	0.5	232
Cattle (feed mixing)	785,672	0	0
Poultry (feed mixing)	36,944	0	0
Other animal production (feed mixing)	110,580	0	0
Dairy	86,022	0	43
Grain, rice, and beans	462,877	0	0
Apples	10,872	10	1,087
Oranges	9,321	10	932
Peaches	14,459	10	1,446
Cherries	8,423	10	842
Pears	8,062	10	806
Other fruit	29,413	10	806
Nuts	14,500	10	1,450
Berries	6,807	20	1,361
Grapes	11,043	20	2,209
Olives	1,363	3	41
Vegetables and melons	31,030	0	0
Organic vegetables	6,206	50	3,103
Honey	7,688	50	3,844
Syrup	4,850	100	4,850
Herbs	1,776	10	178
Total			25,365

Retail facilities that manufacture/process, pack, or hold food, and then transfer the food offsite also would be considered mixed-type facilities under this option. Because FDA lacks data on the number of retail facilities that manufacture/process food for distribution offsite, FDA estimated this number using the total number of grocery stores and specialty food stores in the 2000 CBP and the 1999 Nonemployer Statistics. FDA assumes that grocery and specialty food stores also may manufacture/process food, but that convenience stores do not manufacture/process food. The 1999 Nonemployer Statistics reports the combined number of grocery and convenience stores and, separately, the number of specialty food stores. To adjust for the grouping of grocery and convenience stores, we assume that the percentage of grocery stores out of the combined number of grocery stores and

convenience stores is the same in the 2000 CBP and the 1999 Nonemployer Statistics and reduce the number of grocery and convenience stores from the 1999 Nonemployer Statistics by the percentage in the 2000 CBP. FDA then assumes that 10 percent of these retail facilities manufacture/process, in addition to direct selling to consumers. This gives a total of 10,410 affected mixed-type retail facilities. Because the number of retail facilities is large, the number of facilities covered is highly sensitive to the percentage assumed to be in mixed-type facilities. FDA requests comments on the number of attached retail facilities under Option 2.

iii. *Foreign manufacturers.* FDA estimates the number of foreign manufacturers that would be affected by the regulation from a count in FDA's OASIS database (Ref. 4). OASIS is an automated FDA system for processing and making admissibility determinations for shipments of foreign-origin FDA-regulated products seeking to enter domestic commerce. There are 125,450 foreign manufacturers in the OASIS database. Table 8 presents the number of foreign manufacturers by the type of food they manufacture/process.

TABLE 8.—NUMBER OF FOREIGN FACILITIES EXPORTING FOOD TO THE UNITED STATES IN FISCAL YEAR 1999

Foods	110,392
Food additives	2,979
Color additives	378
Infant formula	235
Vitamins	7,986
Animal feeds	3,330
Medicated animal foods	150
Total	125,450

iv. *Foreign holders.* Also covered under this regulatory option are the final food holders in the foreign country prior to export of the product. FDA does not have any information on how many foreign facilities hold foods that are to be exported to the United States. FDA, therefore, assumed that the number of foreign final holders is equal to the number of consignees, brokers, and importers of food products in the United States. The OASIS data has a count of 77,427 U.S. importers, brokers, and consignees, so FDA assumed that there are also 77,427 foreign final holders (Ref. 4). FDA requests comments on this estimate.

v. *Foreign facilities that do de minimis processing or packaging.* Facilities that do de minimis processing or packaging of the food, such as affixing a label, are also required to register. Because their processing is minimal, these facilities are not included in the OASIS count of foreign manufacturers. To estimate the number of affected foreign facilities, FDA takes the number of packers/repackers in the FACTS database, 6,204, and adjusts it by the ratio of domestic manufacturers in FACTS to the number of foreign manufacturers in OASIS. This adjustment of 3.64, (125,450 foreign facilities divided by 34,437 domestic facilities), gives the total number of de minimis processing foreign facilities as 22,600. FDA requests comments on this estimate.

vi. *New and closing facilities.* In addition to the facilities currently in existence, in future years, new businesses will open and some existing businesses will close. These new businesses would have to register and closing businesses would have to notify FDA to cancel their registration. According to the Small Business Administration (SBA) Office of Advocacy, in 2001, about 10 percent of all businesses were new and 10 percent of businesses closed (Ref. 8). FDA assumes that the rate of new and closing businesses is the same in other countries as in the United States. Thus, in future years 10 percent of the total count of facilities will be new facilities and 10 percent of the total count of food facilities will go out of business and will need to cancel their registration.

b. *Costs*—i. *Market reaction.* It is expected that most firms will register correctly and on time. If most facilities do not register correctly and on time, then the costs will be higher than estimated. It is also likely that some manufacturers/processors will not register prior to attempting to introduce their products into U.S. interstate commerce, which would increase the amount of time their products are held at the port. In addition, some foreign facilities may determine that registration, in conjunction with prior notice, would make it no longer profitable to continue to manufacture/process and ship food to the United States. That is, if the expected profit from exports is projected to be less than the cost of a U.S. agent, the cost of registration, and the cost of prior notification, they would cease to export to the United States. The marginal costs and benefits that would result from these changes in manufacturer/processor behavior are estimated in the following paragraphs.

ii. *Wage rates.* FDA uses two hourly wage rates from the Bureau of Labor Statistics' National Compensation Survey (Ref. 9). These wage rates then are doubled to include overhead costs, such as office space, health insurance, and retirement benefits. For an administrative worker, the cost per hour is $25.10, and for a manager, who would be the owner, operator, or agent in charge, $56.74. FDA lacks wage data specific to food industry workers in each of the foreign countries that export to the United States and thus used the wage rate for an administrative worker in the United States for the foreign wage rate. We assume that the nature of the worker and the worker's wage would be about the same in foreign countries as in the United States. In open markets where trade takes place, real wage rates tend to be equal for similar work and productivity across countries. However, FDA tests this assumption in the sensitivity analysis and re-calculates the costs if the foreign wage rate is lower than the domestic wage rate.

iii. *First year costs incurred by domestic facilities.* Domestic facilities would incur administrative and form-associated costs to comply with the regulation. The administrative costs would be partially shared between the registration and recordkeeping rules. FDA estimates administrative costs for the recordkeeping regulation and this proposed rule separately, but this probably gives an overestimate of administrative costs. Although recordkeeping has different requirements than registration, it would affect many of the same facilities and FDA expects that the recordkeeping final rule will be published soon after the registration final rule. Individuals from facilities affected by both regulations would most likely search for information for both regulations at the same time and find information in the same places.

There are four steps associated with a domestic facility complying with the regulation. One, the facility becomes aware of the regulation; two, the facility learns what the requirements are; three, an administrative worker fills out the form; and four, the owner, operator, or agent in charge certifies the form.

First, the facility becomes aware of the regulation through normal business activities; reading trade press or industry news; FDA outreach; or conversations with other business operators. Because facility owners, operators, or agents-in-charge must be aware of the requirement to change their activity, FDA assumes that becoming aware of the regulations would occur as part of normal business practice and we thus have included no economic costs for the facility. There may be costs incurred, however, by FDA or trade organizations to undertake the outreach. FDA costs will be considered in a separate section. FDA does not quantify

the costs undertaken by trade organizations, but discusses these costs in the qualitative costs section.

Second, once a representative of the facility becomes aware of the regulations, he or she would need to research the requirements of the regulation. This would require finding a copy of the requirements and reading and understanding them. Representatives of the facility may find a copy of these requirements on the Internet, in the **Federal Register**, in trade association meetings or mailings, or at a library. Several comments stated that many businesses might not have access to the Internet. Administrative costs would be higher for facilities that do not have access to the Internet, and would have to write to FDA or find other sources of information. In the United States, 59.10 percent of the population has accessed the Internet at least once in the three months prior to being surveyed (Ref. 11). An SBA report (Ref. 12) cites two studies that report 40 and 47 percent of small businesses had Internet access in 1998. An updated report from Dun and Bradstreet in 2002 reports 71 percent of small businesses have Internet access (Ref. 13).

Electronic registration will allow facilities an immediate confirmation and registration number. FDA believes that most domestic facilities with Internet access will register electronically. However, some may register on paper forms they receive from trade organizations, newsletters, or other sources. However, FDA believes that this number of paper submissions will be offset by registrants that choose to register electronically who do not have Internet access at their place of business. These registrants may use computers with Internet access belonging to libraries, friends, or in an Internet café. Therefore, FDA assumes that 71 percent of domestic registrants will research and register electronically. FDA estimates it would take facilities with Internet access 1 hour to research the requirements and facilities without Internet access 2 hours. FDA requests comments on this assumption.

Third, once the requirements are understood, the form has to be filled out and sent to FDA, either by mail or electronically. FDA estimates it would take 45 minutes of an administrative worker's time to find the correct information and fill out the form.

Fourth, the owner, operator, or agent in charge must verify the form. This cost would be 15 minutes of the owner, operator, or agent in charge's time.

iv. *Domestic facilities updates, cancellations, and new registrations (annual costs).* Facilities are required to update their registration when a change occurs in any information previously submitted on the registration form. Several comments suggested the requirement to update registrations might be burdensome because some information such as product lines and facility names change frequently and, therefore, could require frequent changes to registrations. FDA does not have any data on how often changes in product lines or other information included in the registration submission would occur. However, given that 10 percent of facilities go out of business each year, FDA estimates that a higher percentage, 20 percent, of all facilities will have to update their registration each year. FDA requests comments on this assumption. FDA also considers an alternative option (option 5) where product codes are not included on the registration form.

To update a registration, a worker at the facility will have to find a copy of the form, look up the facility's registration number, fill out the form, and the owner, operator, or agent in charge will have to verify the form to update a submission. The cost to the facility of updating would be 45 minutes of an administrative worker's time and 15 minutes of a manager's time to certify the changed registration.

New facilities would incur the same costs to learn about the regulation and fill out the registration form in future years as existing facilities experience in the first year. FDA estimates the number of new facilities entering each year would be equal to 10 percent of the total current number of facilities. Thus, the annual cost for registering new facilities would equal 10 percent of the first year costs to existing facilities.

Facilities that go out of business would need to notify FDA of the cancellation of their registration. Similar to updating registration, a worker at the facility will have to find a copy of the form, look up their registration number, fill out the form, and the owner, operator, or agent in charge will have to verify the form to cancel a registration. The cost to the facility of canceling the registration would be 45 minutes of an administrative worker's time to find and fill out the form and 15 minutes of a manager's time to cancel the registration. FDA estimates that 10 percent of the total, current number of facilities would go out of business each year. Table 9 presents a summary of domestic facilities covered under option 2, and table 10 summarizes the data used to estimate the cost of complying with option 2.

TABLE 9.—NUMBER OF DOMESTIC FACILITIES COVERED UNDER OPTION 2

2000 CBP	103,125
1999 Nonemployer statistics	68,424
Mixed-type facilities that engage in farming	25,365
Retail processors	10,410
Total domestic	207,324

TABLE 10.—SUMMARY OF COSTS FOR DOMESTIC FACILITIES UNDER OPTION 2

Administrative worker wage (includes overhead)	25.1
Manager wage (includes overhead)	56.74
Percent with Internet access US	71%
Research time with Internet (hours)	1
Research time without Internet (hours)	2
Research cost with Internet	$3,695,000
Research cost without Internet	$3,018,000
Administrative time for form (hours)	0.75
Manager time for form (hours)	0.25
Form costs	$6,844,000
Percent of businesses going out of business	10%
Percent of businesses entering	10%
Percent of businesses with changes	20%
Annual facility costs	$3,409,000
Total domestic costs	$13,557,000

v. *Foreign facility first year costs.* FDA expects foreign facilities to go through the same four steps to comply with the regulation as domestic facilities: a worker must become aware of the regulation, learn the requirements, and fill out the form; the owner, operator, or agent in charge then must verify the form. There are additional fifth and sixth steps for foreign facilities to find, and then hire a U.S. agent. To estimate the cost of registration for foreign facilities, FDA assumes that they would incur the same per facility costs as

domestic facilities, plus additional costs.

Costs would be higher for many foreign facilities than for domestic facilities at each step due to distance, language difficulties, and lack of Internet access. For some foreign facilities, it may be so difficult to become informed about the regulation, that rather than become informed about the requirements before shipping, some are likely to learn about the requirements at the U.S. port. For these foreign facilities, the cost of learning about the registration requirement would be a possible loss of value to their product due to a delay at the port, storage costs, and transaction costs associated with the delay.

Foreign facilities may learn about the requirements through trade press, importers, U.S. business or trading partners, distributors, or their governments. Foreign facilities, like domestic facilities, then would have to find the requirements of the regulation, obtain the registration form either electronically or in hard copy, and fill out and verify the form. Costs for foreign facilities would vary depending on whether the worker entering the registration information or the owner, operator, or agent in charge of the foreign facility can read and write in English. Comments suggest that many foreign manufacturers are limited in their ability to read and write in English. Estimates of the number of people outside of countries where English is the primary language, who are able to speak English fluently vary widely, ranging from 300 to 750 million (Ref. 14).

To find the number of English speakers outside of the United States, FDA adds the number of English speakers in countries where English is the primary language, excluding the United States, 151 million, the number of English speakers in countries where English is a secondary language, 300 million, and the midpoint, 525 million, of the range of the estimate of the number of speakers of English as a foreign language. FDA then divides this total number of English speakers by the world population minus the U.S. population, 5.9 billion (Ref. 15). Therefore, FDA assumes that 16 percent of foreign manufacturers read and write English well enough to research the registration requirement and fill out the form. FDA requests comments on this assumption. Registrants who do not read and write English would have to hire a translator to aid them in registering and understanding the registration requirements. Alternatively, trade groups, distributors, or the Government may provide translation services. Regardless of whether the translation is paid for directly by the registrant or a third party, for ease of computation, we assume there is a cost per registration for translation for 84 percent of foreign facilities. FDA assumes it would take facility operators who do not understand English one additional hour to fill out the form, 5 additional hours to find an agent, and 5 additional hours to read and understand the registration requirements. FDA requests comments on these assumptions.

Whether a foreign facility has access to the Internet will determine, in part, the cost of learning about and complying with the registration requirements. Although 71 percent of the small businesses in the United States have Internet access, only 3 percent of the population of China, the country that has the largest number of manufacturers that export to the United States, has access to the Internet (Ref. 11). To get an idea of how many manufacturers that export to the United States have access to the Internet, FDA looked at Internet access for the 26 countries that represent 80 percent of the manufacturers that export to the United States (Ref. 4) and the percent of the population that has access to the Internet worldwide for the remaining 20 percent. A weighted average of these 26 countries by the number of manufacturers suggests that 26 percent of the population that exports to the United States has Internet access. FDA lacks data on the percent of businesses in other countries with Internet access. Because businesses are more likely to have Internet access than individuals, FDA adjusts the percent of the populations of other countries with Internet access upward by the percent difference in Internet access between individuals and small businesses in the United States. Seventy-one percent of small businesses in the United States have Internet access versus 59 percent of the population, or the percent of businesses with Internet access represents a 20 percent increase over the population. Applying this adjustment to Internet access in foreign countries increases the percent of businesses with Internet access from 26 to 31 percent. FDA therefore assumes that 31 percent of foreign manufacturers would register electronically. In option 7, FDA considers how many facilities will be registered electronically if the U.S. agent is able to register on behalf of the foreign facility. Table 11 provides a summary of the 26 countries and the percentage of their population with Internet access. The remaining 69 percent would either register by mail or would be aided in registering electronically.

Regardless of whether the cost of obtaining Internet access is borne by the facility, or by a third party, for ease of computation, FDA estimates the cost per facility. FDA expects it will be more difficult for foreign facilities that do not have Internet access at their place of business than domestic facilities to access the Internet elsewhere due to the overall lower level of Internet access in foreign countries. FDA assumes it would take facility operators that do not have access to the Internet, one additional hour to fill out the form, 5 additional hours to find an agent, and 5 additional hours to find, read, and understand the registration requirements. FDA requests comments on these assumptions.

TABLE 11.—PERCENT OF THE POPULATION WITH INTERNET ACCESS FOR THE 26 COUNTRIES THAT ARE HOME TO 80 PERCENT OF FOOD EXPORTERS TO THE UNITED STATES

Country	Percent of Total Manufacturers	Percent of Population With Internet Access
China (mainland) ..	9.05	2.92
France	8.61	28.39
Italy	7.96	33.37
Canada	7.78	52.79
Japan	7.69	40.43
Mexico	6.24	3.38
United Kingdom	3.80	59.88
Germany, Federal Republic of.	3.30	36.37
Taiwan, Republic Of China.	2.96	51.85
Korea, Republic Of (South).	2.95	46.40
India	2.76	0.67
Spain	2.56	19.69
Thailand	2.39	1.96
Netherlands	1.40	58.07
Australia	1.30	54.38
Philippines	1.29	2.46
Hong Kong	1.26	59.58
Chile	1.21	20.02
Poland	1.19	16.57
Brazil	1.18	7.74
Indonesia	1.06	1.93
Belgium	0.89	33.14
Switzerland	0.86	46.82
Portugal	0.85	34.37
Vietnam	0.83	0.49
Rest of the world ..	20.00	9.57
Weighted average		25.50
Business adjustment		20.34
Percent of foreign facilities with Internet access.		30.69

vi. *Foreign facility costs to hire a U.S. agent.* The U.S. agent is a person residing or maintaining a place of business in the United States, whom the owner, operator, or agent in charge of a foreign facility designates as its agent. Only one U.S. agent per foreign facility is permitted. The U.S. agent acts as a communications link between the FDA and the facility and FDA would consider providing information to the U.S. agent the same as providing information directly to the foreign facility.

In option 7, facilities can designate their U.S. agent as their agent in charge of the facility for purposes of registration and the agent can register in behalf of the facility. The costs and benefits of permitting the U.S. agent to register on behalf of the facility are considered in option 7.

FDA has little information on how many foreign facilities already have a U.S. agent. Comments stated that many exporters do not currently have a U.S. agent; they would have to hire an agent in response to the regulation. FDA expects, however, that some foreign facilities already have a U.S. representative that can function as a U.S. agent. The U.S. representative may be a business partner, broker, U.S. lawyer, or parent company. FDA assumes that the likelihood that a foreign facility has an existing U.S. agent is related directly to the quantity of product the foreign facility exports to the United States.

To estimate the number of foreign facilities that already have a U.S. agent, FDA assumes that manufacturers/processors that do more business in the United States are more likely to have an existing U.S. agent. To estimate the amount of product a foreign manufacturer/processor exports to the United States, FDA estimates the number of line entries exported to the United States by foreign manufacturers. The term ''line entry'' refers to a group of products that are subject to the same FDA admissibility decision because they have the same FDA product code, brand name, size or packaging, manufacturer/processor, shipper, consignee, importer's product description, and country of production. One shipment may contain multiple line entries.

FDA used data from OASIS on the average number of line entries and the average number of manufacturers/processors (listed in OASIS under the category ''manufacturers'') by country and product code to estimate the number of line entries for foreign manufacturers/processors. A shortcoming of these data is that entries are by product code; thus, manufacturers/processors that are exporting products in more than one product code are in the count of manufacturers/processors for every product code in which they export. A product code designates a category of product, such as cheese and cheese products. The OASIS data consequently have approximately twice as many manufacturers/processors as actually exist. To adjust for this double-counting, FDA assumed the average foreign manufacturer/processor exports in two product categories. To find an approximate number of line entries per manufacturer, FDA divided the total number of manufacturers/processors into the total number of line entries for each country and applied the average number of line entries per manufacturer/processor to all the manufacturers/processors from that country. This method will underestimate the number of very small and very large manufacturers/processors, because it removes the variation in number of line entries exported from countries with a large number of manufacturers/processors exporting to the United States.

To estimate the number of foreign facilities that would have to hire a U.S. agent, FDA assumed that foreign facilities that export more than 100 line entries each year into the United States, or 10 percent of foreign manufacturers/processors, already have a U.S. representative who can function as a U.S. agent. FDA also assumed that the 16 percent of manufacturers/processors that are exporting 10 or fewer line entries to the United States would stop exporting to the United States, rather than incur the expense of registering, hiring a U.S. agent, and providing prior notice under 21 CFR part 1, subpart I. FDA requests comments on these assumptions. Table 12 presents average numbers of line entries and the percent of foreign manufacturers/processors that export that number.

TABLE 12.—AVERAGE NUMBER OF LINE ENTRIES FROM FOREIGN MANUFACTURERS/PROCESSORS

Average Number of Line Entries	Percent of Total Number of Foreign Manufacturers/ Processors	Cumulative Percent of Manufacturers/ Processors
≤10	15.81	15.81
11–20	25.43	41.24
21–40	32.27	73.51
41–60	7.30	80.81
61–80	5.88	86.69
81–100	3.64	90.33
101–120	1.78	92.11
121–140	0.72	92.83
141–160	1.59	94.42
161–180	0.48	94.90
181–200	0.83	95.73
>200	4.27	100.00

FDA anticipates that foreign facilities would find U.S. agents through the Internet or business contacts. Finding and hiring an agent would result in labor costs for the facility. FDA requests comments on these assumptions.

FDA bases the estimated cost of hiring a U.S. agent on the fees charged by U.S. agents for foreign drug, biologic, and device manufacturers. The requirements for a U.S. agent for drugs, biologics, and devices (parts 207, 607, and 807, respectively) are very similar to the requirements for a U.S. agent for foods in this proposed regulation, and many of the U.S. agents began working as a response to the drug, biologic, and device foreign facility registration regulations. FDA contacted some active U.S. agents, whose annual cost estimates for their services ranged from $700 to $2,000 (Refs. 16 and 17).

vii. *Annual costs for foreign facilities.* Foreign facilities have to retain a U.S. agent. In the first year, the facility would incur costs to hire and retain an agent. In future years, the facility would have to pay an annual fee of approximately one thousand dollars to the agent.

Like domestic facilities, foreign facilities are required to update their registration when a change occurs in any of the information previously submitted. FDA estimates the frequency of registration updates for foreign facilities as 20 percent per year. FDA requests comments on this assumption. The cost to the facility of updating would be 1 hour to find and fill out the form, including translation if necessary, and to certify the changed registration.

New facilities would incur the same costs to learn about the regulation, hire a U.S. agent, and fill out the registration information in future years as existing facilities would incur in the first year.

FDA estimates the number of new facilities entering each year would be equal to 10 percent of the total current number of facilities. Thus, the annual cost for registration of new foreign facilities would equal 10 percent of the first year cost to facilities.

Facilities that go out of business would need to notify FDA of the cancellation of their registration. The cost to the facility of canceling the registration would be the wage rate times 1 hour to cancel the registration. FDA estimates that 10 percent of the total, current number of facilities would go out of business each year. Table 13 presents a summary of the data used to estimate the cost to foreign facilities to comply with option 2.

TABLE 13.—NUMBER OF FOREIGN FACILITIES COVERED UNDER OPTION 2

Foreign holders and packagers	100,027
Foreign manufacturers/processors	125,450
Stops exporting	16%
Total facilities	205,405

TABLE 14.—SUMMARY OF COSTS INCURRED BY FOREIGN FACILITIES UNDER OPTION 2

Speaks English	16%
Has Internet access	31%
Has U.S. agent	10%
Cost of U.S. agent (annual)	$1,000
Hourly wage rate	$25
Time to find agent (hours)	5
Additional time language (hours)	5
Additional time Internet (hours)	5
First year agent cost	$67,340,000
Agent fee (annual cost)	$194,868,000
Administrative time (hours)	1
Additional time language (hours)	5
Additional time Internet (hours)	5
First year administrative costs	$44,418,929
Time to fill out form (hours)	1
Additional time language (hours)	1
Additional time Internet (hours)	1
Percent of businesses going out of business	10%
Percent of businesses entering	10%
Percent of businesses with changes	20%
First year form cost	$12,992,000
Total first year costs	$319,619,000
Total annual costs	$228,370,000

viii. *Cost due to port delays.* FDA anticipates that some foreign facilities would not learn of the requirements before shipping their products to the United States. The administrative costs of learning about the registration requirements for these foreign facilities would be the cost of finding out at the port of entry. FDA requests comment on the percentage of foreign facilities that would become aware of the registration requirement at the U.S. port of entry. For these facilities, the cost of complying would be the possible one-time loss of value of their shipment and other costs of delay, in addition to the cost of registering and finding and hiring a U.S. agent. FDA estimates the cost to foreign facilities of becoming informed about the regulatory requirement is the number of foreign facilities multiplied by either the cost of information, re-exporting the shipment, or a delayed shipment at the U.S. port, whichever is lower.

FDA must hold shipments at the U.S. port for as long as it takes the foreign facility to register with FDA. To register, a foreign facility first must be informed of the delay at the port by the importer, consignee, owner, or transporter. This may happen very quickly via a phone call or e-mail message, or take hours if there is a large difference in time zones. Next, the foreign facility must find and hire a U.S. agent, if it does not already have one. If the foreign facility is open during U.S. business hours and has access to the Internet and a fax machine to find an agent and sign a contract, it may find an agent quickly. If the foreign facility is not in a time zone compatible with customary business hours in the United States or does not have easy access to the Internet or fax machine, finding and hiring an agent may take longer. The cost of the delay to the foreign facility is the cost of storing the shipment and loss of value of the shipment due to the delay. For perishable products, a delay may reduce the value of the shipment significantly, perhaps even to zero. For nonperishable products, there may be transaction costs due to cancellation of a contract and finding a new buyer. FDA expects that to the extent there are significant port delays, they typically will occur with food manufactured/processed, packed or held at facilities that ship infrequently to the United States. Delays also will be longer and more likely for shipments from facilities that are more distant from the United States or have difficulty communicating with the United States. Perishables, due to their short shelf life, are more likely to be shipped from countries that are geographically close to the United States. For these reasons, FDA expects that costs arising from delays for nonperishable products may be as high or higher than costs arising from perishable products. FDA requests comments on the length of delay for shipments held while waiting for the foreign facility to register and on the costs of the delay, such as loss of product value, storage costs, and transaction costs.

ix. *FDA costs.* FDA's costs include creating and maintaining a database, processing paper submissions, and sending annual mailings to registrants. Developing and maintaining a database includes automatically entering registrations into the database that arrive electronically and sending an electronic receipt and facility registration number back to the registrant. FDA estimates that four full time employees (FTEs) would be needed to oversee the database. An employee's wage is estimated to be equal to a GS–12, step one, in the Washington, DC metro area, which is $55,924 per year (Ref. 10). To get the cost of the labor to FDA, FDA doubles the wage rate to include overhead costs, such as health insurance, office space, and retirement benefits. Additionally, paper submissions would have to be entered manually, at an estimated cost of $10 per submission. FDA estimates that facilities that do not have access to the Internet would submit paper registrations. FDA also estimates a 10 percent error rate for paper submissions based on estimates of error rates for another FDA database (Ref. 18). Each paper submission with an error will result in an additional cost for mailing and re-processing. FDA intends to send an annual e-mail or mailing to all

registrants reminding them to keep their registrations up-to-date and verifying the mailing addresses of the registrants. FDA presents costs for the first 5 years in table 15 of this document. Wage rates and paper submission costs are increased by 3 percent each year to account for inflation. Annual costs are discounted at 7 percent.

TABLE 15.—YEARLY COST ESTIMATE FOR FDA UNDER OPTION 2

FDA Costs	2003	2004	2005	2006	2007
Development/modification/enhancement	$8,200,000	$3,000,000	$3,300,000	$2,300,000	$2,300,000
Maintenance/steady state	$1,560,000	$3,500,000	$4,300,000	$4,300,000	$4,300,000
Number of FTEs	4	4	4	2	2
Cost per FTE	$110,588	$110,588	$110,588	$110,588	$110,588
Cost per paper submission	$10	$10.00	$10.00	$10.00	$10.00
Number of domestic paper submissions	60,124	24,050	24,050	24,050	24,050
Number of foreign paper submissions	22,677	9,071	9,071	9,071	9,071
Total number of domestic registrations in database	207,324	207,324	207,324	207,324	207,324
Total number of foreign registrations in database	205,405	205,405	205,405	205,405	205,405
Mailings to domestic facilities	$1	$1.00	$1.00	$1.00	$1.00
Mailings to foreign facilities	$1	$1.00	$1.00	$1.00	$1.00
Error rate for paper submissions	10%	10%	10%	10%	10%
Number of errors	8,280	3,312	3,312	3,312	3,312
Cost per error	$15	$15.00	$15.00	$15.00	$15.00
Total costs	$11,279,000	$7,398,000	$8,498,000	$7,276,000	$7,276,000
Discounted total costs	$11,279,000	$6,914,000	$7,422,000	$5,939,000	$5,551,000

3. Option Three: Require Registration of Domestic and Foreign Facilities That Manufacture/Process, Pack, or Hold Food That Sell Their Products in Interstate Commerce, Including Mixed-Type Facilities

Option three has the same requirements as option two, but does not require domestic facilities that participate only in intrastate commerce to register. FDA tentatively concludes that this option is not legally viable. The Bioterrorism Act does not seem to limit the scope of the statute to facilities that engage only in interstate commerce. Tables 16, 17, 18, 19, and 20 of this document provide a summary of the data for cost estimates under option 3 for domestic facilities, foreign facilities, and FDA, respectively.

Excluding intrastate facilities would lower the number of affected, domestic facilities from 207,324 affected facilities under option two to 107,646. This would lower the first year cost for domestic facilities from $13.6 to $7.0 million dollars. The annual cost would be lowered from $3.4 to $1.8 million dollars. Total first year costs would be lowered from $344.5 to $337.6 million dollars.

TABLE 16.—NUMBER OF DOMESTIC FACILITIES COVERED UNDER OPTION 3

FACTS data	71,871
Mixed-type farms	25,365
Retail processors	10,410
Total domestic	107,646

TABLE 17.—SUMMARY OF COSTS INCURRED BY DOMESTIC FACILITIES UNDER OPTION 3

Administrative worker wage (includes overhead)	25.1
Manager wage (includes overhead)	56.74
Percent with Internet access US	71%
Research time with Internet (hours)	1
Research time without Internet (hours)	2
Research cost with Internet	$1,918,000
Research cost without Internet	$1,567,000
Administrative time for form (hours)	0.75
Manager time for form (hours)	0.25
Form costs	$3,553,000
Percent of businesses going out of business	10%
Percent of businesses entering	10%
Percent of businesses with changes	20%
Annual facility costs	$1,770,000
Total domestic costs	$7,038,000

TABLE 18.—NUMBER OF FOREIGN FACILITIES COVERED UNDER OPTION 3

Foreign holders and packagers	100,027
Foreign manufacturers/processors	125,450
Stops exporting	16%
Total facilities	205,405

TABLE 19.—SUMMARY OF COSTS INCURRED BY FOREIGN FACILITIES UNDER OPTION 3

Speaks English	16%
Has Internet access	31%
Has U.S. agent	10%
Cost of U.S. agent (annual)	$1,000
Hourly wage rate	$25
Time to find agent (hours)	5
Additional time language (hours)	5
Additional time Internet (hours)	5
First year agent cost	$67,340,000
Agent fee (annual cost)	$194,868,000
Administrative time (hours)	1
Additional time language (hours)	5
Additional time Internet (hours)	5
First year administrative costs	$44,418,929
Time to fill out form (hours)	1
Additional time language (hours)	1
Additional time Internet (hours)	1
Percent of businesses going out of business	10%
Percent of businesses entering	10%
Percent of businesses with changes	20%
First year form cost	$12,992,000
Total first year costs	$319,619,000
Total annual costs	$228,370,000

TABLE 20.—COSTS INCURRED BY FDA UNDER OPTION 3

FDA Costs	2003	2004	2005	2006	2007
Development/modification/enhancement	$8,200,000	$3,000,000	$3,300,000	$2,300,000	$2,300,000
Maintenance/steady state	$1,560,000	$3,500,000	$4,300,000	$4,300,000	$4,300,000
Number of FTEs	4	4	4	2	2
Cost per FTE	$110,588	$110,588	$110,588	$110,588	$110,588
Cost per paper submission	$10	$10	$10	$10	$10
Number of domestic paper submissions	31,217	12,487	12,487	12,487	12,487
Number of foreign paper submissions	22,677	9,071	9,071	9,071	9,071
Total number of domestic registrations in database	107,646	107,646	107,646	107,646	107,646
Total number of foreign registrations in database	205,405	205,405	205,405	205,405	205,405
Mailings to domestic facilities	$1	$1	$1	$1	$1
Mailings to foreign facilities	$1	$1	$1	$1	$1
Error rate for paper submissions	10%	10%	10%	10%	10%
Number of errors	5,389	2,156	2,156	2,156	2,156
Cost per error	$15	$15	$15	$15	$15
Total costs	$10,907,000	$7,243,000	$8,343,000	$7,122,000	$7,122,000
Discounted total costs	$10,907,000	$6,769,000	$7,287,000	$5,814,000	$5,433,000

4. Option Four: Require Registration of Domestic and Foreign Facilities That Manufacture/Process, Pack, or Hold Food That Sell Their Products in Interstate and Intrastate Commerce, Not Including Mixed-Type Facilities

Option four has the same registration and U.S. agent requirements as option two, but does not require mixed-type facilities to register. Tables 21, 22, 23, 24, and 25 provide a summary of the data for cost estimates under option 4 for domestic facilities, foreign facilities, and FDA, respectively.

FDA does not believe this option is legally viable, since some mixed-type facilities engage in activities (such as manufacturing/processing for commercial distribution) that are clearly within the scope of the registration requirement as enacted by Congress. Nevertheless, we are including a discussion of this option for comparison purposes.

Excluding mixed-type facilities lowers the number of affected domestic facilities, from 207,324 affected facilities under option 2 to 171,549. This would lower the first year cost for domestic facilities from $13.6 to $11.2 million dollars. The annual cost for domestic facilities would be lowered from $3.4 to $2.8 million. Total first year costs would be lowered from $344.5 to $342.0 million dollars.

TABLE 21.—NUMBER OF DOMESTIC FACILITIES COVERED UNDER OPTION 4

2000 CBP	103,125
1999 Nonemployer statistics	68,424
Total domestic	171,549

TABLE 22.—SUMMARY OF COSTS INCURRED BY DOMESTIC FACILITIES UNDER OPTION 4

Administrative worker wage (includes overhead)	25.1
Manager wage (includes overhead)	56.74
Percent with Internet access US	71%
Research time with Internet (hours)	1
Research time without Internet (hours)	2
Research cost with Internet	$3,057,000
Research cost without Internet	$2,497,000
Administrative time for form (hours)	0.75
Manager time for form (hours)	0.25
Form costs	$5,663,000
Percent of businesses going out of business	10%
Percent of businesses entering	10%
Percent of businesses with changes	20%
Annual facility costs	$2,821,000
Total domestic costs	$11,217,000

TABLE 23.—NUMBER OF FOREIGN FACILITIES COVERED UNDER OPTION 4

Foreign holders and packagers	100,027
Foreign manufacturers/processors	125,450
Stops exporting	16%
Total facilities	205,405

TABLE 24.—SUMMARY OF COSTS INCURRED BY FOREIGN FACILITIES UNDER OPTION 4

Speaks English	16%
Has Internet access	31%
Has U.S. agent	10%
Cost of U.S. agent (annual)	$1,000
Hourly wage rate	$25
Time to find agent (hours)	5
Additional time language (hours)	5
Additional time Internet (hours)	5
First year agent cost	$67,340,000
Agent fee (annual cost)	$194,868,000
Administrative time (hours)	1
Additional time language (hours)	5
Additional time Internet (hours)	5
First year administrative costs	$44,418,929
Time to fill out form (hours)	1
Additional time language (hours)	1
Additional time Internet (hours)	1
Percent of businesses going out of business	10%
Percent of businesses entering	10%
Percent of businesses with changes	20%
First year form cost	$12,992,000
Total first year costs	$319,619,000
Total annual costs	$228,370,000

TABLE 25.—COSTS INCURRED BY FDA UNDER OPTION 4

FDA Costs	2003	2004	2005	2006	2007
Development/modification/enhancement	$8,200,000	$3,000,000	$3,300,000	$2,300,000	$2,300,000
Maintenance/steady state	$1,560,000	$3,500,000	$4,300,000	$4,300,000	$4,300,000
Number of FTEs	4	4	4	2	2
Cost per FTE	$110,588	$110,588	$110,588	$110,588	$110,588
Cost per paper submission	$10	$10	$10	$10	$10
Number of domestic paper submissions	49,749	19,900	19,900	19,900	19,900

TABLE 25.—COSTS INCURRED BY FDA UNDER OPTION 4—Continued

FDA Costs	2003	2004	2005	2006	2007
Number of foreign paper submissions	22,677	9,071	9,071	9,071	9,071
Total number of domestic registrations in database	171,549	171,549	171,549	171,549	171,549
Total number of foreign registrations in database	205,405	205,405	205,405	205,405	205,405
Mailings to domestic facilities	$1	$1	$1	$1	$1
Mailings to foreign facilities	$1	$1	$1	$1	$1
Error rate for paper submissions	10%	10%	10%	10%	10%
Number of errors	7,243	2,897	2,897	2,897	2,897
Cost per error	$15	$15	$15	$15	$15
Total costs	$11,145,000	$7,342,000	$8,442,000	$7,221,000	$7,221,000
Discounted total costs	$11,145,000	$6,862,000	$7,374,000	$5,894,000	$5,509,000

5. Option Five: Require Registration of Domestic and Foreign Facilities That Manufacture/Process, Pack, or Hold Food That Sell Their Products in Interstate and Intrastate Commerce for Consumption in the United States, Including Mixed-Type Facilities as Defined in Option 2, but Not Including Product Categories on the Registration Form

Option five covers the same facilities as option two, but requires less information from the registrants. Registrants still would be required to submit the facility's name, address, emergency contact information, name and address of the parent company, trade names, U.S. agent information (if a foreign facility), and the name of the owner, operator, or agent in charge of the facility, but would not be required to submit the general food product categories under § 170.3. Tables 26, 27, 28, 29, and 30 of this document provide a summary of the data for cost estimates under option 5 for domestic facilities, foreign facilities, and FDA, respectively.

Removing the product categories from the registration would decrease the frequency with which facilities have to update their registrations and reduce the amount of time required to register by 15 minutes. FDA requests comment on this estimate. FDA estimates that removing the product categories would reduce the percentage of facilities that have to update their registration from 20 percent each year to 10 percent. First year costs would be lower for foreign and domestic facilities due to facilities needing less time to fill out the form. Total first year domestic costs would be lowered from $13.6 to $12.3 million. Annual costs for domestic firms would be lowered from $3.4 to $2.3 million due to less frequent updates. Total first year foreign costs would be lowered from $319.6 to $318.3 million and total costs would be raised from $334.5 to $341.9 million.

TABLE 26.—NUMBER OF DOMESTIC FACILITIES COVERED UNDER OPTION 5

2000 CBP	103,125
1999 Nonemployer statistics	68,424
Mixed-type facilities that engage in farming	25,365
Retail processors	10,410
Total domestic	207,324

TABLE 27.—SUMMARY OF COSTS INCURRED BY DOMESTIC FACILITIES UNDER OPTION 5

Administrative worker wage (includes overhead)	25.1
Manager wage (includes overhead)	56.74
Percent with Internet access US	71%
Research time with Internet (hours)	1
Research time without Internet (hours)	2
Research cost with Internet	$3,695,000
Research cost without Internet	$3,018,000

TABLE 27.—SUMMARY OF COSTS INCURRED BY DOMESTIC FACILITIES UNDER OPTION 5—Continued

Administrative time for form (hours)	0.5
Manager time for form (hours)	0.25
Form costs	$5,543,000
Percent of businesses going out of business	10%
Percent of businesses entering	10%
Percent of businesses with changes	10%
Annual facility costs	$2,334,000
Total domestic costs	$12,256,000

TABLE 28.—NUMBER OF FOREIGN FACILITIES COVERED UNDER OPTION 5

Foreign holders and packagers	100,027
Foreign manufacturers/processors	125,450
Stops exporting	16%
Total facilities	205,405

TABLE 29.—SUMMARY OF COSTS INCURRED BY FOREIGN FACILITIES

Speaks English	16%
Has Internet access	31%
Has U.S. agent	10%

TABLE 29.—SUMMARY OF COSTS INCURRED BY FOREIGN FACILITIES—Continued

Cost of U.S. agent (annual)	$1,000
Hourly wage rate	$25
Time to find agent (hours)	5
Additional time language (hours)	5
Additional time Internet (hours)	5
First year agent cost	$67,340,000
Agent fee (annual cost)	$194,868,000

TABLE 29.—SUMMARY OF COSTS INCURRED BY FOREIGN FACILITIES—Continued

Administrative time (hours)	1
Additional time language (hours)	5
Additional time Internet (hours)	5
First year administrative costs	$44,418,929
Time to fill out form (hours)	0.75
Additional time language (hours)	1

TABLE 29.—SUMMARY OF COSTS INCURRED BY FOREIGN FACILITIES—Continued

Additional time Internet (hours)	1
Percent of businesses going out of business	10%
Percent of businesses entering	10%
Percent of businesses with changes	10%
First year form cost	$11,708,000
Total first year costs	$318,335,000
Total annual costs	$227,729,000

TABLE 30.—COSTS INCURRED BY FDA UNDER OPTION 5

FDA Costs	2003	2004	2005	2006	2007
Development/modification/enhancement	$8,200,000	$3,000,000	$3,300,000	$2,300,000	$2,300,000
Maintenance/steady state	$1,560,000	$3,500,000	$4,300,000	$4,300,000	$4,300,000
Number of FTEs	4	4	4	2	2
Cost per FTE	$110,588	$110,588	$110,588	$110,588	$110,588
Cost per paper submission	$10	$10	$10	$10	$10
Number of domestic paper submissions	60,124	18,037	18,037	18,037	18,037
Number of foreign paper submissions	22,677	6,803	6,803	6,803	6,803
Total number of domestic registrations in database	207,324	207,324	207,324	207,324	207,324
Total number of foreign registrations in database	205,405	205,405	205,405	205,405	205,405
Mailings to domestic facilities	$1	$1	$1	$1	$1
Mailings to foreign facilities	$1	$1	$1	$1	$1
Error rate for paper submissions	10%	10%	10%	10%	10%
Number of errors	8,280	2,484	2,484	2,484	2,484
Cost per error	$15	$15	$15	$15	$15
Total costs	$11,279,000	$7,294,000	$8,394,000	$7,173,000	$7,173,000
Discounted total costs	$11,279,000	$6,817,000	$7,332,000	$5,855,000	$5,472,000

6. Option Six: Require Registration of Domestic and Foreign Facilities That Manufacture/Process, Pack, or Hold Food That Sell Their Products in Interstate and Intrastate Commerce, Including Mixed-Type Facilities.

Mixed-type facilities that engage in farming are covered if they pack or hold food not grown or raised on that facility or manufacture/process food not for consumption on that facility. However, facilities of these types that manufacture/process food solely for direct sale to consumers from that same facility are exempt.

A mixed-type facility performs activities of a facility that is ordinarily required to register and activities of a facility that is ordinarily exempt, such as a farm or retail facility. Mixed-type facilities that are required to register differ under options 2 and 6. In option 2, mixed-type facilities that manufacture/process food for consumption offsite, where offsite includes both distribution directly to consumers and distribution to nonconsumers, must register. In option 6, facilities that manufacture/process food and distribute it directly to consumers would not be included in the registration requirement. Option 6 requires registration for mixed-type facilities that pack or hold food that was not grown or raised at that facility; these facilities are not included in the option 2 definition. These changes in coverage raise the total number of affected mixed-

type facilities from 25,365 to 30,497. Facilities that engage in the activities of a retail facility but also manufacture/process food and distribute it to nonconsumers are considered as manufacturers/processors in the count of facilities in this analysis. FDA requests comment on this categorization. Table 31 of this document shows the number of affected mixed-type facilities by category of product.

TABLE 31.—NUMBER OF AFFECTED MIXED-TYPE FACILITIES UNDER OPTION 6

Type	Number of Farms	Percent Mixed Use	Percent Mixed Use
Pig farms (feed mixing)	46,353	1.5	695
Cattle (feed mixing)	785,672	1	7,857
Poultry (feed mixing)	36,944	1	369
Other animal production (feed mixing)	110,580	1	1,106
Dairy	86,022	1.1	903
Grain, rice, and beans	462,877	1	4,629
Apples	10,872	1.5	163
Oranges	9,321	1.5	140
Peaches	14,459	1.5	217
Cherries	8,423	1.5	126
Pears	8,062	1.5	121
Other fruit	29,413	1.5	441
Nuts	14,500	2	290
Berries	6,807	1.5	102
Grapes	11,043	10.5	1,160
Olives	1,363	3.5	48
Vegetables and melons	31,030	0.5	155
Organic vegetables	6,206	50	3,103
Honey	7,688	50	3,844
Syrup	4,850	100	4,850
Herbs	1,776	10	178
Total			30,497

Tables 32, 33, 34, 35, and 36 of this document provide a summary of the data for cost estimates under option 6 for domestic facilities, foreign facilities, and FDA, respectively. The total number of affected domestic facilities under this option is 202,046. The total first year cost for domestic facilities is reduced from $13.6 to $13.2 million, annual cost is reduced from $3.4 to $3.2 million. Total first year cost is reduced from $344.5 to $344.1 million. The greater total cost for foreign facilities is primarily attributable to the costs associated with hiring and retaining a U.S. agent.

TABLE 32.—NUMBER OF DOMESTIC FACILITIES COVERED UNDER OPTION 6

2000 CBP	103,125
1999 Nonemployer statistics	68,424
Mixed-type facilities that engage in farming	30,497
Total domestic	202,046

TABLE 33.—SUMMARY OF COSTS INCURRED BY DOMESTIC FACILITIES UNDER OPTION 6

Administrative worker wage (includes overhead)	25.1
Manager wage (includes overhead)	56.74
Percent with Internet access US	71
Research time with Internet (hours)	1
Research time without Internet (hours)	2
Research cost with Internet	$3,601,000

TABLE 33.—SUMMARY OF COSTS INCURRED BY DOMESTIC FACILITIES UNDER OPTION 6—Continued

Research cost without Internet	$2,941,000
Administrative time for form (hours)	0.75
Manager time for form (hours)	0.25
Form costs	$6,670,000
Percent of businesses going out of business	10%
Percent of businesses entering	10%
Percent of businesses with changes	20%
Annual facility costs	$3,322,000
Total domestic costs	$13,212,000

TABLE 34.—NUMBER OF FOREIGN FACILITIES COVERED UNDER OPTION 6

Foreign holders and packagers	100,027
Foreign manufacturers/processors	125,450

TABLE 34.—NUMBER OF FOREIGN FACILITIES COVERED UNDER OPTION 6—Continued

Stops exporting	16%
Total facilities	205,405

TABLE 35.—SUMMARY OF COSTS INCURRED BY FOREIGN FACILITIES UNDER OPTION 6

Speaks English	16%
Has Internet access	31%
Has U.S. agent	10%
Cost of U.S. agent (annual)	$1,000
Hourly wage rate	$25
Time to find agent (hours)	5
Additional time language (hours)	5
Additional time Internet (hours)	5
First year agent cost	$67,340,000
Agent fee (annual cost)	$194,868,000
Administrative time (hours)	1

TABLE 35.—SUMMARY OF COSTS INCURRED BY FOREIGN FACILITIES UNDER OPTION 6—Continued

Additional time language (hours)	5
Additional time Internet (hours)	5
First year administrative costs	$44,418,929
Time to fill out form (hours)	1
Additional time language (hours)	1
Additional time Internet (hours)	1
Percent of businesses going out of business	10%
Percent of businesses entering	10%
Percent of businesses with changes	20%
First year form cost	$12,992,000
Total first year costs	$319,619,000
Total annual costs	$228,370,000

TABLE 36.—COSTS INCURRED BY FDA UNDER OPTION 6

FDA Costs	2003	2004	2005	2006	2007
Development/modification/enhancement	$8,200,000	$3,000,000	$3,300,000	$2,300,000	$2,300,000
Maintenance/steady state	$1,560,000	$3,500,000	$4,300,000	$4,300,000	$4,300,000
Number of FTEs	4	4	4	2	2
Cost per FTE	$110,588	$110,588	$110,588	$110,588	$110,588
Cost per paper submission	$10	$10	$10	$10	$10
Number of domestic paper submissions	58,593	23,437	23,437	23,437	23,437
Number of foreign paper submissions	22,677	9,071	9,071	9,071	9,071
Total number of domestic registrations in database	202,046	202,046	202,046	202,046	202,046
Total number of foreign registrations in database	205,405	205,405	205,405	205,405	205,405
Mailings to domestic facilities	$1	$1	$1	$1	$1
Mailings to foreign facilities	$1	$1	$1	$1	$1
Error rate for paper submissions	10%	10%	10%	10%	10%
Number of errors	5,860	2,345	2,345	2,345	2,345
Cost per error	$15	$15	$15	$15	$15
Total costs	$11,225,000	$7,376,000	$8,476,000	$7,255,000	$7,255,000
Discounted total costs	$11,225,000	$6,893,000	$7,403,000	$5,922,000	$5,535,000

7. Option Seven: Require Registration of Domestic and Foreign Facilities That Manufacture/Process, Pack, or Hold Food That Sell Their Products in Intrastate and Interstate Commerce, Including Mixed-Type Facilities, as Defined in Option 6. Permits the U.S. Agent to Register on Behalf of the Foreign Facility

Permitting the U.S. agent to register on behalf of the foreign facility would reduce the number of paper registrations significantly. Foreign facilities still would have to go through administrative steps to learn about the regulation and to find and hire a U.S. agent. However, foreign facilities now would have a third option for registering. In addition to electronic and paper registration by a representative at the facility, the foreign facility can authorize its U.S. agent to register the facility. FDA assumes that U.S. agents who register on behalf of foreign facilities will register electronically. Characteristics of foreign facilities, such as access to the Internet, fluency in English, and whether they are informed about the registration requirement before their product reaches the U.S. port, determine whether foreign facilities would be registered by themselves electronically, registered by mail, or registered by their U.S. agent.

FDA assumes that foreign facilities with Internet access would register directly via the Internet. Registration via the Internet would be the fastest, most reliable method for these facilities, and they would receive their confirmation of registration and facility registration number automatically.

Foreign facilities that do not have Internet access or representatives who read or write in English would register through their U.S. agent. The inability to read and write in English increases the cost for foreign facilities that register directly. U.S. agents operating in response to FDA registration requirements for other FDA-regulated products market themselves to certain regions of the world. FDA anticipates these agents would speak the language of the representative of the foreign facility, as well as English, and so could register in English for the facility.

Foreign facilities that do not have Internet access and do not learn of the registration requirements until their product reaches the U.S. border also are likely to register through their U.S. agent. For electronic registrations, the facility is considered registered once FDA enters the registration data into the registration system and the system generates a registration number. For paper registrations, the facility is considered registered when FDA sends the registration number to the facility. For electronic registrations, confirmation should happen almost instantly. The electronic submission would be automatically entered into the database, undergo consistency checks, and if the information is entered correctly, the confirmation of registration and the facility's registration number would be sent out electronically.

Paper submissions are subject to longer lag times at several points. First, the facility may have to mail or phone in a request for a registration form. Second, the facility may have to wait to receive the form. Third, the registration takes time to travel through the mail from the facility to FDA. Fourth, FDA would require more time to process paper submissions, because the information has to be entered manually into the system. Fifth, FDA has to mail out a copy of the registration as entered, the registration confirmation, and the registration number if the facility's information is complete and legible. Sixth, the registration confirmation has to travel through the mail to the facility. At this time, the facility would know it is registered and have its registration number.

Because time will be important to foreign facilities bringing products into the United States, FDA assumes that they will choose to be registered by their U.S. agent, because the registration process will be much faster. Facilities that do not have Internet access, that have representatives who can read and write in English, and learn about the registration requirements before exporting their product to the United States are most likely to register by a paper submission. These facilities already would have invested the time to learn about the registration requirements and thus are likely to have a hard copy of the form. If time were not a major consideration, a facility is likely to prefer to fill out the registration form onsite. FDA plans to conduct extensive outreach efforts to communicate the registration requirements to affected facilities both domestically and abroad, both at the proposed rule stage and at the final rule stage to minimize the number of facilities that find out about the requirements at the port. FDA does not have the information to estimate how many foreign facilities would not learn about the registration requirements until their goods are at the port. FDA instead estimates the number of foreign paper submissions to FDA as the percent of foreign facilities that do not have Internet access and whose managers are able to read and write in English. FDA requests comments on this assumption.

Under this option, U.S. agents would have a larger role than under other options. U.S. agents may charge a higher fee if they register for the facility. A higher U.S. agent fee is considered in the sensitivity analysis.

Port delays would be shorter under this option than under alternative options. Foreign facilities still would have delays associated with communication and finding a U.S. agent, but the process would be shortened by allowing the U.S. agent to register on behalf of the foreign facility. This would shorten the time that the product sits in storage and lower the loss of value of the product.

Tables 37, 38, 39, 40, and 41 of this document provide a summary of the data for cost estimates under option 7 for domestic facilities, foreign facilities, and FDA, respectively. The first year costs to foreign facilities would be reduced from $319.6 to $311.8 million, annual costs would be reduced from $228.4 to $227.6 million. Total costs for the first year would be reduced from $344.5 to $336.2 million.

TABLE 37.—NUMBER OF DOMESTIC FACILITIES COVERED UNDER OPTION 7

2000 CBP	103,125
1999 Nonemployer statistics	68,424
Mixed-type facilities that engage in farming	30,497
Total domestic	202,046

TABLE 38.—SUMMARY OF COSTS INCURRED BY DOMESTIC FACILITIES UNDER OPTION 7

Administrative worker wage (includes overhead)	25.1
Manager wage (includes overhead)	56.74
Percent with Internet access US	71%
Research time with Internet (hours)	1
Research time without Internet (hours)	2
Research cost with Internet	$3,601,000
Research cost without Internet	$2,941,000
Administrative time for form (hours)	0.75

TABLE 38.—SUMMARY OF COSTS INCURRED BY DOMESTIC FACILITIES UNDER OPTION 7—Continued

Manager time for form (hours)	0.25
Form costs	$6,670,000
Percent of businesses going out of business	10%
Percent of businesses entering	10%
Percent of businesses with changes	20%
Annual facility costs	$3,322,000
Total domestic costs	$13,212,000

TABLE 39.—NUMBER OF FOREIGN FACILITIES COVERED UNDER OPTION 7

Foreign holders and packagers	100,027
Foreign manufacturers/processors	125,450
Stops exporting	16%
Total facilities	205,405

TABLE 40.—SUMMARY OF COSTS INCURRED BY FOREIGN FACILITIES

Speaks English	16%
Has Internet access	31%
Has U.S. agent	10%
Cost of U.S. agent (annual)	$1,000
Hourly wage rate	$25
Time to find agent (hours)	5
Additional time language (hours)	5
Additional time Internet (hours)	5
First year agent cost	$67,340,000
Agent fee (annual cost)	$194,868,000
Administrative time (hours)	1
Additional time language (hours)	5
Additional time Internet (hours)	5
First year administrative costs	$44,418,929

TABLE 40.—SUMMARY OF COSTS INCURRED BY FOREIGN FACILITIES—Continued

Time to fill out form (hours)	1
Additional time language (hours)	0
Additional time Internet (hours)	0
Percent of businesses going out of business	10%
Percent of businesses entering	10%
Percent of businesses with changes	20%
First year form cost	$5,135,000
Total first year costs	$311,762,000
Total annual costs	$227,585,000

TABLE 41.—COSTS INCURRED BY FDA UNDER OPTION 7

FDA Costs	2003	2004	2005	2006	2007
Development/modification/enhancement	$8,200,000	$3,000,000	$3,300,000	$2,300,000	$2,300,000
Maintenance/steady state	$1,560,000	$3,500,000	$4,300,000	$4,300,000	$4,300,000
Number of FTEs	4	4	4	2	2
Cost per FTE	$110,588	$110,588	$110,588	$110,588	$110,588
Cost per paper submission	$10	$10	$10	$10	$10
Number of domestic paper submissions	58,593	23,437	23,437	23,437	23,437
Number of foreign paper submissions	22,677	9,071	9,071	9,071	9,071
Total number of domestic registrations in database	202,046	202,046	202,046	202,046	202,046
Total number of foreign registrations in database	205,405	205,405	205,405	205,405	205,405
Mailings to domestic facilities	$1	$1	$1	$1	$1
Mailings to foreign facilities	$1	$1	$1	$1	$1
Error rate for paper submissions	10%	10%	10%	10%	10%
Number of errors	5,860	2,345	2,345	2,345	2,345
Cost per error	$15	$15	$15	$15	$15
Total costs	$11,225,000	$7,376,000	$8,476,000	$7,255,000	$7,255,000
Discounted total costs	$11,225,000	$6,893,000	$7,403,000	$5,922,000	$5,535,000

8. Option Eight: Issue No New Regulation and Allow the Bioterrorism Act's Default Registration Requirements to Take Effect

The Bioterrorism Act requires facilities to register with FDA by December 12, 2003, even if FDA has not issued final regulations by this date. Failure to do so for both foreign and domestic facilities is a prohibited act, and FDA must hold food from unregistered foreign facilities at the port of entry until they are registered. Thus, facilities have an incentive to register with FDA. Failure to issue a final regulation would result in an unworkable, chaotic system. The Bioterrorism Act also requires facilities that register in the absence of a final rule to re-register with FDA as specified in the final rule once it is issued.

It is not possible to predict the costs or benefits of this option because the statute is not specific enough to predict how it would be implemented. It seems likely that many facilities will attempt to register, given the penalties for failure to register. However, if FDA receives all paper, non-standardized registrations, it will be extremely difficult for FDA to process the registrations and to use the information provided. It would also be a slow process for FDA to issue registration numbers.

9. Summary of Costs

Table 42 of this document presents a summary of costs for options 2 through 7 for domestic facilities, foreign facilities, and FDA. Costs in future years are discounted at 7 percent.

TABLE 42.—TOTAL COST OF OPTIONS 2 THROUGH 7 FOR DOMESTIC FACILITIES, FOREIGN FACILITIES, AND FDA.

	Option 2	Option 3	Option 4	Option 5	Option 6	Option 7
Domestic first year costs	$13,557,000	$7,038,000	$11,217,000	$12,256,000	$13,212,000	$13,212,000
Foreign first year costs	$319,619,000	$319,619,000	$319,619,000	$318,335,000	$319,619,000	$311,762,000
FDA first year costs	$11,279,000	$10,907,000	$11,145,000	$11,279,000	$11,225,000	$11,225,000
Total first year costs	$344,455,000	$337,564,000	$341,981,000	$341,870,000	$344,056,000	$336,199,000
Domestic second year costs	$3,186,000	$1,654,000	$2,636,000	$2,181,000	$3,105,000	$3,105,000
Foreign second year costs	$213,430,000	$213,430,000	$213,430,000	$212,831,000	$213,430,000	$212,696,000
FDA second year costs	$6,914,000	$6,769,000	$6,862,000	$6,817,000	$6,893,000	$6,893,000
Total second year costs	$223,530,000	$221,853,000	$222,928,000	$221,829,000	$223,428,000	$222,694,000
Domestic third year costs	$2,978,000	$1,546,000	$2,464,000	$2,039,000	$2,902,000	$2,902,000
Foreign third year costs	$199,467,000	$199,467,000	$199,467,000	$198,907,000	$199,467,000	$198,782,000
FDA third year costs	$7,422,000	$7,287,000	$7,374,000	$7,332,000	$7,403,000	$7,403,000
Total third year costs	$209,867,000	$208,300,000	$209,305,000	$208,278,000	$209,772,000	$209,087,000
Domestic fourth year costs	$2,783,000	$1,445,000	$2,303,000	$1,905,000	$2,712,000	$2,712,000
Foreign fourth year costs	$186,418,000	$186,418,000	$186,418,000	$185,895,000	$186,418,000	$185,777,000
FDA fourth year costs	$5,939,000	$5,814,000	$5,894,000	$5,855,000	$5,922,000	$5,922,000
Total fourth year costs	$195,140,000	$193,677,000	$194,615,000	$193,655,000	$195,052,000	$194,411,000

a. *Sensitivity to assumptions.* A number of assumptions in the analysis significantly affect the cost estimates. To understand how these assumptions affect the cost estimates, FDA re-estimates the total costs under alternative assumptions. FDA uses option 7, the proposed option, to compare across assumptions. Table 43 summarizes the results of the sensitivity analysis.

FDA looked at the number of mixed-type facilities. In option 6, FDA estimated that there are approximately 30,497 mixed-type facilities that manufacture/process food for distribution to nonconsumers or pack or

hold food received from off the facility based on data from the Census of Agriculture and information from CES (Ref. 7). Because there are over 2 million farms in the United States, small changes in assumptions about the percentage of farms that are mixed-type facilities would result in a large change in the total number of affected farms. If the total number of farms that are mixed-type facilities were 100,000, the total, first year, domestic costs increase from $13.2 to $17.8 million.

Another significant source of uncertainty is the amount of time it would take facility employees to read and understand the requirements and for foreign facilities to find a U.S. agent. To test the time assumptions, FDA estimated the costs assuming all the time estimates for administrative activities were doubled. This increases the cost estimates for domestic facilities from $13.2 to $19.8 million and increases the cost estimates for foreign facilities from $311.8 to $423.5 million.

Hiring and retaining a U.S. agent is a significant cost for foreign facilities. FDA tested how this affects total cost estimates by doubling the percent of foreign manufacturers that have U.S. agents from 10 percent to 20 percent. This lowers the first year cost for foreign facilities from $311.8 to $297.3 million.

Also subject to a great deal of uncertainty is the number of foreign manufacturers/processors who can read and write in English. Research on the topic shows widely ranging estimates of the number of English speakers in countries where English is not the primary language. Even in countries where English is a primary or secondary language, many inhabitants may not be fluent in English (Ref. 14). However, more than one individual may work in a facility in an appropriate position to fill out the registration form. This increases the probability that an individual with English skills sufficient to fill out the registration form may be available. FDA estimated that 16 percent of foreign facilities had employees that were fluent in English. To test our assumption about the percentage of foreign facilities with employees who are fluent in English, FDA looked at the alternate assumption that 32 percent of foreign facilities would have a worker with the capability to research and fill out the form in English. This change decreases the total cost to foreign facilities from $311.8 to $303.4 million.

FDA assumed that the number of foreign facilities that hold food products before exporting them to the United States is equal to the number of domestic brokers and consignees, because of the lack of data about foreign facilities holding and doing de minimis processing of food. To test this assumption, FDA looked at the costs if the number of foreign holders and de minimis processors is 160,000. Changing this assumption has a large effect on the foreign and total cost, increasing the foreign cost from $311.8 to $405.2 million and the total cost from $336.2 to $429.7 million.

FDA tested the effect of changing the annual U.S. agent fee. If the average U.S. agent fee is $1,500, instead of $1,000, the costs to foreign facilities will be increased from $311.8 to $409.2 million.

Finally, FDA tested the assumption that the foreign wage rate is the same as the domestic wage rate and re-estimated the costs for a foreign wage rate of $15 per hour. The total cost to foreign facilities was reduced from $311.8 to $265.0 million under this assumption.

TABLE 43.—SENSITIVITY ANALYSIS (RELATIVE TO OPTION 7)

First Year Costs	Total Domestic Cost (dollars)	Total Foreign Cost (dollars)	Total FDA Cost (dollars)	Total Cost (dollars)
Under current assumptions[1]	13,212,000	311,762,000	11,225,000	336,199,000
Percentage change from baseline	0%	0%	0%	0%
100,000 mixed-type facilities that engage in farming	17,756,000	311,762,000	11,484,000	341,002,000
Percentage change from baseline	34%	0%	2%	1%
Time costs are doubled	19,754,000	423,521,000	11,225,000	454,500,000
Percentage change from baseline	50%	36%	0%	35%
20 percent of foreign manufacturers have U.S. agents	13,212,000	297,257,000	11,225,000	$321,694,000
Percentage change from baseline	0%	-5%	0%	-4%
32 percent of foreign facilities are fluent in English	13,212,000	303,395,000	11,474,000	$328,081,000
Percentage change from baseline	0%	-3%	2%	-2%
160,000 foreign holders	13,212,000	405,168,000	11,304,000	429,684,000
Percentage change from baseline	0%	30%	1%	28%
U.S. agent fee $1,500	13,212,000	409,195,000	11,225,000	433,632,000
Percentage change from baseline	0%	31%	0%	29%
Foreign wage rate $15	13,212,000	265,004,000	11,225,000	289,441,000

TABLE 43.—SENSITIVITY ANALYSIS (RELATIVE TO OPTION 7)—Continued

First Year Costs	Total Domestic Cost (dollars)	Total Foreign Cost (dollars)	Total FDA Cost (dollars)	Total Cost (dollars)
Percentage change from baseline	0%	-15%	0%	-14%

[1] 30,497 mixed-type facilities, time costs under option 7, 10 percent of foreign manufacturers/processors have U.S. agents, 16 percent of foreign facilities are fluent in English, 100,027 foreign holders and packagers, and U.S. agent fee of $1,000.

b. *Qualitative costs.* For all of the options, except option one, there are a number of costs that FDA was unable to quantify. Loss of products from small exporters who would choose to stop exporting to the United States due to the increased cost of business may represent significant costs. Earlier in the analysis, we estimated that about 16 percent of foreign manufacturers export 10 or fewer line entries per year, and that these manufacturers would cease exporting to the United States. This could result in the elimination of some specialty products that market to very small niche markets in the United States, which would represent a loss to consumers who use these products.

The cost of port delays for facilities that do not learn of the requirements before exporting is another cost FDA was unable to quantify. FDA is unable to estimate how many foreign facilities would not learn about the new requirements before exporting. For this analysis, we estimate the expected cost of learning about registration as the number of hours a worker in a foreign facility needs to learn about the requirements. However, we expect that for some facilities, the cost of learning about the requirements would be much higher than the expected cost. Facilities that do not learn about the registration requirements before reaching the United States port would still have their shipment held at the port. The loss of value may be as low as the cost of storage, or as high as the value of the shipment, if perishable.

Under option 7, FDA expects this cost to be lower. If the U.S. agent registers the foreign facility, this will speed up the registration process and the product would be released into U.S. commerce faster.

FDA also was unable to quantify the costs incurred by FDA, trade associations, and others for outreach about the registration requirements. FDA will undertake outreach to notify domestic and foreign facilities about registration through public meetings, satellite downlink to five continents, and providing help desk support. FDA also anticipates that trade organizations and others, such as brokers, foreign governments, and U.S. businesses, will undertake to notify facilities of the registration requirements. FDA requests comments on the size and the basis for estimating these costs.

10. Benefits

These provisions would improve FDA's ability to respond to outbreaks from accidental and deliberate contamination from food and deter deliberate contamination. Based on historical evidence, a strike on the food supply has a very low probability, but would be a potentially high cost event. FDA lacks data to estimate the likelihood and resulting costs of a strike occurring. Without knowing the likelihood or cost of an event, we cannot quantitatively measure the reduction in probability of an event occurring or the possible reduction in cost of an event, associated with each regulatory option. Further hindering any quantification of benefits is the interactive effect of the other regulations that are being developed to implement title III of the Bioterrorism Act. Prior notice for imported shipments (section 307 of the Bioterrorism Act) would aid in the enforcement of registration, and in turn, registration would aid in the verification of prior notice submissions. Registration and recordkeeping also would work cooperatively.

These regulations also improve FDA's ability to prevent and respond to accidental foodborne outbreaks. FDA lacks data on the number of accidental outbreaks that will be prevented or shortened from this proposed rule, as well as from registration working in conjunction with the other regulations being developed to implement title III of the Bioterrorism Act. To understand possible costs of inadvertent foodborne illness and from an intentional strike on the food supply, FDA presents five outbreaks resulting from accidental and deliberate contamination, involving both domestic and imported foods in table 44. Registration will aid FDA in preventing and shortening foodborne outbreaks, but we do not know how frequently an outbreak would occur or the size and severity of the outbreak in the absence of registration. These foodborne outbreaks also do not represent the form a terrorist attack might undertake, but merely illustrate the public health costs of foodborne disasters. It is possible that an intentional attack on the food supply that sought to disrupt the food supply and sicken many U.S. citizens would be much larger. However, the probability of an attack occurring and the exact reduction in risk resulting from registration is unknown. Therefore, FDA is unable to quantify the benefits of registration arising from preventing or lessening the impact of a foodborne outbreak. Instead, we examine four mechanisms through which each regulatory option might act and analyze how each of the options affects these mechanisms.

TABLE 44.—SUMMARY OF FIVE FOODBORNE OUTBREAKS

Pathogen	Location and Year	Vehicle	Confirmed or Reported Cases	Estimated Number of Cases	Total Illness Cost (dollars)
Salmonella enteritidis	Minnesota 1994	Ice cream	150 cases; 30 hospitalized	29,100 in MN; 224,00 nationwide	3,187,744,000 to 5,629,792,000
Shigella sonnei	Michigan 1988	Tofu salad	3,175 cases	Not available	45,183,000 to 79,797,000

TABLE 44.—SUMMARY OF FIVE FOODBORNE OUTBREAKS—Continued

Pathogen	Location and Year	Vehicle	Confirmed or Reported Cases	Estimated Number of Cases	Total Illness Cost (dollars)
Outbreaks resulting from deliberate contamination					
Salmonella Typhimurium	Dalles, Oregon 1984	Salad bars	751 cases; 45 hospitalized	Not available	10,687,000 to 18,875,000
Shigella dysentreriae type 2	Texas 1996	Muffins and doughnuts	12 cases; 4 hospitalized	All cases identified	83,000
Outbreaks resulting from imported foods					
Cyclospora cayaetanensis	United States and Canada 1996	Raspberries (probably imported from Guatemala)	1465 cases identified, less than 20 hospitalized	Not available	3,941,000

a. *Salmonella enteritidis in ice cream.* In 1994, approximately 224,000 people were sickened by ice cream contaminated with Salmonella enteritidis. The source of the contamination appeared to be pasteurized pre-mix that had been contaminated during transport in tanker trailers that carried nonpasteurized eggs. There were 150 confirmed cases of salmonellosis associated with the outbreak in Minnesota. However, ice cream produced during the contamination period was distributed to 48 States. To calculate the total number of illnesses associated with the outbreak, researchers calculated an attack rate of 6.6 percent. This attack rate was extrapolated to the population that consumed the ice cream, giving a total number sickened of 224,000 (Ref. 19).

Salmonellosis most commonly causes gastrointestinal symptoms. Almost 91 percent of cases are mild and cause 1 to 3 days of illness with symptoms including diarrhea, abdominal cramps, and fever. Moderate cases, defined as cases that require a trip to a physician, account for 8 percent of the cases. These cases typically have a duration of 2 to 12 days. Severe cases require hospitalization and last 11 to 21 days. In addition to causing gastroenteritis, salmonellosis also can cause reactive arthritis in a small percentage of cases. Reactive arthritis may be short or long term and is characterized by joint pain. Just over 1 percent of cases develop short-term reactive arthritis and 2 percent of cases develop chronic, reactive arthritis.

FDA estimated the costs associated with salmonellosis, including medical treatment costs and pain and suffering. Table 45 of this document provides a summary of these estimates. Pain and suffering is measured by lost quality adjusted life days (QALDs). QALDs measure the loss of utility associated with an illness. A QALD is measured between zero and one, with one being a day in perfect health. The total loss of a quality adjusted life year (QALY), or the loss of a year of life is valued at $100,000, based on economic studies of how consumers value risks to life (Ref. 20). Thus, an entire lost QALD would be valued at $274 and fractions of QALDs are a fraction of the day's value. FDA presents two estimates of values of pain and suffering associated with arthritis, one based on physician estimates (Ref. 21) and another based on a regression analysis approach (Ref. 22). This gives a range of costs for the average case of salmonellosis between $14,231 and $25,133.

TABLE 45.—THE COST OF A TYPICAL CASE OF SALMONELLOSIS

Severity	Case Breakdown (percent)	Total QALDs Lost per Illness	Health Loss (dollars) per Case (Discounted)	Medical Costs (dollars) per Case (Discounted)	Weighted Dollar Loss per Case
Illness					
Mild	90.7	1.05	660	0	599
Moderate	8.1	3.68	2,310	283	209
Severe	1.2	9.99	6,266	9,250	188
Arthritis					
Regression approach					
Short-term	1.26	5.41	3,391	100	44
Long-term	2.40	2,613.12	452,554	7,322	11,048
Direct survey approach					
Short-term	1.26	10.81	6,778	100	87
Long-term	2.40	5,223.15	904,573	7,322	21,906
Death	0.04		5,000,000		2,143
Total expected loss per case					
Regression approach					14,231
Direct survey approach					25,133

To estimate the economic cost due to illness associated with this outbreak, FDA used the range for the average cost per case. For 224,000 people, this is a total cost of between $3,187,744,000 and $5,629,792,000 from this accidental food disaster.

b. *Shigella sonnei in tofu salad.* In 1988, a tofu salad at an outdoor music festival was contaminated with Shigella sonnei and sickened an estimated 3,175 people. Over 2,000 volunteer food handlers served communal meals at the festival (Ref. 23). Shigellosis causes similar symptoms and is of similar duration to salmonellosis. It also is associated with short term and chronic reactive arthritis; thus FDA assumed the average case of shigellosis has the same cost as salmonellosis. This gives a total cost of $45,183,000 to $79,797,000.

c. *Salmonella typhimirium in salad bars.* During September and October of 1984, two outbreaks of *Salmonella typhimirium* occurred in association with salad bars in restaurants in The Dalles, OR. At least 751 people were affected. Members of the local Rajneeshpuram commune intentionally caused the outbreak by spraying *Salmonella typhimirium* on the salad bars in local restaurants. Their apparent motivation was to influence a local election by decreasing voter turnout. Intentional contamination was not suspected immediately and no charges were brought until a year after the attacks (Ref. 24).

The 751 people affected primarily were identified through passive surveillance; thus the true number of people actually sickened is undoubtedly much higher. The Dalles is located on Interstate 84 in Oregon and is a frequent stop for travelers who were unlikely to be identified by passive or active surveillance for salmonellosis. However, since we do not have any estimates of the true size of the outbreak, we estimated the costs associated with known cases, recognizing this is an underestimate of the true cost of the outbreak. We use the cost estimates for salmonellosis as ranging from $14,231 to $25,133. This gives an estimated cost of known cases for the outbreak of $10,687,000 to $18,875,000.

d. *Shigella dysenteriae type 2 among laboratory workers.* Twelve people working in a laboratory who consumed muffins left in the laboratory break room contracted shigellosis. Affected workers had diarrhea, nausea, and abdominal discomfort. Investigators concluded that the outbreak likely was the result of deliberate contamination. All twelve affected workers were treated by, or consulted with, a physician. Nine affected workers went to the emergency room, four of whom were hospitalized (Ref. 25).

To estimate the cost of this outbreak, FDA assumed that the eight cases requiring consultation with a doctor, but not requiring hospitalization, had the same cost as a moderate case of salmonellosis. The four cases requiring hospitalization were estimated to have the same cost as a severe case of gastroenteritis resulting from salmonellosis. This gives a cost of $83,000 for illnesses associated with the event. Table 46 summarizes the costs associated with this outbreak.

TABLE 46.—SUMMARY OF COSTS FOR CASES OF SHIGELLOSIS

Severity	Number of cases	Cost per case (dollars)	Total cost (dollars)
Mild	0	0	0
Moderate	8	2,593	21,000
Severe	4	15,516	62,000
Grand total			83,000

e. *Cyclospora cayatanensis in imported raspberries.* In 1996, 1,465 cases of cyclosporiasis were linked to consumption of raspberries imported from Guatemala. Nine hundred and seventy eight of these cases were laboratory confirmed. No deaths were confirmed and less than 20 hospitalizations were reported (Ref. 26). Case control studies indicated that raspberries imported from Guatemala were the source of the illnesses. Fifty-five clusters of cases were reported in 20 states, two Canadian provinces, and the District of Columbia (Ref. 27).

Cyclosporiasis typically causes watery diarrhea, loss of appetite, weight loss, and fatigue. Less common symptoms include fever, chills, nausea, and headache. The median duration of illness associated with the outbreak was more than 14 days and the median duration of diarrheal illness was 10 days (Ref. 27). We estimated the cost of a mild case of cyclosporiasis as two and a half times higher than the cost of a mild case of gastroenteritis from salmonellosis due to the longer duration. The reports of cyclosporiasis outbreaks did not include information on the number of physician visits. We assumed that the percentage of total cases that result in physician visits would be larger than the corresponding percentage for salmonellosis illnesses, due to the longer duration of illnesses. We assumed, therefore, that 40 percent of those infected with cyclosporiasis visited a physician. Less than 20 hospitalizations were reported from the cyclosporiasis outbreak (Ref. 26). No deaths were confirmed. Table 47 summarizes the costs associated with this outbreak.

TABLE 47.—SUMMARY OF COSTS FOR CASES OF CYCLOSPORIASIS

Severity	Number of cases	Cost per case (dollars)	Total cost (dollars)
Mild	879	1,650	1,450,000
Moderate	586	3,748	2,196,000
Severe	19	15,516	295,000
Grand total			$3,941,000

f. *Mechanisms.* Requiring registration of manufacturers/processors, packers, and holders of food would aid in deterring and limiting the effects of foodborne outbreaks in four ways: (1) By requiring registration, persons who might intentionally contaminate the food supply would be deterred from entering the food production chain; (2) if FDA is aware of a specific food threat, then it would be able to inform the facilities potentially affected by the threat; (3) FDA would be able to deploy more efficiently its domestic compliance and regulatory resources and better able to identify facilities affected by future FDA actions (including possible regulations); and (4) FDA inspectors, using prior notice and registration, can better identify shipments for inspection.

Registering with FDA creates a paper trail, which would, even if the information in the registration were falsified, provide evidence that could link the registration to the false registrant. By creating this paper trail, persons who might intentionally contaminate the food supply and are considering starting a business in the food supply chain would be deterred by the creation of additional evidence that might be used against them. Persons who might intentionally contaminate the food supply that refuse to register, if foreign, would risk having their product held at the port and, if foreign or domestic, would be subject to criminal sanctions.

With correct contact information and product categories, FDA can quickly contact domestic and foreign facilities that may be targeted by a specific food threat. This quick communication would allow facilities to respond quickly to a threat and possibly limit the effect of a deliberate strike on the food supply, as well as public health emergencies due to accidental contamination.

A complete list of facilities in the food supply chain would aid FDA in scheduling inspections and undertaking compliance activities. Domestically, a complete list of facilities with correct contact information would aid inspectors in contacting facilities, and with product information would aid in identifying facilities for inspections. Because of the turnover in the food industry and the ratio of inspectors to food facilities, FDA never has had a complete list of foreign or domestic facilities that provide food for consumption in the United States. Also, a complete list of facilities would aid FDA in understanding which facilities would be affected by future FDA actions (including possible regulations), which would result in targeting communication and outreach to these facilities.

In conjunction with the prior notification requirements in 21 CFR part 1, subpart I, FDA can better identify imported food shipments for inspection at the port. The registration would identify the country of the manufacturer, which may not be the same as the country from which the product has been shipped. This information would assist FDA in identifying specific shipments to inspect, if we have information that a particular type of food or shipments from a particular country may be adulterated. Additionally, the database of registrants and products also would aid FDA in verifying that a product is correctly identified by where and by whom it was produced. For example, if the registration information identifies a facility as producing only dairy products and FDA receives a prior notice purportedly from the facility for the shipment indicating that the facility is shipping nuts, FDA can target that shipment for verification based on the discrepancy.

Because we cannot quantify the benefits, we cannot differentiate the benefits of each option in dollar terms. Instead, we look at how effectively each of the mechanisms would operate under each of the options relative to no regulation (option one).

i. Registration would deter persons who might intentionally contaminate the food supply from entering the food production chain.

Option 1: No impact.
Option 2: This option is the most comprehensive in the registration requirements and thus would have the largest impact on deterring persons who might intentionally contaminate the food supply.
Option 3: If FDA does not require intrastate facilities to register, then persons who might intentionally contaminate the food supply might be more likely to choose an intrastate facility for carrying out an attack on the food supply. However, intrastate facilities are more likely to be small, and generally do not distribute product widely or in large quantities. These are all characteristics that would make intrastate facilities less attractive to a person who would intentionally contaminate the food supply. Therefore, FDA expects that excluding intrastate facilities would reduce the function of the first mechanism, but not to a great extent.
Option 4: Option four still would cover many of the same facilities as option 2. However, if mixed-type facilities are not required to register, then these types of facilities may be more vulnerable. However, many state and local agencies have registration requirements for mixed-type facilities. Some of these facilities would be covered under these State or local agencies. Persons who might intentionally contaminate the food supply might be more likely to choose a mixed-type facility that is not required to register for carrying out an attack on the food supply.
Option 5: This option provides the same coverage of facilities as option 2. It does not require the inclusion of food product categories on the registration form. FDA anticipates that excluding product categories, by reducing the amount of information required by the registrant, would reduce slightly this regulation's ability to deter persons who might intentionally contaminate the food supply.
Option 6: This option provides coverage of the food production chain similar to option two, and so will have a similar effect in deterring persons who might intentionally contaminate the food supply from entering the food production chain.
Option 7: Option 7 would provide the same coverage of the food production chain as option 6, and so would be equally as effective in preventing persons who might intentionally contaminate the food supply from entering the food production chain.

ii. FDA would be better able to inform facilities if they are affected by a threat.

Option 1: No impact.
Option 2: This option is the most comprehensive in its coverage and thus would have the largest effect.
Option 3: Excluding intrastate facilities from registering would reduce FDA's ability to inform intrastate facilities of a specific threat. However, intrastate facilities are less likely to be the focus of a threat because of their small size and small distribution range.
Option 4: FDA's ability to inform facilities would be better than without a registration system, but excluding mixed-type facilities from registering would reduce FDA's ability to inform mixed-type facilities of a specific threat.
Option 5: FDA's ability to inform facilities would be better than without a registration system, but not including product categories on the registration form would significantly limit FDA's ability to inform facilities of threats related to specific foods. For example, if FDA receives credible information that persons who might intentionally contaminate the food supply have threatened foreign or domestic cheeses,

inclusion of product categories would allow FDA to communicate quickly with only those facilities impacted by this threat.
Option 6: This option provides coverage of food production chain similar to option 2, and so would have a similar effect in aiding FDA in contacting facilities in response to a threat.
Option 7: Option 7 would provide the same coverage of the food production chain as option 6, and thus would be as effective in aiding FDA in contacting facilities in response to a threat.

iii. FDA would be more efficient in deploying its enforcement resources and better able to identify facilities affected by future FDA actions (including possible regulations).

Option 1: No impact.
Option 2: This option is the most comprehensive in its coverage and thus would have the largest beneficial effect of the options.
Option 3: Because FDA exercises less regulatory authority over facilities that operate only in intrastate commerce, and thus seldom inspects these facilities, not requiring facilities that operate only in intrastate commerce to register will have a small effect on FDA's ability to deploy enforcement resources and identify facilities that are affected by future regulations.
Option 4: FDA shares enforcement responsibilities for a number of mixed-type facilities with other Federal, State, and local agencies. Therefore, option 4 would aid FDA in its enforcement activities, though not as fully as option 2. However, FDA would be less able to identify mixed-type facilities that are affected by future regulations for outreach and other activities.
Option 5: Excluding product categories would limit FDA's ability to use the registration database to deploy its enforcement resources. Although FDA still would be aided by the registration requirements under option 5, our efforts would not be as efficient as under option 2. Information from registration makes enforcement more efficient; thus, the more information provided, the greater the increase in efficiency.
Option 6: This option provides similar coverage of the food production chain as option 2 and so will have a similar effect in aiding FDA in deploying enforcement resources and identifying facilities that are affected by future regulations.
Option 7: Option 7 would provide the same coverage of the food production chain as option 6, and thus would be as effective in aiding FDA in deploying resources as option 6.

iv. Registration, in conjunction with prior notice, would give FDA information that will aid FDA in determining which shipments to inspect.

Option 1: No impact.

Option 2: This option is the most comprehensive in its coverage and thus would have the largest effect.

Option 3: FDA's ability to target imported foods would be unaffected by excluding intrastate facilities. Option 3 would be as effective as option 2.

Option 4: FDA's ability to target imported foods would be lessened slightly by excluding mixed-type facilities.

Option 5: Not including food product categories would limit FDA's ability to target specific products and country product combinations at the ports. Excluding food categories also would limit FDA's ability to evaluate as thoroughly as possible prior notifications of food imports we receive under 21 CFR part 1, subpart I. For example, if a facility registers as manufacturing/processing only canned goods and we receive a prior notice purportedly from this facility for fresh seafood, FDA would have critical information indicating that the shipment may warrant examination.

Option 6: this option provides similar coverage of the food production chain as option 2, and so would have a similar effect in aiding FDA in determining which shipments to inspect.

Option 7: Option 7 would be as effective as option 2 in aiding FDA in targeting import inspections.

V. Initial Regulatory Flexibility Analysis

A. Introduction

FDA has examined the economic implications of this proposed rule as required by the Regulatory Flexibility Act (5 U.S.C. 601–612). If a rule has a significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act requires agencies to analyze regulatory options that would lessen the economic effect of the rule on small entities. FDA is unsure whether or not this proposed rule would have a significant economic impact on a substantial number of small entities, but has analyzed various regulatory options to examine the impact on small entities. The following analysis, together with other relevant sections of this document, serves as the agency's initial regulatory flexibility analysis under the Regulatory Flexibility Act.

B. Economic Effect on Small Entities

Of the 202,046 domestic entities covered by option 7, the proposed option, 99 percent are small according to the definitions of the Small Business Administration. Because such a large percentage of the domestic entities are small, all options considered in the Benefit-Cost Analysis in section IV.A of this document are regulatory relief options. The expected burden for most small entities is low, between $58 and $83. However, over 200,000 entities are affected by this rule. If a small percentage of these entities incur costs significantly higher than the expected cost, then a substantial number of small entities may be significantly affected. FDA requests comment on the effect of this proposed rule on small entities.

C. Additional Flexibility Considered

Because of the requirements of the Bioterrorism Act, FDA is precluded from selecting some of the options that typically would be considered to lessen the economic effect of the rule on small entities, including granting an exemption to small entities. FDA tentatively concludes that it would be inconsistent with section 305 of the Bioterrorism Act to allow small entities more time to register, since the Bioterrorism Act established a registration deadline that applies to all covered facilities. Although the recordkeeping provision of the Bioterrorism Act directs FDA to take into account the size of a business when issuing implementing regulations, the registration provision contains no such language. Thus, it appears that Congress intended for all facilities to be subject to the deadline established in the Bioterrorism Act. Nonetheless, the agency recognizes that the registration requirement may cause an economic burden to some small businesses; therefore, we are seeking comment on whether it would be consistent with section 305 of the Bioterrorism Act for the agency to set staggered compliance dates that would give small businesses more time to comply.

However, the Bioterrorism Act does have considerable flexibility for small businesses built into the statute. First, retail facilities and farms are both exempt from registration. Many of these are small entities. Second, the economic impact on small entities is lessened by allowing entities to register either electronically or by mail. Small entities that do not have reasonable access to a computer or the Internet can submit their registration by mail.

VI. Unfunded Mandates

Title II of the Unfunded Mandates Reform Act of 1995 (Public Law 104–4) requires cost-benefit and other analyses before any rule making if the rule would include a ''Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any 1 year.'' The current inflation-adjusted statutory threshold is $112.3 million. Because the total cost to the domestic private sector would be $13 million, FDA has determined that this proposed rule does not constitute a significant rule under the Unfunded Mandates Reform Act.

VII. Small Business Regulatory Enforcement Fairness Act Major Rule

The Small Business Regulatory Enforcement Fairness Act (SBREFA) 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 United States-based enterprises to compete with foreign-based enterprises in domestic or export markets. In accordance with the Small Business Regulatory Enforcement Fairness Act, OMB has determined that this proposed rule, when final, will be a major rule for the purpose of congressional review.

VIII. Paperwork Reduction Act of 1995

This proposed rule contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). A description of these provisions is given in the following paragraphs with an estimate of the annual reporting burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information would have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Title: Registration of food facilities

Description: The Bioterrorism Act contains a provision requiring the Secretary to issue a regulation requiring that domestic and foreign facilities that manufacture/process, pack, or hold food intended for consumption in the United States register with FDA by December 12, 2003. The Bioterrorism Act defines foreign facilities as those that manufacture/process, pack, or hold food for export to the United States without further processing or packaging outside the United States before export. Information FDA proposes to require on the form includes the name and full address of the facility; emergency contact information, including an individual's name, title, office phone, home phone, cell phone (if available) and e-mail address; all trade names the facility uses; general food product categories under § 170.3; and a certification statement that includes the name, title/position, and phone number (e-mail address and fax number if available) of the registrant. Additionally, under the proposed rule, facilities would be encouraged to submit their preferred mailing address; type of activity conducted at the facility; food categories not included under § 170.3, but which are helpful to FDA for responding to an incident; type of storage, if the facility is solely a warehouse/holding facility, and approximate dates of operation if the facility's business is seasonal. Under the proposed rule, facilities would also be required to submit timely updates when any information on their registration form changes, including cancellation of the registration on a separate form.

Description of Respondents: Domestic facilities that manufacture/process, pack, or hold food for consumption in the United States are required to register. This includes facilities engaged in both interstate and intrastate commerce and mixed-type facilities as described in option 6. Foreign facilities are required to register if they are manufacture/process, pack, or hold food that is not further processed or packaged outside the United States. The number of respondents is shown in table 48.

TABLE 48.—RESPONDENTS

Foreign	205,405
Domestic	202,046
Total	407,451

Burden:

Hour Burden Estimate

FDA estimates that initially it would take an administrative worker with Internet access one hour to read and understand the registration requirements; this time is doubled to two hours of an administrative worker's time for those facilities without Internet access. Foreign facilities' workers would need one hour to read and understand the registration requirements, if they have access to the Internet and can read and write in English. An additional 5 hours would be needed if they do not have Internet access, and an additional 5 hours would be needed if they do not read or understand English. In subsequent years, facilities that enter the industry would have to register, facilities that close would have to notify FDA of their closure, and facilities that have changes in the registration information would have to provide updates to FDA. FDA estimates that annually 10 percent of covered facilities would close, 10 percent would open (Ref. 9) and 20 percent of registered facilities would have changes to their registration information.

Next, FDA estimates that filling out a registration form would take a total of 1 hour: 45 minutes of an administrative worker's time and 15 minutes of a owner, operator, or agent in charge's time to certify the registration before submitting the form to FDA. Foreign facilities' workers would need 1 hour to fill out the form, if they have access to the Internet and can read and write in English. An additional 1 hour would be needed if they do not have Internet access and an additional 1 hour would be needed if they do not read or understand English. Table 49 of this document shows the burden by domestic and foreign facilities, availability of the Internet, and fluency in English. For foreign facilities, FDA only had data on the percentage of facilities with Internet access and percentage fluent in English, but no information on what percentages of facilities are both fluent in English and have Internet access. To calculate the total number of burden hours, FDA assigned the correct percentages of fluent facilities and facilities with Internet access to the total number of

facilities, but for ease of computation excluded a category of facilities that are not fluent in English and have Internet access. FDA requests comments on the number of facilities not fluent in English and without Internet access.

TABLE 49.—ESTIMATED ANNUAL REPORTING BURDEN—FIRST YEAR[1]

21 CFR Part	FDA Form Number	Number of Respondents	Annual Frequency per Respondent	Total Annual Responses	Hours per Response	Total Hours
1.241(a)[2]	FDA 3537	143,453	1	143,453	2	286,906
1.241(b)[3]	FDA 3537	58,593	1	58,593	3	175,779
1.241(a)[4]	FDA 3537	32,864	1	32,864	2	65,728
1.241(b)[5]	FDA 3537	30,811	1	30,811	7	215,677
1.241(b)[6]	FDA 3537	141,730	1	141,730	12	1,700,760
Total hours						2,444,850

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Domestic facilities with Internet access
[3] Domestic facilities without Internet access
[4] Foreign facilities with Internet access and fluent in English
[5] Foreign facilities without Internet access and fluent in English
[6] Foreign facilities without Internet access and not fluent in English

In the following years, new facilities will have to register with FDA. These new facilities will bear the same burden to register that facilities incurred in the first year. Based on estimates by SBA that 10 percent of all businesses are new (Ref. 8), FDA estimates that the number of new facilities each year will be equal to 10 percent of the total number of facilities. Also, facilities that go out of business will have to notify FDA to cancel their registration. FDA estimates that 10 percent of the total number of facilities will go out of business each year, also based on SBA statistics. Facilities exiting the business will have to send FDA a cancellation of their registration. FDA estimates that it will take these facilities approximately 1 hour to locate the correct form, enter their information, and send it to FDA. Finally, facilities that have a material change of information submitted in their registration will have to notify FDA of the new information. FDA estimates 20 percent of facilities will have a material change in the information submitted in their registration each year. It will take these facilities approximately 1 hour to locate the correct form, enter their information, and send it to FDA. Table 50 presents an estimate of the burden hours for new facilities, and updates and cancellations for existing facilities in future years.

TABLE 50.—ESTIMATED ANNUAL REPORTING BURDEN—SUBSEQUENT YEARS[1]

21 CFR Part 1	FDA Form Number	Number of Respondents	Annual Frequency per Respondent	Total Annual Responses	Hours per Response	Total Hours
New facilities						
1.241(a)[2]	FDA 3537	14,345	1	14,345	2	28,690
1.241(b)[3]	FDA 3537	5,859	1	5,859	3	17,577
1.241(a)[4]	FDA 3537	3,286	1	3,286	2	6,572
1.241(b)[5]	FDA 3537	3,081	1	3,081	7	21,567
1.241(b)[6]	FDA 3537	14,173	1	14,173	12	170,076
Previously registered facilities						
1.244(a)[2]	FDA 3537/3537a	43,036	1	43,036	1	43,036
1.244(b)[3]	FDA 3537/3537a	17,578	1	17,578	1	17,578
1.244(a)[4]	FDA 3537/3537a	9,859	1	9,859	1	9,859
1.244(b)[5]	FDA 3537/3537a	9,243	1	9,243	1	9,243

TABLE 50.—ESTIMATED ANNUAL REPORTING BURDEN—SUBSEQUENT YEARS[1]—Continued

21 CFR Part 1	FDA Form Number	Number of Respondents	Annual Frequency per Respondent	Total Annual Responses	Hours per Response	Total Hours
1.244(b)[6]	FDA 3537/3537a	42,519	1	42,519	1	42,519
Grand total						366,717

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Domestic facilities with Internet access
[3] Domestic facilities without Internet access
[4] Foreign facilities with Internet access and fluent in English
[5] Foreign facilities without Internet access and fluent in English
[6] Foreign facilities without Internet access and not fluent in English

In compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)), the agency has submitted the information collection provisions of this proposed rule to OMB for review. Interested persons are requested to send comments regarding information collection to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Stuart Shapiro, FDA Desk Officer.

IX. Analysis of Environmental Impact

The agency has carefully considered the potential environmental effects of this action. FDA has concluded under 21 CFR 25.30(h) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

X. Federalism

FDA has analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the proposed rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the agency tentatively concludes that the proposed rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement has not been prepared.

XI. Comments

Interested persons may submit to the Dockets Management Branch (see **ADDRESSES**) written or electronic comments regarding this document. Two copies of any mailed comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. FDA cannot be responsible for addressing comments submitted to the wrong docket or that do not contain a docket number. Received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

FDA notes that the comment period for this document is shorter than the 75-day period that the agency customarily provides for proposed rules that are technical or sanitary or phytosanitary (SPS) measures. FDA believes that a 60-day comment period is appropriate in this instance. Executive Order 12889, ''Implementation of the North American Free Trade Agreement'' (58 FR 69681, December 30, 1993), states that any agency subject to the Administrative Procedure Act must provide a 75-day comment period for any proposed Federal technical regulation or any Federal SPS measure of general application. Executive Order 12889 provides an exception to the 75-day comment period where the United States considers a technical regulation or SPS measures of general application necessary to address an urgent problem related to the protection of human, plant, or animal health or sanitary or phytosanitary protection. FDA has concluded that this proposed rule is subject to the exception in Executive Order 12889.

The Bioterrorism Act states that it is intended ''[t]o improve the ability of the United States to prevent, prepare for, and respond to bioterrorism and other public health emergencies.'' In order to meet these objectives, section 305 of the Bioterrorism Act requires FDA to propose and issue final regulations requiring the registration of food facilities within 18 months of the Bioterrorism Act's enactment, which is by December 12, 2003. Section 305 of the Bioterrorism Act also provides that if FDA does not issue final regulations by this date, facilities still must register with FDA by December 12, 2003, subject to compliance with the final regulations when the final regulations are made effective. This expedited timeframe reflects the urgency of the U.S. Government's need to prepare to respond to bioterrorism and other food-related emergencies. In addition, section 801 of SBREFA (5 U.S.C. 801), states that a major final rule may not take effect until 60 days after the agency has published the rule and submitted it to Congress for review. A major rule for this purpose is defined in 5 U.S.C. 804 as one that the Administrator of the Office of Information and Regulatory Affairs of OMB has determined has resulted in or is likely to result in: (a) An annual effect on the economy of $100 million or more; or (b) a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or (c) significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of U.S.-based enterprises to compete with foreign-based enterprises in domestic or export markets.

OMB has determined that this proposed rule, when finalized, will be a major rule. Accordingly, FDA must publish the final registration rule no later than October 12, 2003, for it to be effective by the statutory deadline of December 12, 2003. For these reasons, FDA has concluded that the urgency of this matter is sufficient justification for shortening the public comment period for this proposal to 60 days, consistent with Executive Order 12889.

FDA will not consider any comments submitted after the 60-day comment period closes and does not intend to grant any requests for extension of the comment period due to the Bioterrorism Act's requirement to have a final regulation in effect by December 12, 2003, which requires publication on or before October 12, 2003.

XII. References

The following references have been placed on display 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. FDA has verified the Web site addresses in this document, but is not responsible for subsequent changes to the Web sites after this document publishes in the **Federal Register**.

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List of Subjects in 21 CFR Part 1

Cosmetics, Drugs, Exports, Food labeling, Imports, Labeling, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 1 be amended as follows:

PART 1—GENERAL ENFORCEMENT REGULATIONS

1. The authority citation for 21 CFR part 1 is revised to read as follows:

Authority: 15 U.S.C. 1453, 1454, 1455; 21 U.S.C. 304, 321, 331, 334, 343, 350c, 350d, 352, 355, 360b, 362, 371, 374, 381, 382, 393; 42 U.S.C. 216, 241, 243, 262, 264.

2. Subpart H is added to part 1 to read as follows (subparts F and G are reserved):

Subparts F–G [Reserved]

Subpart H—Registration of Food Facilities

General Provisions

Sec.

1.225 Who must register under this subpart?
1.226 Who is exempt from this subpart?
1.227 What definitions apply to this subpart?

Procedures for Registration of Food Facilities

1.230 When must you register?
1.231 How and where do you register?
1.232 What information is required in the registration?
1.233 What optional items are included in the registration form?
1.234 How and when do you update your registration information?

Additional Provisions

1.240 What other registration requirements apply?
1.241 What happens if you fail to register?
1.242 What does assignment of a registration number mean?
1.243 Is food registration information available to the public?

General Provisions

§ 1.225 Who must register under this subpart?

(a) You must register under this subpart if you are the owner, operator, or agent in charge of either a domestic or foreign facility, as defined in this subpart, and your facility is engaged in the manufacturing/processing, packing, or holding of food for consumption in the United States, unless you qualify for one of the exemptions in § 1.226.

(b) An owner, operator, or agent in charge of a domestic facility must register whether or not the food from the facility enters interstate commerce.

(c) An owner, operator, or agent in charge of a foreign facility must register the facility. A foreign facility may designate its U.S. agent as its agent in charge for purposes of registering the facility.

§ 1.226 Who is exempt from this subpart?

This subpart does not apply to the following facilities:

(a) Foreign facilities, if food from such facilities undergoes further manufacturing/processing (including packaging) by another foreign facility outside the United States. This exemption does not apply to a facility if the further manufacturing/processing (including packaging) conducted by the subsequent facility consists of adding labeling or any similar activity of a de minimis nature;

(b) Farms;

(c) Retail facilities;

(d) Restaurants;

(e) Nonprofit food facilities in which food is prepared for, or served directly to, the consumer;

(f) Fishing vessels, including those that not only harvest and transport fish but also engage in practices such as heading, eviscerating, or freezing

intended solely to prepare fish for holding on board a harvest vessel. However, those fishing vessels otherwise engaged in processing fish, which for purposes of this section means handling, storing, preparing, heading, eviscerating, shucking, freezing, changing into different market forms, manufacturing, preserving, packing, labeling, dockside unloading, or holding are subject to all of the regulations in this subpart; and

(g) Facilities that are regulated exclusively, throughout the entire facility, by the U.S. Department of Agriculture under the Federal Meat Inspection Act (21 U.S.C. 601 *et seq.*), the Poultry Products Inspection Act (21 U.S.C. 451 *et seq.*), or the Egg Products Inspection Act (21 U.S.C. 1031 *et seq.*).

§ 1.227 What definitions apply to this subpart?

(a) *The act* means the Federal Food, Drug, and Cosmetic Act.

(b) The definitions of terms in section 201 of the act (21 U.S.C. 321) apply to such terms when used in this subpart.

(c) In addition, for the purposes of this subpart:

(1) *Calendar day* means every day shown on the calendar.

(2) *Facility* means any establishment, structure or structures under one management at one general physical location or, in the case of a mobile facility traveling to multiple locations, that manufactures/processes, packs, or holds food for consumption in the United States. Individual homes are not facilities if the food that is manufactured/processed, packed, or held in the home does not enter commerce. A facility may consist of one or more contiguous structures. A single building may house distinct facilities if they are under separate management.

(i) *Domestic facility* means any facility located in any State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico.

(ii) *Foreign facility* means a facility other than a domestic facility that manufactures/processes, packs, or holds food for consumption in the United States.

(3) *Farm* means a facility in one general physical location devoted to the growing of crops for food, the raising of animals for food (including seafood), or both. The term ''farm'' includes:

(i) Facilities that pack or hold food, provided that all food used in such activities is grown or raised on that farm or is consumed on that farm; and

(ii) Facilities that manufacture/process food, provided that all food used in such activities is consumed on that farm or another farm under the same ownership.

(4) *Food* has the meaning given in section 201(f) of the act. Examples of food include, but are not limited to, fruits, vegetables, fish, dairy products, eggs, raw agricultural commodities for use as food or components of food, animal feed, including pet food, food and feed ingredients and additives, including substances that migrate into food from food packaging and other articles that contact food, dietary supplements and dietary ingredients; infant formula, beverages, including alcoholic beverages and bottled water, live food animals, bakery goods, snack foods, candy, and canned foods.

(5) *Holding* means storage of food. Holding facilities include, but are not limited to, warehouses, cold storage facilities, storage silos, grain elevators, or liquid storage tanks.

(6) *Manufacturing/processing* means making food from one or more ingredients, or synthesizing, preparing, treating, modifying or manipulating food, including food crops or ingredients. Examples include, but are not limited to: Cutting, peeling, trimming, washing, waxing, eviscerating, rendering, cooking, baking, freezing, cooling, pasteurizing, homogenizing, mixing, formulating, bottling, milling, grinding, extracting juice, distilling, labeling, or packaging.

(7) *Nonprofit food facility* means a charitable entity that prepares, serves, or otherwise provides food to the public. The term includes, but is not limited to, food banks, soup kitchens, and nonprofit food delivery services. To qualify as a nonprofit food facility, the entity must be exempt from paying federal income tax under the U.S. Internal Revenue Code.

(8) *Packing* means placing, putting, or repacking food into different containers without making any change to the form of the food.

(9) *Port of entry* means the water, air, or land port at which the article of food is imported or offered for import into the United States, i.e., the port where food first arrives in the United States. This port may be different than the port where the article of food is entered for U.S. Customs Service purposes.

(10) *Restaurant* means a facility that prepares and sells food directly to consumers for immediate consumption. Restaurants include, but are not limited to, cafeterias, lunchrooms, cafes, bistros, fast food establishments, food stands, saloons, taverns, bars, lounges, catering facilities, hospital kitchens, day care kitchens, and nursing home kitchens. Facilities that provide food to interstate conveyances, rather than directly to consumers, are not restaurants.

(11) *Retail facility* means a facility that sells food products directly to consumers only. The term includes, but is not limited to, grocery and convenience stores, vending machine locations, and commissaries. The term includes facilities that not only sell food directly to consumers, but that also manufacture/process food in that facility solely for direct sale to consumers from that same facility.

(12) *U.S. agent* means a person residing or maintaining a place of business in the United States whom a foreign facility designates as its agent. A U.S. agent cannot be in the form of a mailbox, answering machine, or service, or other place where an individual acting as the foreign facility's agent is not physically present. The U.S. agent acts as a communications link between FDA and the facility. FDA will treat representations provided by the U.S. agent as those of the foreign facility, and consider information provided to the U.S. agent as the equivalent of providing the same information or documents to the foreign food facility.

(13) *You* or *registrant* means the owner, operator, or agent in charge of a facility that manufactures/processes, packs, or holds food for consumption in the United States.

Procedures for Registration of Food Facilities

§ 1.230 When must you register?

The owner, operator, or agent in charge of a facility that manufactures/processes, holds, or packs food for consumption in the United States must be registered no later than December 12, 2003. Facilities that begin to manufacture/process, pack, or hold food for consumption in the United States on or after December 12, 2003, must be registered before they begin such activities.

§ 1.231 How and where do you register?

(a) Electronic registration: To register electronically, you must register at [a Web site that will be provided in the final rule], which will be available for registration 24 hours a day, 7 days a week. This Web site will be available wherever the Internet is accessible, including libraries, copy centers, schools, and Internet cafes, as well as a foreign facility's U.S. agent if the facility makes such arrangements. FDA strongly encourages electronic registration for the benefit of both FDA and the registrant. Once you complete your registration, FDA will provide you with an automatic electronic confirmation of

registration and a permanent registration number. You will be considered registered once FDA electronically transmits your confirmation and registration number unless notified otherwise.

(b) Registration by mail: (1) If you do not have reasonable access to the Internet through any of the methods provided under paragraph (a) of this section, you must register by obtaining a copy of the registration from (Office name or mail code), the Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, or by phone at [toll-free number that will be provided in the final rule].

(2) When you receive the form in the mail, you must fill it out completely and legibly and mail it to the address in paragraph (b) of this section.

(3) If any required information on the form is incomplete or illegible when FDA receives it, FDA will send the form back to you for completion, provided that your mailing address is legible and valid.

(4) FDA will enter completed registration submissions into the system as soon as practicable, in the order received.

(5) FDA will then mail to the mailing address shown on the registration form a copy of the registration as entered, confirmation of registration, and your registration number.

(6) If any information you previously submitted is incorrect as entered into the system, you must update your registration as specified in § 1.234.

(7) You will be considered registered once FDA enters your registration data into the registration system and the system generates a registration number.

(c) No registration fee is required.

(d) You must submit all registration information in the English language.

§ 1.232 What information is required in the registration?

Each registrant must submit the following information through either of the methods described in § 1.231:

(a) The name, full address, phone number, fax number, and e-mail address of the facility;

(b) The name and address of the parent company, if the facility is a subsidiary of the parent company;

(c) Emergency contact information, including an individual's name, title, office phone, home phone, cell phone (if available), and e-mail address (if available);

(d) All trade names the facility uses;

(e) Product categories as identified in § 170.3 of this chapter;

(f) For a foreign facility, the name, address, phone number, fax number (if available), and e-mail address (if available) of its U.S. agent; and

(g) A statement certifying that the information submitted is true and accurate, and that the person submitting the registration is authorized by the facility to register on its behalf. The statement requires the name of the person registering the facility. This statement also requires the phone number, e-mail address (if available), and fax number (if available) of the person submitting the registration.

§ 1.233 What optional items are included in the registration form?

FDA encourages, but does not require, you to submit the following optional items in your registration. These data will enable FDA to communicate more quickly with facilities that may be the target of a terrorist threat or attack, or otherwise affected by, an outbreak of foodborne illness. This information includes:

(a) Preferred mailing address, if different from that of the facility;

(b) Type of activity conducted at the facility (e.g., manufacturing/processing or holding);

(c) Food categories not included under § 170.3 of this chapter, but which are helpful to FDA for responding to an incident (e.g., infant formula, dietary supplements, and food for animal consumption);

(d) Type of storage, if the facility is solely a holding facility;

(e) A food product category of ''most/all food product categories'', if the facility manufactures/processes, packs, or holds foods in most or all of the categories under § 170.3 of this chapter; and

(f) Approximate dates of operation, if the facility's business is seasonal.

§ 1.234 How and when do you update your registration information?

(a) The owner, operator, or agent in charge must submit an update to the registration within 30 calendar days of any change to any of the information previously submitted, including, but not limited to, the name of the owner, operator, or agent in charge of a facility.

(b) A facility canceling its registration must do so on the cancellation of registration form.

(c) The cancellation of a facility's registration must include the following information:

(1) The facility's registration number;

(2) Whether the facility is domestic or foreign;

(3) The facility name and address;

(4) The name, address, and e-mail address (if available) of the individual submitting the cancellation; and

(5) A statement in which the individual submitting the cancellation will certify that the information submitted is true and accurate and the submitter is authorized by the facility to cancel its registration.

Additional Provisions

§ 1.240 What other registration requirements apply?

In addition to these regulations, you must comply with the registration regulations found in part 108 of this chapter, related to emergency permit control, and any other registration requirements that apply to the facility.

§ 1.241 What happens if you fail to register?

(a) Failure of a domestic or foreign facility to register in accordance with this regulation is a prohibited act under section 301 of the act (21 U.S.C. 331).

(b) Any person who imports or offers for import an article of food without complying with the requirements of section 801(l) of the act (21 U.S.C. 381(l)) as set out in this subpart, or otherwise violates any requirement under section 801(l) of the act, or any person who causes such an act, commits a prohibited act within the meaning of section 301(dd) of the act.

(c) Under section 302 of the act (21 U.S.C. 332), the United States can bring a civil action in Federal court to enjoin persons who commit prohibited acts. Under section 303 of the act (21 U.S.C. 333), the United States can bring a criminal action in Federal court to prosecute persons who commit prohibited acts. Under section 306 of the act (21 U.S.C. 335a), FDA can seek debarment of any person who has been convicted of a felony relating to importation of food into the United States.

(d) If an article of food is imported or offered for import and a foreign facility that manufactured/processed, packed, or held that food has not registered in accordance with this subpart, the food must be held at the port of entry unless FDA directs its removal to a secure facility in accordance with paragraph (e) of this section.

(e) Under paragraph (d) of this section, if FDA determines that removal to a secure facility is appropriate (e.g., due to a concern with the security of the article of food or due to space limitations in the port of entry), FDA may direct that the article of food be removed to a bonded warehouse, container freight station, centralized examination station, or another appropriate secure facility approved by FDA.

(f) Under paragraph (d) of this section, the owner, purchaser, importer or consignee must arrange for storage of the article of food in an FDA-designated secure facility and must promptly notify FDA of the location. Any movement of the article to the facility must be accomplished under bond. Transportation and storage expenses shall be borne by the owner, purchaser, importer, or consignee.

(g)(1) Under paragraph (d) of this section, the article of food must be held at the port of entry or in the secure facility until the owner, operator, or agent in charge of the foreign facility has submitted its registration information to FDA, FDA has registered the facility in accordance with § 1.231, and FDA has notified the U.S. Customs Service and the person who submitted the registration that the article of food no longer is subject to a hold under section 801(l) of the act.

(2) Under paragraph (d) of this section, notwithstanding section 801(b) of the act (21 U.S.C. 381(b)), while any article of food is held at its port of entry or in a secure facility under section 801(l) of the act, it may not be delivered to any of its importers, owners, or consignees.

(h) Under paragraph (d) of this section, a determination that an article of food is no longer subject to hold under section 801(l) of the act is different than, and may come before, determinations of admissibility under other provisions of the act or other U.S. laws. A determination that an article of food is no longer subject to hold under section 801(l) does not mean that it will be granted admission under other provisions of the act or other U.S. laws.

§ 1.242 What does assignment of a registration number mean?

Assignment of a registration number to a facility means that the facility is registered with FDA. Assignment of a registration number does not in any way denote FDA's approval or endorsement of a facility or its products.

§ 1.243 Is food registration information available to the public?

(a) Registration forms submitted under this subpart, and any information contained in those forms that would disclose the identity or location of a specific registered person, is not subject to disclosure under 5 U.S.C. 552 (the Freedom of Information Act).

(b) Paragraph (a) does not apply to any information obtained by other means or that has previously been disclosed to the public as defined in § 20.81 of this chapter.

Dated: January 27, 2003.

Tommy G. Thompson,

Secretary of Health and Human Services.

Dated: January 27, 2003.

Kenneth W. Dam,

Acting Secretary of the Treasury.

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

BILLING CODE 4160–01–C

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DHHS/FDA - DRAFT FOOD FACILITY REGISTRATION FORM

Date: _____ (MONTH/DAY/YEAR)

Section 1 - TYPE OF REGISTRATION

1a. ❑ **DOMESTIC REGISTRATION** ❑ **FOREIGN REGISTRATION**

1b. ❑ **INITIAL REGISTRATION**

❑ **UPDATE OF REGISTRATION INFORMATION**
Provide the facility registration number: _____

Check all that apply below and further identify changes in the applicable sections.

❑ **Facility Name/Address Change**	❑ **Seasonal Facility Dates of Operation Change**
❑ **Preferred Mailing Address Change**	❑ **Establishment Type Change**
❑ **Parent Company Change**	❑ **Warehouse Storage Type Change**
❑ **Emergency Contact Change**	❑ **Human Food Product Category Change**
❑ **Trade Name Change**	❑ **Animal Food Product Category Change**
❑ **United States Agent Change - Foreign Countries only**	❑ **Owner, Operator, or Agent in Charge Change**

Section 2 - FACILITY NAME / ADDRESS INFORMATION

FACILITY NAME:	
FACILITY STREET ADDRESS:	
CITY:	STATE:
ZIP CODE (POSTAL CODE):	PROVINCE/TERRITORY:
COUNTRY:	PHONE NUMBER (If a foreign facility, include Area & Country Codes):
FAX NUMBER (If available; if a foreign facility, include Area & Country Codes):	E-MAIL ADDRESS (if available):

Section 3 - OPTIONAL: PREFERRED MAILING ADDRESS INFORMATION
(only complete this section if different from Section 2, Facility Name/Address Information)

NAME:	
ADDRESS:	
CITY:	STATE:
ZIP CODE (POSTAL CODE):	PROVINCE/TERRITORY:
COUNTRY:	PHONE NUMBER (If a foreign facility, include Area & Country Codes):
FAX NUMBER (If available; if a foreign facility, include Area & Country Codes):	E-MAIL ADDRESS:

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Section 4 - PARENT COMPANY NAME / ADDRESS INFORMATION (IF APPLICABLE)	
NAME OF PARENT COMPANY:	
STREET ADDRESS OF PARENT COMPANY:	
CITY:	STATE:
ZIP CODE (POSTAL CODE):	PROVINCE/TERRITORY:
COUNTRY:	PHONE NUMBER (If a foreign facility, include Area & Country Codes):
FAX NUMBER (If available; if a foreign facility, include Area & Country Codes):	E-MAIL ADDRESS (if available):
Section 5 - FACILITY EMERGENCY CONTACT INFORMATION	
INDIVIDUAL'S NAME:	
TITLE:	OFFICE PHONE (If a foreign facility, include Area & Country Codes):
HOME PHONE (If a foreign facility, include Area & Country Codes):	CELL PHONE (if available; if a foreign facility, include Area & Country Codes):
E-MAIL ADDRESS (if available):	
Section 6 - TRADE NAMES (IF THIS FACILITY USES TRADE NAMES OTHER THAN THAT LISTED IN SECTION 2 ABOVE, LIST THEM BELOW (E.G., "ALSO DOING BUSINESS AS," "FACILITY ALSO KNOWN AS"):	
ALTERNATE TRADE NAME #1:	
ALTERNATE TRADE NAME #2:	
Section 7 - UNITED STATES AGENT (TO BE COMPLETED BY FACILITIES LOCATED OUTSIDE ANY STATE OR TERRITORY OF THE UNITED STATES, THE DISTRICT OF COLUMBIA, OR THE COMMONWEALTH OF PUERTO RICO.)	
NAME OF UNITED STATES AGENT:	
TITLE:	
ADDRESS:	
CITY:	STATE:
ZIP CODE:	COUNTRY:
PHONE NUMBER (include Area Code):	
FAX NUMBER (if available; include Area Code):	
E-MAIL ADDRESS (if available):	

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Section 8 - OPTIONAL: SEASONAL FACILITY DATES OF OPERATION

(GIVE THE APPROXIMATE DATES THAT YOUR FACILITY IS OPEN FOR BUSINESS, IF ITS OPERATIONS ARE ON A SEASONAL BASIS)

DATES OF OPERATION:

Section 9 - OPTIONAL: ESTABLISHMENT TYPES

(CHECK **ALL** TYPES OF OPERATIONS THAT ARE PERFORMED AT THIS FACILITY REGARDING THE MANUFACTURING, PROCESSING, PACKING OR HOLDING OF FOOD)

❑ Warehouse / Holding Facility (e.g., storage facilities, including storage tanks, grain elevators)
NOTE: If the facility is a warehouse / holding facility only, ***go to Section 10 (solely warehouse / holding facility) and check all that apply.***

❑ Acidified / Low Acid Food Processor	❑ Labeler / Relabeler
❑ Interstate Conveyance Caterer/Catering Point	❑ Manufacturer / Processor
❑ Molluscan Shellfish Establishment	❑ Repacker / Packer
❑ Commissary	❑ Salvage Operator (Reconditioner)
❑ Contract Sterilizer	❑ Animal food manufacturer / processor / holder

Section 10 - OPTIONAL: IF YOUR FACILITY IS *SOLELY* A WAREHOUSE / HOLDING FACILITY, COMPLETE THIS SECTION; ALL OTHER FACILITIES, COMPLETE SECTION 11 (human or animal product categories) INSTEAD OF THIS SECTION.

❑ Ambient Storage (including heated storage)	❑ Refrigerated Storage	❑ Frozen Storage

Section 11 - GENERAL PRODUCT CATEGORIES - FOOD FOR HUMAN CONSUMPTION

To be completed by all human food facilities except those that are solely warehouses.
[Note: Categories are derived from the Product Code Builder (www.fda.gov/search/databases.html), with cross-references to the categories found under 21 CFR 170.3. Please see instructions for further examples.]

❑ 1. ALCOHOLIC BEVERAGES [21 CFR 170.3 (n) (2)]

❑ 2. BABY (INFANT AND JUNIOR) FOOD PRODUCTS Including Infant Formula (Optional Selection)

❑ 3. BAKERY PRODUCTS, DOUGH MIXES, OR ICINGS [21 CFR 170.3 (n) (1), (9)]

❑ 4. BEVERAGE BASES [21 CFR 170.3 (n) (3), (16), (35)]

❑ 5. CANDY WITHOUT CHOCOLATE, CANDY SPECIALITIES & CHEWING GUM [21 CFR 170.3 (n) (6), (9), (25), (38)]

❑ 6. CEREAL PREPARATIONS, BREAKFAST FOODS, QUICK COOKING/INSTANT CEREALS [21 CFR 170.3 (n) (4)]

❑ 7. CHEESE AND CHEESE PRODUCTS [21 CFR 170.3 (n) (5)]

❑ 8. CHOCOLATE AND COCOA PRODUCTS [21 CFR 170.3 (n) (3), (9), (38), (43)]

❑ 9. COFFEE AND TEA [21 CFR 170.3 (n) (3), (7)]

❑ 10. COLOR ADDITIVES FOR FOODS [21 CFR 170.3 (o) (4)]

❑ 25. MULTIPLE FOOD DINNERS, GRAVIES, SAUCES AND SPECIALTIES [21 CFR 170.3 (n) (11), (14), (17), (18), (23), (24), (29), (34), (40)]

❑ 26. NUT AND EDIBLE SEED PRODUCTS [21 CFR 170.3 (n) (26), (32)]

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❑ 11. DIETARY CONVENTIONAL FOODS OR MEAL REPLACEMENTS (includes Medical Foods) [21 CFR 170.3 (n) (31)]

12. DIETARY SUPPLEMENTS

❑ Proteins, Amino Acids, Fats and Lipid Substances [21 CFR 170.3 (o) (20)]
❑ Vitamins and Minerals [21 CFR 170.3 (o) (20)]
❑ Animal By-Products and Extracts (Optional Selection)
❑ Herbals and Botanicals (Optional Selection)

❑ 13. DRESSINGS AND CONDIMENTS [21 CFR 170.3 (n) (8), (12)]

❑ 14. FISHERY/SEAFOOD PRODUCTS [21 CFR 170.3 (n) (13), (15), (39), (40)]

❑ 15. SUBSTANCES THAT MIGRATE INTO FOOD FROM FOOD PACKAGING AND OTHER ARTICLES THAT CONTACT FOOD (Optional Selection)

❑ 16. FOOD ADDITIVES, GENERALLY RECOGNIZED AS SAFE (GRAS) INGREDIENTS, OR OTHER INGREDIENTS USED FOR PROCESSING [21 CFR 170.3 (n) (42); 21 CFR 170.3 (o) (1), (2), (3), (5), (6), (7), (8), (9), (10), (11), (12), (13), (14), (15), (16), (17), (18), (19), (22), (23), (24), (25), (26), (27), (28), (29), (30), (31), (32)

❑ 17. FOOD SWEETENERS (NUTRITIVE) [21 CFR 170.3 (n) (9), (41), 21 CFR 170.3 (o) (21)]

❑ 18. FRUITS AND FRUIT PRODUCTS [21 CFR 170.3 (n) (16), (27), (28), (35), (43)]

❑ 19. GELATIN, RENNET, PUDDING MIXES, OR PIE FILLINGS [21 CFR 170.3 (n) (22)]

❑ 20. ICE CREAM AND RELATED PRODUCTS [21 CFR 170.3 (n) (20), (21)]

❑ 21. IMITATION MILK PRODUCTS [21 CFR 170.3 (n) (10)]

❑ 22. MACARONI OR NOODLE PRODUCTS [21 CFR 170.3 (n) (23)]

❑ 23. MEAT, MEAT PRODUCTS AND POULTRY (FDA REGULATED) [21 CFR 170.3 (n) (17), (18), (29), (34), (39), (40)]

❑ 24. MILK, BUTTER, OR DRIED MILK PRODUCTS [21 CFR 170.3 (n) (12), (30), (31)]

❑ 28. SHELL EGG AND EGG PRODUCTS [21 CFR 170.3 (n) (11), (14)]

❑ 29. SNACK FOOD ITEMS (FLOUR, MEAL OR VEGETABLE BASE) [21 CFR 170.3 (n) (37)]

❑ 30. SPICES, FLAVORS, AND SALTS [21 CFR 170.3 (n) (26)]

❑ 31. SOUPS [21 CFR 170.3 (n) (39), (40)]

❑ 32. SOFT DRINKS AND WATERS [21 CFR 170.3 (n) (3), (35)]

❑ 33. VEGETABLES AND VEGETABLE PRODUCTS [21 CFR 170.3 (n) (19), (36)]

❑ 34. VEGETABLE OILS (INCLUDES OLIVE OIL) [21 CFR 170.3 (n) (12)]

❑ 35. VEGETABLE PROTEIN PRODUCTS (SIMULATED MEATS) [21 CFR 170.3 (n) (33)]

❑ 36. WHOLE GRAINS, MILLER GRAIN PRODUCTS (FLOURS), OR STARCH [21 CFR 170.3 (n) (1), (23)]

❑ 37. MOST/ALL HUMAN FOOD PRODUCT CATEGORIES (Optional Selection)

Form 3537 (1/03)

Form Approval: OMB No. 0910-xxxx
Expiration Date:
See OMB Statement at end of form

DHHS/FDA - DRAFT FOOD FACILITY REGISTRATION FORM

Section 11a - OPTIONAL GENERAL PRODUCT CATEGORIES – FOOD FOR ANIMAL CONSUMPTION

- ❑ 1. GRAIN PRODUCTS (E.G., BARLEY, GRAIN SORGHUMS, MAIZE, OAT, RICE, RYE AND WHEAT)
- ❑ 2. OILSEED PRODUCTS (E.G., COTTONSEED, SOYBEANS, OTHER OIL SEEDS)
- ❑ 3. ALFALFA AND LESPEDEZA PRODUCTS
- ❑ 4. AMINO ACIDS
- ❑ 5. ANIMAL-DERIVED PRODUCTS
- ❑ 6. BREWER PRODUCTS
- ❑ 7. CHEMICAL PRESERVATIVES
- ❑ 8. CITRUS PRODUCTS
- ❑ 9. DISTILLERY PRODUCTS
- ❑ 10. ENZYMES
- ❑ 11. FATS AND OILS
- ❑ 12. FERMENTATION PRODUCTS
- ❑ 13. MARINE PRODUCTS
- ❑ 14. MILK PRODUCTS
- ❑ 15. MINERALS
- ❑ 16. MISCELLANEOUS AND SPECIAL PURPOSE PRODUCTS
- ❑ 17. MOLASSES
- ❑ 18. NON-PROTEIN NITROGEN PRODUCTS
- ❑ 19. PEANUT PRODUCTS
- ❑ 20. RECYCLED ANIMAL WASTE PRODUCTS
- ❑ 21. SCREENINGS
- ❑ 22. VITAMINS
- ❑ 23. YEAST PRODUCTS
- ❑ 24. MIXED FEED (POULTRY, LIVESTOCK, AND EQUINE)
- ❑ 25. PET FOOD
- ❑ 26. MOST/ALL ANIMAL FOOD PRODUCT CATEGORIES

Form Approval: OMB No. 0910-xxxx
Expiration Date:
See OMB Statement at end of form

DHHS/FDA - DRAFT FOOD FACILITY REGISTRATION FORM

Section 12 - CERTIFICATION STATEMENT		
The owner, operator, or agent in charge of the facility must submit this form. *By submitting this form to FDA, the owner, operator, or agent in charge certifies that the above information is true and accurate and that the facility has authorized the submitter to register on its behalf. Under 18 U.S.C. 1001, anyone who makes a materially false, fictitious, or fraudulent statement to the U.S. Government is subject to criminal penalties.*		
PRINT NAME OF PERSON SUBMITTING THE REGISTRATION FORM		
PHONE NUMBER (If a foreign facility, include Area & Country Codes):	FAX NUMBER ((If available; **if a foreign facility, include Area & Country Codes):**	E-MAIL ADDRESS (if available):

FDA USE ONLY	
DATE REGISTRATION FORM RECEIVED	**DATE NOTIFICATION SENT TO FACILITY**

Public reporting burden for this collection of information is estimated to average between 1 and 12 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
CFSAN (HFS-024)
5100 Paint Branch Parkway
College Park, MD 20740

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.

Form 3537 (1/03)

Form Approval: OMB No. 0910-xxxx
Expiration Date:
See OMB Statement at end of form

DHHS/FDA - CANCELLATION OF FOOD FACILITY REGISTRATION	
PROVIDE THE FACILITY REGISTRATION NUMBER:	
☐ **DOMESTIC REGISTRATION**	☐ **FOREIGN REGISTRATION**
FACILITY NAME / ADDRESS INFORMATION	
FACILITY NAME:	
FACILITY STREET ADDRESS:	
CITY:	**STATE:**
ZIP CODE (POSTAL CODE):	**PROVINCE/TERRITORY:**
COUNTRY:	
CERTIFICATION STATEMENT	
The owner, operator, or agent in charge of the facility must submit this form. *By submitting this form to FDA, the owner, operator, or agent in charge certifies that the above information is true and accurate and that the facility has authorized the submitter to cancel the registration on its behalf. Under 18 U.S.C. 1001, anyone who makes a materially false, fictitious, or fraudulent statement to the U.S. Government is subject to criminal penalties.*	
PRINT NAME OF PERSON SUBMITTING THE CANCELLATION FORM	
ADDRESS	**E-MAIL ADDRESS (IF AVAILABLE)**
FDA USE ONLY	
DATE CANCELLATION FORM RECEIVED	**DATE CONFIRMATION SENT TO FACILITY**

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
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Form 3537a (1/03)

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BILLING CODE 4160–01–C

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1

[Docket No. 02N–0278]

RIN 0910–AC41

Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Food and Drug Administration (FDA) is proposing a regulation that would require U.S. purchasers or U.S. importers or their agents to submit to FDA prior notice of the importation of food. The proposed regulation implements the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act), which requires prior notification of imported food to begin by December 12, 2003. The Bioterrorism Act requires FDA to issue final regulations that specify the period of advance notice by this date or a statutory notice provision requiring not less than 8 hours prior notice and not more than 5 days prior notice will take effect until a final rule is issued.

DATES: Submit written or electronic comments by April 4, 2003. Submit written or electronic comments on the collection of information by March 5, 2003.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments. Submit written comments on the information collection provisions to the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, ATTN: Stuart Shapiro, Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Mary Ayling, Center for Food Safety and Applied Nutrition (HFS–32), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–2428.

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I. Background and Legal Authority

The events of September 11, 2001, highlighted the need to enhance the security of the U.S. food supply. Congress responded by passing the Bioterrorism Act, which was signed into law on June 12, 2002. The Bioterrorism Act includes a provision in Title III (Protecting Safety and Security of Food and Drug Supply), Subtitle A—Protection of Food Supply, section 307, which amends the Federal Food, Drug, and Cosmetic Act (the act) by adding section 801(m) (21 U.S.C. 381(m)). This new provision changes when FDA will receive certain information about imported foods by requiring the Secretary of Health and Human Services (the Secretary), after consultation with the Secretary of the Treasury, to issue implementing regulations by December 12, 2003, mandating prior notification to FDA of food that is imported or offered for import into the United States. Functions of the U.S. Customs Service (U.S. Customs) will soon be a part of the Department of Homeland Security (DHS). Future consultations may be with DHS instead of, or in addition to, the Department of Treasury.

Section 801(a) of the act sets out procedures for imports under FDA's jurisdiction. When an FDA-regulated product is imported or offered for import, generally brokers submit entry information to the U.S. Customs on behalf of the importers of record. U.S. Customs then provides entry information and may deliver samples to FDA to enable admissibility decisions to be made. Under U.S. Customs authorities, entry of the merchandise must be made within 15 days after importation.

U.S. Customs regulations provide for different kinds of entries. Commonly, merchandise is the subject of an entry for consumption (i.e., unrestricted, general use) under a basic importation and entry bond at the first port of arrival, but U.S. Customs authorities also allow for the entry of merchandise for transportation under a custodial bond from the port of arrival to another port where the consumption entry will be made. If no entry of any kind is made within 15 days, the article cannot move and the carrier or other authorized party must notify U.S. Customs and a general order (i.e., bonded or secure) warehouse that the article remains unentered. Generally, at that point, the article is moved to the bonded warehouse (or

such other facility as the U.S. Customs port director might require) and held pending the filing of an entry or other action.

Accordingly, under current laws and regulations, there are times when FDA does not receive complete information about the food imports it regulates until days after the food has arrived in the U.S. and been moved from the port it arrived in.

FDA receives information about imported food through its Operational and Administrative System for Import Support (OASIS). Entry information is usually provided electronically to OASIS by U.S. Customs via its Automated Broker Interface (ABI) of the Automated Commercial System (ACS). The information that is currently supplied to FDA through this system includes: the entry type, the entry number (both ACS line number and FDA line identifier); the mode of transportation; the carrier code; the name and address of the manufacturer, shipper, importer, and ultimate consignee; the country of origin; the FDA product code; a written description of the product in common business terms; and the quantity. If neither FDA nor U.S. Customs wishes to examine or detain the entry, the product is allowed to proceed.

By adding section 801(m) to the act, Congress changed when information about FDA-regulated food imports must be provided to FDA. The major components of new section 801(m) of the act are:

- Requires prior notice of imported food shipments beginning on December 12, 2003;
- Provides that, if adequate notice is not provided, the food shall be refused admission and held until adequate notice is given;
- Amends section 301 of the act to make it a prohibited act to import or offer for import an article of food in violation of any requirements under section 801(m) of the act; and
- Mandates that prior notice be submitted no less than 8 hours and not more than 5 days before it is imported or offered for import, if final rules are not in effect on December 12, 2003, and until such rules become effective.

In addition to section 307 of the Bioterrorism Act, which establishes the requirement for prior notice for food imported or offered for import into the U.S., FDA is relying on sections 701(a) and 701(b) of the act (21 U.S.C. 371(a) and (b)) in issuing this proposed rule. Section 701(a) authorizes the agency to issue regulations for the efficient enforcement of the act, while section 701(b) of the act authorizes FDA and the Department of Treasury to jointly prescribe regulations for the efficient enforcement of section 801 of the act.

II. Preliminary Stakeholder Comments

On July 17, 2002, FDA sent an open letter to the members of the public interested in food issues outlining the four provisions in Title III of the Bioterrorism Act that require FDA to issue regulations in an expedited time period, and FDA's plans for implementing them (see http://www.cfsan.fda.gov/~dms/sec-ltr.html). In the letter, FDA invited stakeholders to submit comments to FDA by August 30, 2002, for FDA's consideration as it developed this proposed rule. FDA also held meetings with representatives of industry, consumer groups, other Federal agencies, and foreign embassies after sending out the July 17, 2002, letter, to solicit stakeholder comments. In response to these solicitations, FDA received 37 comments regarding section 307 of the Bioterrorism Act.

FDA has considered all the comments received by August 30, 2002. FDA will consider all comments we have received so far with the comments we receive during the public comment period on this proposed rule in developing the final rule. Several broad themes emerged from the comments FDA received on or before August 30, 2002, including:

- Maintaining flexibility when setting the minimum time required for prior notice and taking into account different modes of transportation, the nature of perishable food, and the needs of businesses which operate close to the U.S. border;
- Permitting the prior notice to be amended;
- Integrating with U.S. Customs and other agencies to avoid duplication of notification requirements;
- Allowing a qualified agent to submit prior notices for authorized submitters;
- Providing immediate acknowledgement of the submission, if prior notice is submitted electronically;
- Defining ''food'' consistent with the act's definition;
- Extending FDA's hours of operation;
- Complying with international trade obligations; and
- Including a model of the Prior Notice screen.

III. The Proposed Regulation

This rule would enhance FDA's ability to inspect imported food when it arrives in the U.S. This in turn would result in a significant improvement in FDA's ability to deter, prepare for, and respond effectively to bioterrorism and other public health emergencies that might result from imported food. Additionally, should an outbreak or a bioterrorism event occur, prior notice would enhance FDA's ability to respond to the event by enhancing FDA's ability to prevent entry of shipments that appear related and to facilitate product tracking for containment. This proposed rule would facilitate product tracking because we would know, at the time of receipt of prior notice, the name and address of the actual importer and consignee in the United States. We could then use the U.S. importer and consignee information to follow-up and trace the location of the goods. FDA thus would be better able to ensure that consumers in the United States do not eat food that is contaminated (whether intentionally or otherwise). This information would also assist FDA and other authorities in determining the source and cause of problems and in communicating with affected firms. Finally, we believe that the information provided by prior notice would help us use our foreign inspection resources more effectively.

In establishing and implementing this proposed rule, FDA will comply fully with its international trade obligations, including the applicable World Trade Organization (WTO) agreements and the North American Free Trade Agreement (''NAFTA''). For example, we believe this proposed rule is not more trade restrictive than necessary to meet the objectives of the Bioterrorism Act.

A. Highlights of This Rule

The key features of this proposed rule are:

- The purchaser or importer of an article of food (or their agent) who resides or maintains a place of business in the United States generally is responsible for submitting the notice.
- The notice must be submitted by noon of the calendar day before the day of arrival.
  - Amendments relating to product identity information are allowed under specified circumstances.
  - Updates about arrival information are required if plans change.
- The notice must be submitted electronically through the Prior Notice System unless the FDA system is not functioning. The FDA Prior Notice System will be designed to provide an automatic electronic acknowledgment of receipt of a complete prior notice submission, with a time and date ''stamp.'' The notice must contain information that identifies:
  - The individual and firm submitting the prior notice;
  - The entry type and U.S. Customs

ACS entry number or other U.S. Customs identification number associated with the import;
- If the article of food is under hold under proposed § 1.278, the location where it is being held;
- The identity of the article of food being imported or offered for import:
  - The complete FDA product code;
  - The common or usual name or market name;
  - The trade or brand name, if different from the common or usual name or market name;
  - The quantity described from smallest package size to largest container; and
  - The lot or code numbers or other identifier of the food if applicable;
- The manufacturer;
- All growers, if known;
- The country from which the article originates;
- The shipper;
- The country from which the article of food was shipped;
- The anticipated arrival information;
- Information related to U.S. Customs entry process;
- The importer, owner, and consignee; and
- The carrier.

- Amendments relating to product identity are allowed if complete information about product identity does not exist by the deadline for prior notice for the planned shipment:
  - Information regarding identity of the article may be amended once;
  - Amendments may not be used to change the nature of the article of food;
  - Quantity may be amended; and
  - Any amendments must be submitted no later than 2 hours prior to arrival.
- If a change occurs in the anticipated port of entry or anticipated time of arrival stated in the prior notice, the information must be updated.
- The proposed rule does not apply to:
  - Food that is carried by an individual entering the United States in that individual's personal baggage for that individual's personal use; or
  - Meat food products, poultry products, and egg products that at the time of importation are subject to the exclusive jurisdiction of the U.S. Department of Agriculture (USDA).

B. General Provisions

1. What Imported Food is Subject to This Subpart? (Proposed § 1.276)

Under new section 801(m)(1) of the act, prior notice is required for all food ''being imported or offered for import into the United States.'' Accordingly, prior notice requirements apply to all food that is brought across the U.S. border (with the following four exceptions) regardless of whether the food is intended for consumption in the United States. In other words, FDA believes that food that is brought into the United States to be put into foreign trade zones, or for transshipment or reexport immediate or otherwise, is ''imported or offered for import'' and thus must comply with the prior notice requirements.

The proposed rule establishes four categories of imported food that are not subject to the prior notice requirements. In each of these cases, FDA believes that the statutory language requires this result.

The first category is food that individual travelers carry in their personal baggage for their own personal enjoyment. Although we believe that this food is imported into the United States, the information that section 801(m)(1) of the act requires in a prior notice, in conjunction with the purpose of the provision, demonstrates that Congress did not intend prior notice to apply to food that travelers bring into the United States in their personal baggage for personal use (i.e., consumption by themselves, family or friends, not for sale to anyone). In particular, under section 801(m)(1) of the act, a prior notice must contain the identity of the shipper of the food. When travelers bring food back from their travels in their personal baggage for their own use, we do not believe that Congress intended for us to characterize such travelers as ''shippers'' for purposes of section 801(m) of the act. We seek comment on this reasoning. However, when travelers bring food into the United States in their personal baggage to sell or otherwise distribute in a broader fashion, the travelers would seem to be acting for or on behalf of other entities. Under these circumstances, these travelers would seem to be shippers and subject to the provisions of this proposed rule.

The remaining three categories of imported food not subject to the prior notice requirement are those foods within the exclusive jurisdiction of USDA. In accordance with section 801(m)(3)(B) of the act, FDA is proposing to exempt from the requirements of this regulation imported foods that, at the time of importation, are subject to USDA's exclusive jurisdiction under the Federal Meat Inspection Act (21 U.S.C. 601 *et seq.*), the Poultry Products Inspection Act (21 U.S.C. 451 *et seq.*), or the Egg Products Inspection Act (21 U.S.C. 1031 *et seq.*).

2. What Definitions Apply to This Subpart? (Proposed § 1.277)

The following definitions are used throughout the proposed rule:

a. *The act*. The proposed rule defines ''the act'' as the Federal Food, Drug, and Cosmetic Act. The proposed rule applies the definitions of terms in section 201 of the act to such terms as used in the proposed rule.

b. *Calendar day*. The proposed rule defines ''calendar day'' as ''every day shown on the calendar.''

c. *Country from which the article of food was shipped*. The proposed rule defines ''country from which the article of food was shipped'' as the country in which the article of food was loaded onto the conveyance that brings it to the United States. A conveyance is the means of transportation, e.g., ship, truck, car, van, plane, railcar, etc., not the shipping container that could be moved from a ship to a truck to a train bed.

FDA is requesting comment on whether this term should include the countries of intermediate destination.

d. *Food*. FDA is proposing to refer to the definition of ''food'' in section 201(f) of the act (21 U.S.C. 321(f)), which is: ''(1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article.'' FDA also is proposing to include examples of products that are considered food under section 201(f) of the act. Examples listed in the proposed rule include: fruits; vegetables; fish; dairy products; eggs; raw agricultural commodities for use as food or components of food; animal feed, including pet food; food and feed ingredients and additives, including substances that migrate into food from food packaging and other articles that contact food; dietary supplements and dietary ingredients; infant formula; beverages, including alcoholic beverages and bottled water; live food animals (such as hogs and elk); bakery goods; snack foods; candy; and canned foods. FDA already receives entry information on all these articles of food as defined in section 201(f) of the Act.

With respect to articles that can be used for food and non-food uses, FDA believes that prior notice is required if the article is being imported for use as food.

e. *Originating country*. The proposed rule defines ''originating country'' as ''the country from which the article of food originates.'' FDA is proposing this definition to be consistent with the language used in the Bioterrorism Act.

This proposed definition is also consistent with the definition that describes one of the critical data elements that brokers and other filers currently submit to FDA's OASIS via ACS when entry is made. The proposed definition refers to the country where the product that is shipped to the United States was grown or produced, depending on the kind of article. If the article is fresh produce, for example, the originating country is most likely to be the country where it is grown and harvested. If, on the other hand, the article is a processed food, e.g., canned vegetables, the originating country is likely to be the country in which the vegetables were canned. With respect to wild-caught fish or seafood that is harvested in the waters of the United States or by a U.S. flagged vessel or that is processed aboard a U.S. flagged vessel, FDA is proposing that the originating country be the United States. Otherwise, the originating country is the country under which the vessel is flagged. FDA aligned this aspect of the proposed definition of ''originating country'' with the principles proposed by USDA's Agricultural Marketing Service guidance published in the **Federal Register** on October 11, 2002, in response to the Farm Security and Rural Investment Act of 2002 (commonly known as the 2002 Farm Bill).

FDA recognizes that this proposed definition may not be identical in all respects to the meaning of the term ''country of origin'' traditionally used by U.S. Customs. However, FDA believes that using the U.S. Customs meaning would not serve the purpose of the Bioterrorism Act. The U.S. Customs term primarily serves tariff, quota, and other trade purposes; it does not provide information needed for the evaluations that Congress has directed FDA to make under the Bioterrorism Act and the act. We seek comment on this interpretation and our proposed definition of ''originating country''. FDA also seeks comment on whether its use of a different term will have any impact, and if so, what that impact will be.

f. *Port of entry*. For purposes of the proposed rule, FDA is defining ''port of entry'' as ''the water, air, or land port at which the article of food is imported or offered for import into the United States, i.e., the port where food first arrives in the United States'' FDA is proposing this definition because the port where the food arrives in the United States may be different than the port where the entry of the article of food is processed for U.S. Customs purposes, i.e., where the article is ''entered.'' Under U.S. Customs statutes, products can be imported into one port and then transported to another port under a custodial bond before a consumption entry is filed. For example, food may be imported into the United States from Canada through Buffalo, NY, but not be entered for consumption with U.S. Customs until it reaches St. Louis, MO, several days later. In this example, under FDA's proposed definition, the port of entry is Buffalo, NY. If food is imported into the United States from Mexico through Otay Mesa, CA, for transport through the United States for exportation into Canada, the port of entry under FDA's proposed definition is Otay Mesa, CA.

The prior notice authority in the Bioterrorism Act is intended to give FDA better tools to deter, prepare for, and respond to bioterrorism and other food related problems. Given this purpose, ''port of entry'' must be defined as the port of arrival, that is, the location where the food first physically appeared in the United States. Allowing food that is presented for importation into the United States without prior notice to be shipped around the country and potentially lost to government oversight simply is not consistent with the Bioterrorism Act's stated purpose. FDA believes that its ability to protect U.S. consumers from terrorism or other food-related emergencies will be strongest if food can be examined, and if necessary, held at the point when it first arrives in the United States. FDA requests comments on the proposed definition of ''port of entry.''

g. *You*. The proposed definition of ''you'' is the description of the party responsible for submitting the prior notice in proposed § 1.285. FDA is proposing to define ''you'' in proposed § 1.277(f) as the ''purchaser or importer of an article of food who resides or maintains a place of business in the United States, or an agent who resides or maintains a place of business in the United States acting on the behalf of the U.S. purchaser or importer'' or, ''if the article of food is imported with the intention of in-bond movement through the United States for export, i.e., Transportation for Exportation or Immediate Export entries, the arriving carrier or, if known, the in-bond carrier.''

3. What Are the Consequences of Failing to Submit Adequate Prior Notice or Otherwise Failing to Comply With This Subpart? (Proposed § 1.278)

As set out in section 801(m)(1) of the act, proposed § 1.278(a) provides that, if an article of food is imported or offered for import with no prior notice or inadequate prior notice, the food shall be refused admission under section 801(m) of the act. Examples of inadequacy are untimely, inaccurate, or incomplete prior notice.

As set out in section 801(m)(2)(B)(i) of the act, proposed § 1.278(b) provides that if the food is refused admission under section 801(m), it must be held at the port of entry unless FDA directs its removal to a secure facility.

In accordance with section 801(m)(2)(B)(i), proposed § 1.278(c) provides that FDA may require that an article of food be held in a secure facility as appropriate. FDA may determine such storage is appropriate because of the condition of the product, circumstances of importation, or other information available to the government, e.g., a concern with the safety or security of the article of food or space limitations in the port of entry.

Examples of secure facilities include U.S. Customs Bonded Warehouses, Container Freight Stations, and Centralized Examinations Stations. Perishables, however, may not be stored in U.S. Customs Bonded Warehouses; thus, FDA may direct fresh produce or seafood that requires storage to another facility. FDA and U.S. Customs plan to issue guidance for their field offices that will identify locations of secure storage facilities that may be used for food required to be held for failure to provide adequate prior notice.

In order to minimize confusion about who is responsible for making arrangements if food is refused admission under section 801(m) of the act, proposed § 1.278(d) provides that if FDA requires the article of food to be held at the port of entry or in a secure facility, the carrier or the person who submitted the prior notice must arrange for the movement of the food under appropriate custodial bond and promptly notify FDA of the location. This provision also makes clear that the purchaser, owner, importer, or consignee is responsible for transportation and storage expenses. We note that when section 801(m) of the act requires that food be held, it does not appear to mandate that the government take actual physical custody of the goods; instead it limits both the movement of the goods and the potential storage locations, thereby making government oversight straightforward. As described previously, U.S. Customs has identified a well-established network of storage facilities that are secure. When these storage facilities are used, charges are borne by the private parties. We thus believe that although Congress intended strict controls over food refused admission under § 801(m), it did not intend to require FDA or U.S. Customs

to take custody of or pay for the holding of such food. We seek comment on this issue.

In accordance with section 801(m)(2)(B)(i) of the act, proposed § 1.278(e)(1) provides that the article of food must be held at the port of entry or in the secure facility until prior notice is submitted to FDA in accordance with this subpart, FDA has examined the prior notice, FDA has determined that the prior notice is adequate, and FDA has notified the U.S. Customs Service and the person who submitted the prior notice that the article of food no longer is subject to refusal of admission under section 801(m)(1) of the act.

FDA recognizes that food may be shipped in the same container or truck with non-food items. Since articles that are not food are not subject to this proposed rule, when mixed or consolidated imported freight contains articles of food that must be held at the port of entry or moved to a secure facility, those articles that have been refused must be dealt with before the rest of the shipment proceeds.

In accordance with section 801(m)(2)(B)(i) of the act, proposed § 1.278(e)(2) makes clear that food under a hold may not be delivered to the importer, owner, or consignee and that section 801(b) of the act does not apply. Therefore, delivery will not be allowed under a basic importation or entry bond. Even though delivery to them is not allowed, FDA believes that importers, owners, and consignees of food that has been refused under 801(m) of the act can make arrangements for food to be held: these arrangements can be made without taking possession of the food.

The proposed rule (proposed § 1.278(f)) differentiates between a refusal of admission under section 801(m)(1) of the act (prior notice) and refusal of admission under section 801(a) and other provisions of the act or other U.S. laws. The proposed rule makes clear that a determination that an article of food is no longer subject to refusal of admission under section 801(m)(1) of the act does not mean that it will be admitted to the United States. The other provisions of the act and other U.S. laws that currently apply to food imported or offered for import to the United States still apply and also govern admissibility.

Although FDA believes that information in a prior notice will help facilitate admissibility decisions under section 801(a), FDA is not proposing to specify in the rule that it will make an 801(a) admissibility decision at the time it receives a prior notice. A prior notice is a pre-entry submission to comply with requirements under section 801(m). FDA will make the 801(a) decision when the complete entry information is submitted to U.S. Customs and transmitted to FDA. Normally (in about 98 percent of the cases), this is accomplished by electronically filing certified entry information with U.S. Customs ACS, which electronically transmits it to FDA's OASIS System. FDA's 801(a) admissibility decisions are transmitted from OASIS to the filer.

In accordance with section 301(ee) of the act, the proposed rule (§ 1.278(g)) provides that it is a prohibited act to import or offer for import an article of food without complying with the requirements of section 801(m) of the act or otherwise violate any requirement under section 801(m). The proposed rule explains that, under section 302 of the act, the United States can bring a civil action in federal court to enjoin persons who commit a prohibited act and, under section 303 of the act, can bring a criminal action in Federal court to prosecute persons who commit a prohibited act. The proposed rule also explains that, under section 305a of the act, FDA can seek debarment of any person who has been convicted of a felony relating to importation of food into the United States.

FDA notes that there are several differences between refusal of admission under sections 801(a) and (b) of the act and refusal of admission under new section 801(m). First, in section 801(m) of the act, Congress did not provide for any kind of application, petition, or appeal of FDA's determination that an article shall be refused admission for failing to comply with prior notice requirements. Congress provided that an article that has been refused admission under section 801(m) of the act can be admitted only if the necessary information is subsequently submitted, examined by FDA, and found to be adequate. Second, food refused admission under section 801(m) cannot be delivered under bond pursuant to section 801(b) and, as we describe elsewhere, must be held at the U.S. port of entry. Finally, the Bioterrorism Act does not provide specific procedures for the disposition of food refused admission under section 801(m) when no subsequent adequate notice is submitted. Section 801(a) and (b) provide that food refused admission under section 801(a) must be destroyed or reexported. FDA thus believes that the general requirements of Title 19 of the United States Code and the U.S. Customs implementing regulations that apply to imports for which entry has not been made apply in these circumstances.

Under 19 U.S.C. 1448 and 1484, entry of merchandise must be made within the time period prescribed by regulation, which is 15 days after the food arrives in the United States. See 19 CFR Part 1422. If entry is not made within this timeframe, the carrier or other authorized party is required to notify U.S. Customs and a general order warehouse. Generally, at that point the warehouse must arrange to take and store the food at the expense of the consignee. The disposition of this merchandise is governed by 19 U.S.C. 1491 and the implementing regulations at 19 CFR Part 127. Typically, after 6 months, unentered merchandise is deemed unclaimed and abandoned and can be disposed of by the United States. Before this 6 month period runs, however, such merchandise can be reexported. FDA and U.S. Customs plan to develop additional guidance to explain how the agencies will handle food when it must be placed in general order warehouses due to refusal under section 801(m) of the act.

C. Requirements to Submit Prior Notice of Imported Food

1. Who is Authorized to Submit Prior Notice for an Article of Food That is Imported or Offered for Import Into the United States? (Proposed § 1.285)

FDA is proposing that a purchaser or importer of an article of food who resides or maintains a place of business in the United States is authorized to submit prior notice. FDA is also proposing that an agent who resides or maintains a place of business in the United States acting on the behalf of the U.S. purchaser or U.S. importer is authorized to submit prior notice. FDA believes that the customs broker/filer should be authorized to be a submitter if it is the U.S. agent of the U.S. importer or U.S. purchaser.

FDA is proposing that, if the article of food is imported for in-bond movement through the United States for export, the prior notice must be submitted by the arriving carrier or, if known, the in-bond carrier. The types of entries that cover these importations are known to FDA and U.S. Customs as Transportation for Exportation (T&E) and Immediate Export (IE).

FDA believes that the proposed rule should specify which parties are responsible for submitting prior notice and that this specificity will minimize confusion about who should or will submit prior notice among the several parties who can be involved in importing food. Less confusion will lead

to greater compliance. Less confusion will also mean that fewer imports will be delayed for lack of prior notice.

FDA chose the U.S. entities in proposed § 1.285(a) for several reasons. First, we do not believe that there is importation of food to the United States that does not involve one of the U.S. entities identified, except in those instances where the food is imported with the intention of in-bond movement through the United States for export (where the proposed rule authorizes submission by the arriving carrier or, if known, the in-bond carrier). We also believe that it is the U.S. importer or U.S. purchaser who orders or buys the article of food, thereby initiating its importation into the United States. These persons thus should possess, or have the ability to obtain, the information required to be submitted in the prior notice within the time period in proposed § 1.286. As U.S. businesses, these persons are also more likely to already have web access than some foreign businesses, which reduces potential costs and impacts on trade. Finally, placing responsibility on these U.S. entities will facilitate FDA's ability to conduct audits, investigations, and inspections, which will facilitate efficient enforcement of section 801(m).

FDA notes that the submitter is the entity responsible for ensuring the adequacy and accuracy of the prior notice. For the reasons described above, FDA believes that these entities are in the best position to do so.

FDA seeks comment on whether others should be authorized to provide prior notice and, if so, why.

2. When Must the Prior Notice be Submitted to FDA? (Proposed § 1.286)

Based on consideration of the factors set out in the statute, FDA is proposing that the prior notice must be submitted to FDA no later than noon of the calendar day before the day the article of food will arrive at the border crossing in the port of entry.

Section 801(m)(1) of the act makes clear that a primary purpose of prior notice is to enable inspections or other FDA action upon arrival of food in the United States to protect consumers in the United States from food imports that may be at risk of intentional adulteration or that may pose other risks. Section 801(m)(2)(A) of the act states that the deadline for prior notice ''shall be no less than the minimum amount of time necessary for [FDA] to receive, review, and appropriately respond to such notification.'' In addition, section 801(m)(2)(A) provides that FDA may take other factors into consideration when deciding on the deadline for prior notice, specifically: its effect on commerce; the locations of various ports; various modes of transportation; types of food; and any other consideration. However, although the statute gives FDA some latitude in setting the deadline for prior notice, it nonetheless makes clear that we must establish a timeframe for prior notice that allows FDA to receive, review, and appropriately respond to all prior notices. Finally, section 801(m)(1) states, ''Nothing in this section may be construed as a limitation on the port of entry for an article of food.''

Reading section 801(m) as a whole and in conjunction with other provisions in the Bioterrorism Act, FDA believes that Congress intended that FDA assess the information in the prior notice to determine if inspection upon arrival or other action is appropriate. For FDA to inspect, upon arrival, food imports that may be at risk of intentional adulteration or that may pose other risks to U.S. consumers, FDA must be able to effectively deploy its staff. Although FDA inspectors are located throughout the United States, FDA does not have staff located at or near all of the 250 ports where over 4.7 million entry lines of food were entered in fiscal year (FY) 2001. Port locations are established by U.S. Customs and, under the statute, FDA cannot limit ports at which food may be imported or offered for import. Thus, FDA must have enough time, on a daily basis, to process the information in the approximately 20,000 prior notices we expect to receive and to send inspectors to any port in the United States if necessary. FDA believes that the minimum amount of time necessary to ensure it can plan and that its staff can travel to the arrival point is noon of the calendar day before the day the article arrives at the border crossing. FDA believes that this timeframe will give it the minimum time it needs to conduct its assessments and provide the information to its field offices so they can allocate their inspectional resources on a daily basis and plan any necessary travel.

Before proposing this deadline FDA also considered its potential effects on imported food. FDA believes that in most circumstances information regarding imports is generated when the article to be imported is ordered or purchased, not when it is shipped to the United States. FDA has examined a selection of imported food documents and compared dates of these documents with the dates of arrival in the United States and U.S. Customs entry. FDA asked several field offices to send entry documents with invoices covering imported foods. Sixty-four packages of entry documents were received in response to this request. The dates of the invoices were compared to the dates of arrival and receipt in OASIS. In 48 cases (75 percent), the invoice date or date of sale preceded the arrival date by least 1 day. In 31 cases (48 percent), the invoice or sale date preceded the arrival date by 2 or more days. In 16 cases (25 percent), the invoice date was the same as the arrival date. FDA invites comment on the representativeness of this sampling. Based on this examination, we believe that orders are normally placed a day or more prior to shipment. See the compilation of imported food documents that FDA has placed in the administrative record and the docket (Ref. 1). FDA believes that the information required for prior notice therefore generally does exist by noon of the calendar day before the day of arrival. FDA recognizes, however, that currently one person may not possess all of the information and that some practices regarding the flow of information about food imports will have to change to ensure that the submitter has all of the information needed to submit a prior notice for the food shipment by the deadline.

FDA believes that this proposed deadline will have the most impact on those who import food by truck and rail over the land borders, with less effect at airports, and almost no effect at water ports. However, even on the land borders, FDA believes that the information required by prior notice will be, in most cases, sufficiently fixed by noon of the calendar day before arrival to allow the U.S. importer or U.S. purchaser, or their U.S. agents, to submit prior notice to FDA that meets the proposed requirements without slowing down the shipment.

FDA is proposing to allow submitters to amend prior notices for that portion of the product identity information that cannot be completed, because it does not yet exist by noon of the calendar day prior to arrival. We believe this may be the case with product identity for fresh products imported from countries close to the United States (e.g., Canada or Mexico). For example, fresh seafood may be ordered as ''catch-of-the-day'' from Canada or Mexico; the importer intends to import the fish the day after the order is placed, but cannot find out what exact species and quantity will arrive by the deadline for prior notice because the boat is not due back until late afternoon on the day prior notice is due. Another example is an importer who orders fresh lettuce for import the day after the order but cannot find out the exact variety and quantity of lettuce

that will be shipped by the deadline for prior notice because the field has not been harvested or the supplier has not yet received the day's harvest by the time prior notice of the planned shipment is due. In these instances, the importer knows generally what kind of product has been ordered, but not the exact type (species for fish and variety for lettuce). The proposed amendment process would allow submitters who cannot report complete product identity information to FDA by the prior notice deadline because it does not yet exist to maintain current business practices. However, it would provide FDA some of the information that it needs to begin the assessment of whether a particular shipment of food should be investigated and if so, to ensure that FDA personnel can be available when the food arrives at the port. FDA does not intend this amendment process to apply when a shipper ''tops off a container'' by filling unused space in the container or truck bed with additional different food products.

FDA also recognizes that information concerning the anticipated arrival may change after the article is ordered due to unforeseen traffic or weather issues and has accommodated those potential changes by requiring updates of that information.

''Noon'' means 12:00 p.m. in the time zone in which the FDA office with responsibility over the anticipated port of entry resides. For example, if the anticipated port of entry is the Peace Bridge in the Buffalo, NY, and the anticipated date of entry is January 9, 2004, the prior notice must be submitted to the FDA Prior Notice System before noon Eastern Standard Time (EST) on January 8, 2004.

FDA is proposing that prior notice may not be submitted until all of the information required by § 1.288 exists except as provided in § 1.288(e)(2) and § 1.290, both of which relate to product identity amendments. FDA is also proposing that the prior notice may not be submitted more than 5 days before the anticipated date of arrival of the food at the anticipated port of entry. For example, if the anticipated date of arrival is January 12, 2004, the prior notice may not be submitted before January 7, 2004. This 5 day limitation is consistent with the limitation set by Congress in section 307(a)(2)(A) of the Bioterrorism Act. Such limitations are necessary to ensure that FDA's Prior Notice System is not overburdened with premature information or submissions that may need to be cancelled and resubmitted.

3. How Must You Submit the Prior Notice? (Proposed § 1.287)

FDA is proposing that the prior notice, amendments, and updates must be submitted electronically to FDA through FDA's Prior Notice System. The web-based FDA Prior Notice System is under development with an anticipated completion date of no later than October 12, 2003. A ''mock-up'' of the Prior Notice Screen a submitter would see once he or she accessed this system is part of this proposed rule.

FDA has consulted with the U.S. Customs Service of the Department of the Treasury about this proposed rule. FDA and U.S. Customs considered modifying ACS to accommodate the new prior notice requirement. However, during these consultations, U.S. Customs determined that ACS could not be modified to accommodate the data requirements of the prior notice regulation by the December 12, 2003, statutory deadline. Currently, U.S. Customs is focusing its resources on developing the Automated Commercial Environment (ACE) as a replacement for ACS, and integrating its other electronic systems, such as the Automated Manifest System (AMS). FDA is participating in the development of ACE through the International Trade Data System (ITDS) Board and directly through integration of FDA and U.S. Customs business practices, policies, and border cooperation. FDA intends to allow prior notice to be submitted through ACE when it is fully operational. However, implementation of ACE is not expected before 2005. Given these circumstances, FDA and U.S. Customs agreed that to meet the statutory deadline, an FDA stand-alone, web-based electronic system to execute receipt of prior notice would be necessary until ACE is fully operational.

FDA seeks to minimize the submission of duplicative information. The Bioterrorism Act requires certain prior notice information to be submitted to FDA. FDA seeks comments on the extent to which these proposed prior notice requirements would result in persons submitting duplicative prior notice information to more than one federal agency. FDA also seeks comments on whether there is any way, consistent with the requirements and purpose of the Bioterrorism Act, to minimize the duplication of information required to be submitted to the federal government under these prior notice requirements. As discussed previously, FDA and U.S. Customs are working together on their systems to allow prior notice to be submitted to FDA through U.S. Customs System when ACE is fully operational.

FDA is proposing to require electronic submission of prior notice because we believe an electronic system will be the least burdensome and most efficient way to implement and enforce the requirement of section 801(m) of the act. Nationwide, in FY 2001 FDA received over 4.7 million food entry lines; therefore, we believe a paper system would be unmanageable for FDA, require a longer deadline, and could slow down imports for some food products. Moreover, we currently receive the majority of information we base admissibility decisions on electronically from U.S. Customs. Thus, we already have the electronic capability to process and screen the information. We also believe that an electronic system will mean fewer errors than a paper system. Another important benefit of electronic submission will be immediate and accurate communication between FDA offices and between FDA offices and U.S. Customs about arrivals and adequacy of the prior notice.

An electronic prior notice system will have several key features that will benefit firms that export to the United States, U.S. importers, and FDA. First, the volume of submissions on a daily basis is expected to be such that electronic submission and processing are the only practical way for FDA to manage prior notice—FDA expects, upon average, 20,000 submissions per day. Second, an electronic system will be able to provide instantaneous confirmation of receipt of the prior notice. Third, an electronic system will be able to ensure that the form is filled out completely (though not accurately) by being set to reject submissions until all of the mandatory fields are completed. Finally, an electronic system will make it more likely that information in the submissions is ''legible'' to FDA.

In contrast, prior notice by mail, fax, or e-mail would have several significant downsides for firms that export to the United States, U.S. importers, and FDA. All three of these methods would require FDA to input the data manually to process it, which means that FDA would need to set a longer deadline for submission or devote resources on data entry that are better spent on tasks like inspections. Those whose paper submissions were not legible or complete would not know until their shipments arrived at the port and were refused admission.

Moreover, FDA believes that almost all proposed submitters have access to the Internet, either within their companies or through public libraries, copy centers, schools, or Internet cafes, as well as through agents or brokers. FDA requests comments on this assumption. Because most of the

persons responsible for submitting the prior notice must reside or maintain a place of business in the United States, the FDA Prior Notice System will be in English. This will also allow for the information to be placed in standard data elements that can then be maintained in a database, screened against standard criteria, and used for communication among field offices.

In proposed § 1.287(b), FDA is proposing that if its Prior Notice System is unable to receive prior notice electronically, the prior notice, amendments, and updates must be submitted using a printed version of the Prior Notice Screen delivered in person, by fax, or by e-mail to the FDA field office with responsibility over the geographical area in which the anticipated port of entry is located. If the submitter does not receive electronic acknowledgement from the FDA Prior Notice System then it should check to see if its system is working. If it is, then the submitter should assume that the FDA system might be down and attempt to contact the appropriate FDA field office to confirm.

The Prior Notice System will not provide a response to the submitter of the agency's decision regarding the adequacy or timeliness of the prior notice as this assessment will turn on information that will not be available until the food arrives in the United States. FDA anticipates the system will date and time stamp an electronic confirmation of the system's receipt of each prior notice, amendment, and update, which the system will send to the submitter automatically.

FDA believes that the prior notice process under section 801(m) precedes the review process under section 801(a). Thus, FDA's response to the prior notice will not constitute entry review. The section 801(a) review process will be separate from, and subsequent to, the prior notice process. Therefore, the FDA Prior Notice System's electronic confirmation of a prior notice submission is not an 801(a) admissibility decision and should never be construed as an FDA ''release'' or ''may proceed.''

If a person wishing to submit prior notice to the FDA is unable to do so because his or her own system is not operating, FDA expects the submitter to use an alternative Internet system for submission (e.g., a local library or copy-center with Internet access). FDA is developing a web-based system to reduce the likelihood that intermittent system outages will impact prior notice submissions.

Although the system may be developed in a way that will allow for establishment of a personal account, users will not have to be licensed or otherwise pre-approved or have specialized software. FDA also plans to develop and provide guidance and training to potential submitters and their agents that will further describe the data elements and the submission process before December 12, 2003, which is when the requirement to provide prior notice begins. The Prior Notice Screen of FDA's Prior Notice System also identifies the information that must be submitted.

4. What Information Must be Submitted in a Prior Notice? (Proposed § 1.288)

Proposed § 1.288 lists the information or data elements that must be included in each prior notice. Much of this list is taken directly from section 801(m)(1) of the act. The remainder of the list, although not explicitly listed in section 801(m), is information that FDA believes is necessary for the efficient enforcement of section 801(m) of the act and is thus authorized under section 701(b) of the act. We explain below why each of these items is necessary for the efficient enforcement of section 801(m). Accordingly, as set out in proposed § 1.278(a), FDA is proposing that a prior notice that does not contain all of the information listed in proposed § 1.288 will be considered inadequate. FDA solicits comments on this approach.

Most of this information is already supplied by the filer to FDA through ACS as part of the U.S. Customs entry process, including the entry type; the entry number (both ACS line number and FDA line identifier); the FDA product code; a written description of the product in common business terms; brand name; the quantity; lot numbers; the manufacturer; country of origin; shipper; importer; ultimate consignee; and the carrier (the mode of transportation and the carrier code).

Before discussing each data element in the context of prior notice, we want to emphasize that the prior notice requirement does not apply to a whole shipment; for the purpose of section 801(m) of the act, it applies to ''each article of food.'' FDA believes that in section 801(m) ''each article of food'' means each article of food produced by each manufacturer. Thus, any food product identified by a specific FDA product code and quantity description produced by a single manufacturer (or grower, if fresh) associated with a single entry line number (U.S. Customs entry number plus ACS line number plus OASIS/FDA line number) must be covered by a prior notice. Therefore, each article of food that is represented by an FDA line must be covered by a prior notice.

Thus, if a shipment consists of four different kinds of food products, e.g., 1,000 cases of 48/6 oz. cans each of Brand X tuna, 240 cases of 24/15.25 oz. cans each of yellow corn, 300 cases of 24/12 oz cans each of Brand X tuna, and 1,500 cases of 48/6 oz. cans each of Brand P tuna, four prior notices are required. These four prior notices may be contained in one submission. If the shipment consists of only one product, e.g., 2,400 cases of 24/15.25 oz. cans each of yellow corn, one prior notice is required. If this corn came from two different manufacturers, however, two prior notices would be needed. In its Prior Notice System FDA will give the submitter the option of completing additional prior notices for other articles after each notice is completed. We are working with the developers of the Prior Notice System to accept ''header'' information that will permit repeated information to be automatically entered. This ''header'' would contain information consistent across several articles of food within the same submission, i.e., U.S. Customs entry. This will reduce the amount of data entry and potentially reduce typing and transcription errors. FDA plans to develop its Prior Notice System to allow submitters to automatically repeat information already entered in the submission where appropriate (e.g., all information is the same except for the identity of the article or the manufacturer).

FDA is proposing to require the following information in the prior notice identifying the following details for each article of food:

2. *The submitter.* FDA is proposing to require the identity of the submitter and the associated submitting firm. This information is needed so that FDA may communicate the adequacy or non-adequacy of the prior notice to the responsible party and to follow up when audits, inspections, or enforcement are necessary.

Generally, for all firms that the proposed rule requires to be identified in a prior notice (submitter, importer, owner, consignee, manufacturer, growers (if known), shipper), FDA is proposing that the prior notice include the firm's name, address, phone number, fax number, and e-mail address, and if the firm is required to register a facility associated with the article of food, the facility's registration number. The registration requirement is contained in a separate provision of the Bioterrorism Act (section 305). FDA believes that it needs identifying information in addition to the

registration number (if one exists) to minimize the chance that typographical errors in registration numbers will lead to prior notices being considered incorrect and thus inadequate. We are considering designing the Prior Notice System to require at least one ''confirmatory'' data element (firm name or city or country) in addition to the registration number to allow for validation edits before automatically filling in the remaining data fields.

The phone and fax numbers and e-mail address are required (if they exist) so that FDA can communicate with the firm, if necessary. If the firm does not have a fax number or e-mail address, the prior notice submission should declare this. FDA plans to develop its Prior Notice System to allow submitters to repeat information already entered in the submission where appropriate (e.g., where the submitter is also the importer and consignee of the article).

b. *The U.S. Customs entry type*. FDA is proposing to require the submission of the U.S. Customs entry type associated with the article of food being imported or offered for import (proposed § 1.288(b)). Some examples of types of entries are Consumption entries, Warehouse entries, Temporary Importation Bond entries, Transportation for Exportation Bond entries, Trade Fair entries, mail entries, and baggage entries. Each of these types has a pre-designated U.S. Customs entry type code. That code must be submitted in the prior notice. This information will tell us if the article of food is intended for consumption in the U.S. or is intended for export or other uses. We need this information for proper screening of the information and identification of the appropriate articles for inspection. FDA also believes that submission of this information is critical for matching the prior notice to the corresponding U.S. Customs entry in order to assess the adequacy of the prior notice when shipments arrive and are presented for review.

c. *The U.S. Customs ACS entry line number or other U.S. Customs identification number*. FDA is proposing to require the submission of the U.S. Customs ACS entry line number, consisting of the entry number, the U.S. Customs ACS line number, and the FDA entry line number, which will be associated with the entry of the food for U.S. Customs purposes (proposed § 1.288(c)). For each entry number, there may be one or more U.S. Customs ACS lines and for each U.S. Customs ACS line there may be one or more FDA lines. For example, U.S. Customs entry number 0123456789–0 may identify an entry of peppers; the U.S. Customs ACS line 123456789–0–001 may identify fresh peppers; and the FDA entry line 0123456789–0–001–001 may identify fresh sweet peppers and FDA entry line 0123456789–0–001–002 may identify fresh hot peppers.

If the article of food is not intended for consumption entry, FDA is proposing to require submission of the U.S. Customs identification number associated with that type of entry. Some examples of other types of entries are Warehouse entries, Temporary Importation Bond entries, Transportation for Exportation Bond entries, and Trade Fair entries.

FDA believes that this information is necessary for proper screening of the information and identification of the appropriate articles for inspection. FDA also believes that submission of this information is critical for matching the prior notice to the corresponding U.S. Customs entry in order to assess the adequacy of the prior notice when shipments arrive and are presented for review. FDA believes that these numbers can be obtained by the proposed deadline for prior notice. We seek comment on this issue.

d. *The location where the food is being held under proposed § 1.278, if applicable*. FDA is proposing to require that, if the article of food has been refused admission due to inadequate prior notice and thus is required to be held at the port of entry or in a secure facility, the submitter of the prior notice must inform FDA both that the article is under hold, and the location where the shipment is being held (proposed § 1.288(d)). Additionally, FDA is proposing to require the date that the article will arrive at that location as well as the identification of a contact at that location. This information is necessary to ensure FDA can locate the food for inspection and to ensure that the hold requirement is being compiled with.

e. *The product identity*. Section 801(m)(1) states that a prior notice must contain the identity of the article of food being imported or offered for import. FDA is proposing the following data elements to ensure that each prior notice adequately and completely identifies the food being imported or offered for import.

i. *The complete FDA product code*. FDA is proposing to require the submission of the complete FDA product code as an element of the identity of the product (proposed § 1.288(e)(1)(i)). The FDA product code is a unique code currently used for classification and analysis of merchandise. The FDA product code is currently available via the Internet at www.accessdata.fda.gov/scripts/ora/pcb/pcb.htm as a ''buildable'' code which is used to describe the food by industry, industry class, subclass, container/packaging, process, and specific product. We will work with the developers of the FDA prior notice system to ensure that there is a link from that system to the product code builder. We are working with the developers to design the link to the product code builder which will allow the product code selected to be automatically pasted back to the Prior Notice Screen. We will also design the system so that if the submitter already knows the product code, it can be entered directly into the Prior Notice Screen.

The FDA product code for canned tuna fish is 16AEE45, which translates as 16= fishery/seafood products, A= fish, E= subclass metal (cans), E= commercially sterile, 45= tuna. The filer currently submits the FDA product code to U.S. Custom's ACS when entry is made; it subsequently is transmitted to FDA's OASIS for each entry line.

FDA is proposing that if all of the information concerning the product identity exists by noon of the calendar day before the article will arrive at the port of entry, it must be included in the prior notice and the prior notice may not be subsequently amended. (Proposed § 1.288(e)(2)). If any of the product identity information does not exist by the deadline, the information that does exist must be provided to FDA, and the submitter must indicate that it will amend the prior notice. FDA identifies the conditions appropriate for amendments related to product identity in proposed § 1.290. FDA notes that, in determining whether the information exists, the standard set out in the proposed rule is not whether the submitter knows the information when filing the prior notice, but whether the information could be known by the submitter by the noon deadline. In the discussion of proposed § 1.289, we describe under what circumstances we think complete product identity will not exist. FDA solicits comment on this standard and whether it is sufficiently flexible to achieve our goals.

ii. *The Common or usual or market name*. FDA is proposing to require the submission of the common or usual or market name of the article of food as an element of the identity of the product (proposed § 1.288(e)(1)(ii)). This is a description, in common terms, detailed enough to allow the kind of product to be identified. (See 21 CFR § 102.5 for additional information about common or usual names.) The filer currently submits the common or usual or market name to U.S. Custom's ACS when entry

is made, and it subsequently is transmitted to FDA's OASIS for each entry line. This information is necessary to confirm the accuracy of the product code.

iii. *The trade or brand name.* FDA is proposing to require the submission of the trade or brand name of the article of food, if it is different than the common or usual or market name, as an element of the identity of the product (proposed § 1.288(e)(1)(iii)). For example, the brand name of canned tuna would be XYZ brand tuna. This information is necessary to ensure that FDA knows the brand identity of the product, which is often a critical piece of information when making inspection decisions. The filer currently submits the trade or brand name to U.S. Custom's ACS when entry is made, and it subsequently is transmitted to FDA's OASIS for each entry line.

iv. *The quantity.* FDA is proposing to require the submission of the quantity of food described from smallest package size to largest container as an element of the identity of the product (proposed § 1.288(e)(1)(iv)). The number of container units and units of measure are to be submitted in decreasing size of packing unit (starting with the largest). Some examples of quantity descriptions are: 100 cartons of 48/6 oz. cans each of tuna; 100 pallets of 2/100 lb. totes each of frozen tuna loins for a total of 20,000 pounds; 100 pallets of 2/100 lbs. cartons each of dehydrated pig ears for a total of 20,000 lbs.; and 100 cartons of 20 lbs. of fresh watermelons each for a total of 2000 lbs. The filer currently submits the quantity of each line entry to U.S. Custom's ACS when entry is made, and it subsequently is transmitted to FDA's OASIS. FDA requests comment on whether changes in quantity will occur after the deadline for prior notice and, if so, how commonly changes occur and how significant the changes usually are.

v. *The lot or code numbers or other identifier.* FDA is proposing to require the submission of the lot or code numbers or other identifiers that are specific to the article of food, if applicable, as an element of the identity of the product (proposed § 1.288(f)(1)(v)). These numbers are the identification number or code of a production lot and are needed to more specifically identify a product. Currently, there may be more than one identifier represented in an entry line. The prior notice system will be developed to accept more than one lot identifier per article.

f. *The manufacturer.* As provided for in section 801(m)(1), FDA is proposing to require the submission of the identity of the manufacturer of each article of food (proposed § 1.288(f)). The filer currently submits the identity of the manufacturer to U.S. Custom's ACS when entry is made, and it subsequently is transmitted to FDA's OASIS.

g. *The growers, if known.* As required by section 801(m)(1), FDA is proposing to require the submission of the identity of all growers of each article and the growing location if different from the grower's business address, if known at the time of submission of the prior notice (proposed § 1.288(g)). If the submission is amended, the proposed rule provides that the identity of all growers must be provided if known at the time of the amendment (proposed § 1.290(d)). FDA wants to emphasize that section 801(m)(1) of the act states that grower information must be submitted if it is known. Thus, this information is not optional: if it is known, it must be submitted. If a product is sourced from more than one grower, the prior notice must provide the identification of all growers, if known. The FDA Prior Notice System will be developed to accommodate submission of up to three different growers.

FDA solicits comments on two particular aspects of the statutory requirement that the grower be identified. First, does the act give FDA any flexibility to exempt or otherwise treat differently so-called processed foods produced with products from more than one grower? Second, does the term ''grower'' include a harvester or collector of wild products, e.g., some fish and botanicals?

h. *The originating country.* As provided for in section 801(m)(1), FDA is proposing to require the submission of the identity of the originating country of the article of food (proposed § 1.288(h)). This term is defined in proposed § 1.277(c)(2).

i. *The shipper.* As provided for in section 801(m)(1), FDA is proposing to require the submission of the identity of the shipper of the article of food (proposed § 1.288(i)). FDA considers the shipper to be the person who arranges for a shipment to get to its first destination in the United States. The shipper typically is responsible for initiating the bill of lading or airbill covering the transportation of the article by the carrier. The shipper is usually a foreign firm that is located or maintains an address in the country from which the article was shipped. The shipper is typically not the carrier.

j. *The country of shipping.* As provided for in section 801(m)(1), FDA is proposing to require the submission of the identity of the country from which the article of food was shipped (proposed § 1.288(j)). This term is defined in proposed § 1.277(c)(3).

k. *Anticipated arrival information.*

i. *The anticipated port of entry.* As provided for in section 801(m)(1), FDA is proposing to require the submission of the anticipated port of entry at which the article of food will arrive in the United States (proposed § 1.288(k)(1)(i)). ''Port of entry'' is defined in proposed § 1.277(c)(5).

ii. *The anticipated date of arrival.* FDA is proposing to require the submission of the anticipated date when the article of food will arrive at the port of entry in the United States (proposed § 1.288(k)(1)(ii)). FDA believes that this information is necessary to plan inspections.

iii. *The anticipated time of arrival.* FDA is proposing to require the submission of the anticipated time when the article of food will arrive at the port of entry in the United States (proposed § 1.288(k)(1)(iii)). FDA believes that this information is necessary to plan inspections.

FDA is proposing to require the prior notice to be updated if any of the anticipated arrival information changes after the submission of the prior notice (proposed § 1.288(k)(2)). Updates are necessary so FDA can change its plan when anticipated arrival information changes. The conditions appropriate for updates are provided in proposed § 1.294.

l. *The port where entry will be made for U.S. Customs purposes.* FDA is proposing to require the submission of the identification of the port where entry will be made for U.S. Customs purposes (proposed § 1.288(l)). Often, this port will be different than the port where the article of food arrived in the United States. FDA believes that this information is necessary to facilitate communication with U.S. Customs and FDA field offices concerning the adequacy of the prior notice. It is also necessary to enable FDA to coordinate resources for inspections, examinations, or sampling.

m. *The anticipated date of U.S. Customs entry.* FDA is proposing to require the submission of the anticipated date of entry for U.S. Customs purposes (subpart 1.288(m)). FDA believes that this information is critical to enable it to allocate resources for inspecting imported food shipments and efficient communication with and between U.S. Customs and FDA field offices.

n. *The importer, owner, and consignee.* Under section 801(m)(2)(B)(i) and proposed § 1.278(e)(2), food that is offered for import with no or inadequate notice may not be delivered to the

importer, owner, or consignee. Thus, FDA is proposing to require their identities so that FDA knows who they are and can take steps to ensure that food refused admission under section 801(m) is not delivered to them illegally. FDA is proposing that only one importer, owner, and consignee can be identified for each prior notice. Under most circumstances, FDA believes the importer will be the importer of record for U.S. Customs Entry Summary purposes.

o. *The carrier.* FDA is proposing to require the identity of each carrier or transporter firm that transports the article of food from the country from which the article was shipped into the United States. This identification includes the submission of the Standard Carrier Abbreviation Code. Identification of the carrier is necessary to enable FDA and U.S. Customs to identify the appropriate article of food for inspection or holding when the food arrives in the United States. FDA notes that a carrier typically is a different firm than the shipper. The filer currently submits carrier information to U.S. Custom's ACS when entry is made, and it subsequently is transmitted to FDA's OASIS.

5. What Changes are Allowed to a Prior Notice After it Has Been Submitted to FDA? (Proposed § 1.289)

FDA is allowing additional information to be supplied once a prior notice is submitted in two situations. FDA believes that under the standards in section 801(m)(2)(A) for establishing the timeframes for submission of prior notice, amendments are appropriate when complete product identity will not exist by the deadline for the submission of a prior notice. As described in more detail elsewhere, FDA believes that these situations largely involve fresh produce and fish harvested in countries close to the United States, e.g., Mexico and Canada. Second, FDA believes that it must have accurate arrival information in order to ensure it can inspect an article or take other appropriate action. In the event that other information in the prior notice must be changed, no amendment or update is permitted. The submitter must cancel the initial prior notice and submit a new one.

6. Under What Circumstances Must You Submit a Product Identity Amendment to Your Prior Notice After You Have Submitted It to FDA? (Proposed § 1.290)

FDA is proposing that the prior notice must be amended if all information about the identity of the food required by proposed § 1.288(e)(1) does not exist by noon of the calendar day before the day of arrival. The submitter must indicate his or her intention to amend the information at the time the initial prior notice is submitted. FDA is proposing that the prior notice may be amended only once. FDA is limiting the number of times a prior notice may be amended because FDA believes that it would be an inefficient use of its review and planning resources to address intermediate, still incomplete submissions. FDA wants to encourage submissions that are as complete as possible to allow FDA to deploy its resources effectively. FDA requests comment on our proposal to restrict the number of amendments to one.

FDA is proposing that only the information required by proposed § 1.288(e)(1) and indicated in the initial prior notice as being subject to amendment may thereafter be amended. FDA is proposing to limit the information that may be amended in a prior notice to the product identification information required in proposed § 1.288(e)(1). As we explain elsewhere in this preamble, we believe that in most situations, complete product identity will exist by noon of the calendar day before the day of arrival. However, we recognize that in certain limited circumstances, such as wild-caught fresh fish and fresh produce with many varieties that are caught or harvested close to the time of shipment in locations close to the U.S. border, this specificity may not be known by noon of the calendar day before the day of arrival. FDA is proposing that the last two digits of the FDA product code and other product identity information that provides the specific identity of the article may be amended when this information does not exist by the prior notice deadline.

For example, there may be occasions when an entry of lettuce is ordered and prior notice is submitted by noon the calendar day prior to arrival, but the specific variety of lettuce that will be shipped does not exist because the growers that supply the shippers have not yet harvested their crops. At or before the time when the article is placed in the carrier for shipment, however, the complete identity of the article exists and the prior notice must be amended to identify the specific type of lettuce (e.g., romaine or leaf).

A prior notice may not be amended to change completely the identity of the article, e.g., a prior notice identifying the food as lettuce may not be amended to identify the food as pears.

If an article of food is not covered by a specific FDA product code, e.g., a root vegetable not more specifically described by numerical code in the FDA product code builder, then the last two numbers of the product code may be provided as ''99'' which means root vegetables, not elsewhere classified. However, this prior notice cannot be amended later to identify the product as carrots because, even though carrots are root vegetables, there is an FDA product code that is specific to carrots and thus it should have been used in the initial notice. We plan to design the prior notice system so that it will not acknowledge that a prior notice submission is completely filled out if it does not contain a seven-digit product code. The system will be designed to provide, where appropriate, a reminder about the need for amendment with the electronic message acknowledging receipt of the initial submission.

The information that may be amended also includes the common or usual or trade name, brand name, lot or code or identification numbers, and quantity.

FDA is proposing that, if the identity of the grower was not provided at the time the prior notice was submitted because it was not known at that time but the identity is known at the time of the amendment, the amendment must include information that identifies all known growers.

7. What is the Deadline for Product Identity Amendments Under § 1.290? (Proposed § 1.291)

FDA is proposing a 2 hour minimum deadline for amendments submitted under proposed § 1.291, or updates submitted under proposed § 1.294.

FDA believes that the deadline will allow submitters to provide FDA the information it needs in order to effectively assess whether a particular shipment of food needs to be investigated and if so, to ensure FDA personnel are present to do so when the food arrives at the port of entry, while allowing submitters to amend and/or update information that may not be known with exact certainty by noon of the prior calendar day. FDA considered the type of food in proposing the deadline for amendment to the product identity and updates to the anticipated arrival information.

FDA believes that product identity amendments are most likely to be needed to accommodate articles imported by land or air rather than water arrivals. FDA also recognizes that this limitation on amendments may also affect the practice of ''topping off a container'' by filling unused space in the container or truck bed with last-minute shipments of other food products not covered by prior notice.

FDA notes that under its amendment proposal ''topping off'' with the article of food that is already the subject of a prior notice would be allowed. To the extent ''topping off'' with non-food items occurs, this practice would not be affected. FDA believes, however, that this limitation is dictated by the Bioterrorism Act's requirements and moreover is necessary to ensure that FDA has adequate notice of all FDA-regulated food imports such that FDA can deploy its resources effectively. In this case, a separate prior notice would be required for these foods not already covered by a prior notice. FDA solicits comment how common ''topping off'' is and the quantities of food involved.

8. How Do You Submit a Product Identity Amendment or An Arrival Update to a Prior Notice? (Proposed § 1.292)

FDA is proposing to limit the way in which a prior notice may be amended or updated. FDA is proposing that a product identity amendment or an arrival update to a prior notice may be submitted only in the same manner as an initial prior notice; that is, electronically to FDA through FDA's Prior Notice System. Only the information concerning product identity and grower identity can be electronically amended under proposed § 1.290. Only the information concerning the anticipated location, date, and time of arrival and grower identity can be electronically updated under proposed § 1.294.

FDA proposes to design its Prior Notice System to require identification of the type of submission (Initial, Amended, Updated) and to be capable of differentiating amongst them. If FDA's Prior Notice System is unable to receive submissions electronically, amendments or updates may be communicated directly to FDA using a printed version of the Prior Notice Screen, and delivered either in person, by fax, or by e-mail to the FDA field office with responsibility over the geographical area in which the port of entry is located, as provided by proposed § 1.287(b). If the identification of the anticipated port of entry is being updated, and the FDA system is down, the updated printed version of the Prior Notice Screen should be delivered to the FDA field office with responsibility over the port covered by the initial submission. FDA intends to issue guidance for communication between the field office receiving the initial prior notice and the field office covering the updated port of entry.

9. What Are the Consequences If You Do Not Submit a Product Identity Amendment to Your Prior Notice? (Proposed § 1.293)

FDA is proposing that if a U.S. importer or U.S. purchaser, or their U.S. agent, informed FDA in a prior notice that the submission would be amended, but subsequently does not amend it appropriately and within the applicable timeframe, then the prior notice is inadequate for the purposes of proposed § 1.278(a). By telling FDA that the prior notice will be amended they are telling us that it is incomplete. We therefore will be waiting for complete information upon which to make our inspection decision. Without complete product identity, FDA cannot complete the assessment of whether to inspect or take other action when the food arrives in the United States. The consequences of inadequate prior notice are the same as the consequences for failing to provide prior notice; the food shall be refused admission and held at the port of entry unless FDA directs its removal to a secure facility. The consequences are more fully described previously in the discussion of proposed § 1.278.

10. What Must You Do If the Anticipated Arrival Information (Required Under § 1.288(k)(1)) Submitted in Your Prior Notice Changes? (Proposed § 1.294)

FDA is proposing to require the submitter to update anticipated arrival information submitted in a prior notice, if the anticipated information changes after the submission. The types of information FDA expects may change between submission of prior notice and actual importation are the date, time, and location of arrival. Although the statute requires only anticipated port of entry, accurate, up-to-date arrival information (if different) is necessary for FDA field offices to reschedule inspections. FDA thus believes that it has the authority to require this information.

If anticipated arrival information submitted in a prior notice changes, FDA is proposing that the submitter be required to provide the new port of entry (proposed § 1.294(a)(1)), and the new time of arrival in an update electronically filed in the Prior Notice System (proposed § 1.294(c)). FDA is proposing that if the time of arrival is expected to be more than 1 hour earlier (proposed § 1.294(a)(2)) or more than 3 hours later (proposed § 1.294(a)(3)) than the anticipated time of arrival, the time of arrival must be updated. FDA is proposing that, if the identity of the grower was not provided at the time the prior notice was submitted and that identity is known at the time of the update, the amendment must include information that identifies growers (proposed § 1.294(b)).

The FDA Prior Notice System will be designed to accommodate updates. As stated above, FDA is proposing to design its Prior Notice System to require identification of the type of submission (Initial, Amended, Updated) and to be capable of differentiating amongst them.

FDA is proposing to limit the time within which a prior notice may be updated. The proposed regulation would require updated information to be submitted in accordance with the deadline for amendments under proposed § 1.291, that is, an update to a prior notice must be submitted 2 hours prior to arrival.

IV. Analysis of Economic Impacts

A. Preliminary Regulatory Impact Analysis

FDA 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. FDA has determined that this proposed 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, OMB has determined that

this proposed rule, when final, will be a major rule for the purpose of congressional review.

1. Need for Regulation

Section 307 of the Bioterrorism Act (Public Law 107–188), requires advance notice of all food imported or offered for import into the United States. If FDA fails to issue a final regulation by December 12, 2003, section 307 of the Bioterrorism Act provides for a default minimum period of advance notice that is not fewer than 8 hours and not more than 5 days before an article of food is imported or offered for import into the United States. This regulation is needed to implement the statutory provisions.

2. The Reason for the Regulation

Getting food from the farm or sea to the plate involves a complex system of production and distribution. The system works using local knowledge and information; each participant needs to know only as much about the overall system as is necessary for his or her business. Market prices convey most of the information necessary for the ordinary production and distribution of food. In the event of an actual or suspected contamination of the food supply, however, more complete information is needed where it can be centrally used. The suspect food must be traced backward and forward through the distribution chain, both to protect consumers and to find the source and cause of the event.

No individual firm or organization has sufficient financial incentive to establish a central information system relating to food safety for the entire economy. The nation's food producers and importers as a whole would benefit from such a system because it would be easier to uncover and solve problems, but the private costs to create the system would probably be prohibitive for any single firm or third party organization.

The events of September 11, 2001, led Congress to conclude that public creation and provision of an information system is necessary. The Bioterrorism Act and its implementing regulations would establish an information system that would allow FDA to have a more integrated picture of the food distribution system. This particular regulation addresses one important aspect of this information system: the need to know what imported foods are entering the United States, where they came from, and when they will arrive. FDA is proposing three regulations to address these needs so the costs and benefits of any one regulation will be closely associated with related provisions in other proposed rules. With the regulations in place, the agency would have the additional tools necessary to help deter and respond to deliberate threats to the nation's food supply as well as to other food safety problems.

3. Proposed Rule Coverage

This proposed rule would apply to all FDA-regulated food for human and animal consumption imported or offered for import into the United States with the exception of food carried in a traveler's personal baggage for personal use. As required by the Bioterrorism Act, the notification must provide the identity of the article, the identity of importer, manufacturer, shipper, and grower (if known), the originating country, the country from which the article was shipped, and the anticipated port of entry. In addition, the notification must provide the identity of the person who submits the prior notice, the owner, the consignee, the carrier, the U.S. Customs entry number, anticipated time and date of arrival, and, if the food has already been refused admission and required to be held, the location where it is held.

A growing percentage of food consumed in the United States is imported; the value of food imports is now close to $50 billion per year. (Ref. 2) In the aftermath of the terrorist attacks on the United States on September 11, 2001, Congress determined that the existing requirements for the importation of FDA-regulated food products were insufficient to protect the safety of the U.S. food supply.

Before September 11, 2001, FDA had approximately 150 personnel in the field processing imported food entries based on FDA's programs and assignments, all using guidance documents, such as Import Alerts, Compliance Policy guides, and other manuals. After September 11, 2001, FDA hired three hundred additional counterterrorism Consumer Safety Officers primarily for food imports. This step alone is insufficient to ensure the safety of food imported or offered for import into the United States.

When deciding which imported food shipments to physically inspect and sample, FDA inspectors consider, among other things, compliance programs, assignments, import alerts, and whether the product is a low-risk or high-risk food. New requirements imposed by Section 307 of the Bioterrorism Act will require importers to give notice to FDA of incoming articles of food before the shipment reaches a U.S. border, rather than when the shipment arrives at the U.S. border or as part of the official U.S. Customs entry. Requiring prior notice of imported food shipments will allow FDA inspectors to have earlier information on foods that are coming into the United States, which will enable FDA to better deploy its inspection resources and to use this increased amount of information in cases where FDA action against the food is warranted, e.g., a credible threat to the food supply is suspected.

Number of Establishments Affected

Using 2001 FY information from FDA's OASIS system (industry codes 02 through 52, 54, and 70 through 72), FDA has determined that there are approximately 77,427 importers and consignees who receive imported food shipments. Under the proposed rule, the U.S. importers or U.S. purchasers (or their agents) of the products will be responsible for submitting a timely and accurate prior notice to FDA. Using information from the OASIS system, FDA was also able to determine that there are approximately 100,000 foreign manufacturers (of a finished product). Foreign manufacturers are not responsible for submitting prior notice, and therefore, while not unaffected by prior notice, foreign manufacturer costs associated with this proposed rule will be assumed to be spread across the supply chain and therefore are not directly addressed in this analysis.

FDA requests information on the size of establishments likely to be affected by this rule, including the foreign manufacturers of food products and the importers and consignees receiving the imported food shipments.

New and closing importer establishments

In addition to the U.S. importers currently in existence, in future years some new import businesses will open and some existing import businesses will close. According to the Small Business Administration Office of Advocacy, in 2001 about 10 percent of all businesses were new and 10 percent of all businesses closed. These new importers would have to become familiar with the FDA prior notice system, and some may need to obtain computer equipment and Internet access to comply with prior notice requirements.

Baseline

FDA considers the baseline for this analysis the current state of the world, pre-statute, and we assume this baseline has zero costs and benefits.

Current State of The World

The majority of the information that will be required by section 307 of the Bioterrorism Act now is currently supplied at the time of entry by a U.S. Customs broker or self-filer, and usually is submitted electronically. Although importers already must notify U.S. Customs of entries, the Bioterrorism Act requires notification to FDA prior to the food shipment reaching the U.S. border or point of crossing. This requirement will change the current practice of notifying U.S. Customs and then subsequently FDA upon arrival (and as long as 15 days past arrival based on the time the Consumption Entry may be filed with U.S. Customs) at a U.S. port of entry.

FDA's OASIS reporting system shows that approximately 2.5 million food entry lines were imported via sea and air transportation in FY 2001. Information on food-importing practices indicates that U.S. Customs and FDA are notified of imported food products traveling to the United States by vessel before the products' arrival. Vessels can notify U.S. Customs months before the actual shipping date, but U.S. Customs will not certify the entry until 5 days before the ship is expected to dock at a U.S. port. FDA is notified of the shipment then, through U.S. Customs, as early as 5 days before the vessel's arrival at a U.S. port.

Importers bringing food products in by airplane can notify U.S. Customs of their intent to import food into the United States no more than 24 hours before the scheduled flight departure time, but cannot certify their cargo manifests with U.S. Customs until the plane has taken off from the airport of the exporting country (''wheels-up''). FDA is then notified through U.S. Customs of the plane's scheduled arrival. U.S. Customs has informed FDA that they receive flight information for 87.6 percent of the flights at time of ''wheels up.''

FDA's OASIS reporting system shows that around 2.2 million entry lines of food were imported into the United States via ground transportation in FY 2001. The usual practice today for food brought in by truck or train (mainly products coming directly from Canada or Mexico) is not to notify U.S. Customs and FDA until their actual arrival at a U.S. border or point of entry. (Filers can certify their entry data up to 24 hours before arrival at the border, but U.S. Customs does not give a ''screening response'' to the entry until actual arrival.) Even though these importers most likely have the invoices and orders for these products in advance, they do not currently notify U.S. Customs and FDA until their arrival at the border.

4. Regulatory Options Considered

We analyzed five options for a prior notice regulation:

1. Current state of the world, pre-statute (baseline).

2. Prior notice time of 4 hours or less; electronic submission of information. This option would require the persons responsible for all food imported or offered for import into the United States to notify FDA of their intent to import articles of food through a United States based-importer or purchaser (or their U.S.-based agent). This option applies to all imported foods, except for food exclusively regulated by USDA and food imported with personal baggage for personal use, regardless of entry type or mode of transportation used for import. Submission of prior notice information (including addresses of all importers, owners, manufacturers, consignees, identity and quantity of food, originating country, country of shipping, date, expected time of arrival, expected port of entry, and grower if known) must be electronic.

3. Require all components of option 2, but lengthen the minimum prior notice time to 8 hours (statutory self-executing provision).

4. Require all components of option 2, but lengthen the prior notice time to noon of the calendar day prior to crossing the U.S. border.

5. Require all components of option 4, but allow some prior notice information to be revised prior to arrival at a U.S. port (proposed option).

Option one: Current state of the world, pre-statute.

Having no prior notice requirements is option 1 in our analysis. The statute requires that FDA issue prior notice regulations, so this is not a legally viable option. However, OMB cost-benefit analysis guidelines recommend discussing statutory requirements that affect the selection of regulatory approaches. These guidelines also recommend analyzing the opportunity cost of legal constraints that prevent the selection of the regulatory action that best satisfies the philosophy and principles of Executive Order 12866. This option will serve as the baseline against which other options will be measured for assessing costs and benefits.

Option two: Minimum prior notice timeframe of 4 hours or less; electronic submission of information; any change in information requires resubmission.

Costs: The party responsible for transmitting prior notice to FDA will incur administrative and notification costs to comply with this proposed regulation. The responsible party likely will become aware of the prior notice requirement through normal business activities: reading the trade press, reading industry news, FDA outreach, trade outreach, or conversation with other business operators who also must comply with prior notice. Once the U.S. importer or U.S. purchaser of the food becomes aware of the regulation, he or she will need to learn the requirements of the regulation, which will require finding a copy of the prior notice requirements and reading and understanding them.

To become familiar with the requirements for this rule, FDA estimates that it initially will take responsible parties with Internet access about 1 hour to research the prior notice requirements, and responsible parties without readily available Internet access about 2 hours to research the requirements. Comments from both the Produce Marketing Association (PMA) and the National Food Processors Association (NFPA) indicate that about 96 percent of the industry has readily available Internet access.

FDA used wage rates from the Bureau of Labor Statistics National Compensation Survey (Ref. 3), doubled to include overhead costs, to estimate the cost of the time to research the prior notice requirement. For an administrative worker, the cost per hour is $25.10: for a manager, $56.74. FDA assumes that only the administrative worker's time will be used to research the prior notice requirements. As shown in table 1, total costs of this research activity for firms with Internet access are $1,865,683; for firms without Internet access, the total research costs are $155,469.

Given the 10 percent turnover in business reported by the Small Business Administration, FDA expects 10 percent of the total search costs to be incurred in each subsequent year after prior notice is in effect as new firms enter the industry. This cost and the present value of this cost, using a 7 percent discount rate, are also shown in table 1.

TABLE 1.—COST TO RESEARCH PRIOR NOTICE

Cost to Research Prior Notice	With Internet Access	No Internet Access
Number of Firms	74,330	3,097
Administrative wage rate per hour (including overhead)	$25.10	$25.10

TABLE 1.—COST TO RESEARCH PRIOR NOTICE—Continued

Cost to Research Prior Notice	With Internet Access	No Internet Access
Total time to research regulation	1 hour	2 hours
First year one-time research costs	$1,865,683	$155,469
Annual one time research costs for new firms entering industry in subsequent years	$186,568	$15,547
Present value of cost of firms entering the industry	$2,665,257	$222,100
Total research cost burden	$4,530,940	$377,569

All prior notices must be submitted electronically, so we will assume that the 3,097 responsible parties without Internet access will have to purchase a computer and gain Internet access to actually transmit the information via a prior notice screen. This one-time computer cost and a recurring Internet access cost for these facilities of $7,559,777 are shown in table 2.

Again, given a 10 percent turnover rate for businesses in the import industry, we expect there to be new businesses in the future that may need to purchase electronic transmitting capabilities. However, it becomes more unlikely with the passage of time that persons will be purchasing this computer equipment solely to comply with prior notice. Therefore, a present value of this cost is not calculated.

TABLE 2.—FACILITIES AND RESPONSIBLE PARTIES WITHOUT INITIAL INTERNET ACCESS

Number of Facilities	3,097
Computer equipment cost per facility	$2,000
Annual cost of Internet access ($20 per month x 12)	$240
Search costs for equipment and access ($25.10 x 8 hours)	$201
Total first year one time cost of electronic transmitting capacity	$7,559,777

TABLE 2.—FACILITIES AND RESPONSIBLE PARTIES WITHOUT INITIAL INTERNET ACCESS—Continued

Annual one time cost of electronic transmitting capacity for firms entering industry in subsequent years	$755,978
Total electronic transmitting costs	$8,315,755

FDA used OASIS information to find out that 4.7 million entry lines for food were imported into the United States in FY 2001. An ''entry line'' is an FDA term used by the OASIS reporting system, which refers to a line on an invoice that reflects a certain article specific to manufacturer or packaging: e.g., 100 cases containing 48 six-ounce cans of tuna. This 4.7 million entry line total includes the 2.2 million entry lines for food that came into the United States in 2001 via ground transportation (trucks and trains) and the 2.5 million entry lines for food that came into the United States in 2001 via airplane and vessel.

The entry line totals for FY 2001 do not include food brought into the United States as personal baggage with the food intended for sale or other distribution, not for personal use. Under the proposed rule, persons bringing food into the United States in this manner, however, are required to submit prior notice to the FDA. FDA does not know how common the practice is of importing food for non-personal use as part of personal baggage. For FY 2002, there were only 18 entry lines associated with food imported as U.S. mail and 486 food entry lines imported by courier. FDA believes that entries of food imported as part of personal baggage but not for personal use will fall somewhere between mail and courier entries. Since any number of entries in this range is minimal as compared with the 4.7 million total OASIS entries, FDA likewise believes the costs associated with prior notice for food in personal baggage entries will be minimal and thus these costs are not included in this analysis. FDA requests comment on this assumption.

According to OASIS data, the average imported entry contains 2.6 lines, which means that there are typically more than two different articles of food per import entry: e.g., 100 cases of tuna and 50 cases of canned peaches in the same shipment. A prior notice must be filed for each of the lines in an entry.

U.S. Customs Form 3461, Entry and Immediate Delivery Application, OMB No. 1515–0069, is the entry document upon which information is provided to U.S. Customs by which it makes its decision to release the merchandise. The burden estimate on U.S. Customs Form 3461 for purposes of the Paperwork Reduction Act is 15.5 minutes. The FDA calculation of average time for completion of the prior notice includes verification of accuracy of the data and supervision time.

FDA estimates that it will take, on average, 1 hour to prepare a prior notice each time an import entry of 2.6 lines is submitted, including the time it takes to update or amend information for each entry line as necessary. This time is an average; some prior notices will take longer than 1 hour to complete and other prior notices will take less than 1 hour to complete. FDA requests comment on the time it will take to complete a prior notice form, including the time it will take for amendments and updates to the information.

This hour includes 45 minutes of an administrative worker's time to gather information to initially complete the screen and then update the information as necessary, and then 15 minutes of the manager's time to verify that the information is correct. Assuming that there is an average of 2.6 lines per entry, and each line requires a prior notice, then each line is estimated to take about 23 minutes to complete.

Using the OASIS information that the average imported entry contains 2.6 lines; we can then divide the 4.7 million OASIS lines by 2.6, which results in 1,807,692 expected import entries. Table 3 shows that the annual cost of prior notice submissions based on 1,807,692 entries would be $59,689,990.

TABLE 3.—COST TO FILL OUT PRIOR NOTICE SCREENS BY IMPORT ENTRY (MUST BE ELECTRONIC)

Administrative worker time at $25.10 wage rate	45 minutes
Manager time at $56.74 wage rate	15 minutes
Administrative worker costs per entry	$18.83
Manager costs per entry	$14.19
Total Cost per import entry	$33.02
FY 2001 OASIS entry total based on 4.7 million lines	1,807,692
Total Annual Costs of all prior notice screens based in lines, and including updates and amendments to the information	$59,689,990

FDA Costs: We assume that FDA's information technology (IT) costs for

this option and each option hereafter are the costs of developing a stand-alone, web-based, electronic system to receive prior notice information and then to respond electronically with an acknowledgement of the transmission to the submitting party. The stand-alone prior notice system will be used until U.S. Customs new automated system, ACE, becomes operational. FDA will coordinate with U.S. Customs to develop ACE to accommodate the information required by prior notice. Once ACE is operational, it will simplify prior notice transmissions. For now, building a stand-alone IT system to handle prior notice submissions will require design, development, implementation, maintenance, modernization, and upgrades. These costs include the labor hours, hardware, and software costs needed to make the prior notice system operational. Table 4 shows that FDA estimates the costs to the agency for setting up the prior notice system to be about $4.4 million. This total cost includes FDA personnel, contractor development of the hardware and software needed, industry outreach and training, and a computer firewall.

TABLE 4.—FDA PRIOR NOTICE SYSTEMS COSTS

Hardware	$500,000
Analysis, Design, Implementation	$3,000,000
Software licenses and Security	$500,000
Network Interface	$200,000
FTEs	2
Cost per FTE	$110,588
Total FTE costs	$221,176
Total Systems Cost	$4,421,176

Current operating practices affected: A 4-hour minimum prior notice requirement would be less likely to change current food importing practices than would a longer minimum time requirement for prior notice submission. Some comments received indicated that it would be preferable if the minimum prior notice time were set at 4 hours or less. Comments requested the shorter minimum prior notice time because the source of some food products often is close to the U.S. border, and some products are perishable. However, it is the U.S. importer or U.S. purchaser or their U.S. agent who is responsible for submitting the prior notice, and the information required in prior notice should be sufficiently fixed after the order is placed and will not depend on the location of the source of the food product.

How many business practices will be affected by prior notice requirements largely depends on how early the orders for the food products are placed compared to the time by which prior notice must be submitted. Most orders for products, even for those of a perishable nature, are often placed days or weeks if not months before the actual delivery date. Therefore, if the order for the product was sent a week, or even 1 day, before the delivery date, a minimum prior notice time of 4 hours should not cause any delay in the order. FDA requests comments on this assumption.

Also important in determining how business practices will be affected by the prior notice requirements is when the prior notice was submitted compared with when the shipment corresponding to that prior notice was loaded onto a vehicle. For example, if the prior notice was submitted as soon as the order was received, or even a few hours before loading the vehicle, there is a possibility that unforeseen factors, including composition of the actual shipment, may cause the prior notice information submitted to not match the actual shipment on the vehicle. However, if the prior notice is not submitted until the vehicle is actually loaded, the probability of submitting an incomplete prior notice is greatly reduced. Thus, when the order for the shipment is received, when the prior notice is submitted, and when the vehicle is loaded play large roles in how much the requirement for prior notice will affect operating practices for those importing some perishable products from Mexico and Canada. FDA requests specific information about how business practices for all operations could change as a result of the prior notice requirement.

If importers have orders for perishable products from Canada and Mexico filled more than 4 hours before scheduled arrival at a U.S. border point, then the only change in business practice that should occur is when they will submit their prior notice to FDA.

There will be those shipments by vehicle, however, for which the order was not received in advance of the shipping time, those shipments for which the quantity and composition of the product has changed since the time when the prior notice was submitted, and those shipments for which other changes to the information on the prior notice must be made. Importers, whose shipments fall into this ''changed'' category, must resubmit the prior notice or risk that their products will be refused admission into the United States and held if the notice is deemed inadequate.

FDA does not have information on the number of ground shipments that, under this option, would need to submit or resubmit prior notice information due to a late order or a change in the information provided on the original notice. We know that changes will occur for some percentage of all prior notices; until better information is available, we will assume that 20 percent of the fresh produce and seafood being imported to the United States from Canada and Mexico would have a reason for which their original prior notice submission must be changed and resubmitted less than 4 hours before entry.

FDA chooses 20 percent as the percent of prior notices that need to be submitted based on information that most orders for products are placed well in advance of the actual shipping date, most orders are filled with the exact product and quantity the customer requests, and the 4 hour prior notice entry time is minimal when compared to when the order was actually received. Depending on the entry point, 40 to 100 percent of shipments are loaded onto vehicles less than 4 hours before entry. We chose one-half of the lower percent as the percent of prior notices that would need to be resubmitted under this option.

The following paragraphs and tables outline how FDA calculated a loss in product value to account for the time that fresh produce and seafood being brought by ground transportation into the United States might have to wait to cross the border due to prior notice resubmission. This wait at the border occurs if prior notice is resubmitted with revised information regarding the shipment when the shipment is closer to the border than the 4 hours required; the transporter of the shipment must wait for the minimum prior notice time to elapse before crossing the border or risk being refused entry.

Table 5 of this document shows the volume of fresh, perishable produce imported into the United States from Mexico for the calendar year 2001 (Ref. 4). Produce was included in the count if it was considered 'highly or very highly perishable' (Ref. 5) and if the produce was not regulated under section 8e of the Agricultural Marketing Agreement Act of 1937 (AMAA). Importers of products currently regulated by the Agricultural Marketing Agreement Act, e.g., tomatoes, avocados, oranges, are required to notify USDA at least 1 day prior to U.S. entry to make arrangements for inspection

and certification of the product they are importing. These products therefore are not included in the count because they already have business practices in place that would accommodate the prior notice period. FDA requests comments on the perishability of the produce that is used in this count.

Multiplying the volume of Mexican produce that was imported into the United States in 2001 by the current U.S. border prices per pound (Ref. 6) for these products gives an estimate of wholesale revenue. Then we convert the wholesale revenue to retail revenue using the retail price mark-up on produce in the United States, which can range from 100 percent to 600 percent (Ref. 7). We will increase the wholesale revenue by 100 percent in these estimates to represent a reasonable retail price mark-up rate across produce commodities in the United States. We will reexamine our choice of the 100 percent mark-up rate in a sensitivity analysis presented later in the costs section.

Assuming that perishable produce has an average life span of 7 days, we can then estimate the value of the time lost (4 hours) for 20 percent of the imports waiting to cross the border as a 2.4 percent loss (4 hours out of 168 hours) in the product's value. Applying this percent loss in value to one-quarter of the total retail revenue of imported Mexican fresh produce results in a $16,600,920 loss in produce value.

TABLE 5.—FRESH PRODUCE IMPORTED FROM MEXICO

Perishable produce from Mexico	Total Volume for 2001 (100,000 lb units)	Current Wholesale Price per lb. (Sept. 2002)	Total Revenues Wholesale
Cucumbers	6491	0.29	188,239,000
Peppers (all varieties)	6088	0.53	322,664,000
Squash	4158	0.71	295,218,000
Mangoes	3461	0.57	197,277,000
Papaya	1587	0.45	71,415,000
Broccoli	1138	0.65	73,970,000
Eggplant	887	0.40	35,480,000
Asparagus	856	1.29	110,424,000
Sweet Corn	828	0.26	21,528,000
Strawberries	676	0.96	64,896,000
Beans	559	0.58	32,422,000
Radishes	516	0.31	15,996,000
Fruits-Other	426	2.04	86,904,000
Vegetables-other	365	2.80	102,200,000
Greens	298	0.48	14,304,000
Spinach	197	1.375	27,087,500
Green Peas	129	2.20	28,380,000
Okra	112	0.80	8,960,000
Berries-misc.	78	1.67	13,026,000
Raspberries	32	4.40	14,080,000
Artichokes	23	1.50	3,450,000
Mushrooms	7	1.60	1,120,000
Endive	4	0.37	148,000
Escarole	2	0.37	74,000
Wholesale Value			$1,729,262,500
Retail Value			$3,458,525,000
2.4% reduction in value for 20% of the products			$16,600,920

We repeat the exercise outlined above in table 5 for Canada, as shown in table 6. Again, until FDA acquires updated information, we will assume that Canadian produce growers use business practices that are similar to those used by Mexican growers. FDA solicits comments on this assumption. While FDA acknowledges that their business practices may be different in some ways, it is possible that Canadian produce growers will also have to adjust business practices so that submitters can comply with the prior notice requirement. We seek comment on this issue.

As with the Mexican produce, only Canadian produce that is highly or very highly perishable and did not fall under the purview of the Agricultural Marketing Agreement Act is included in table 6.

We again calculate the 2.4 percent loss in product value due to the importer having to resubmit prior notice for 20 percent of the Canadian imported fresh produce. This loss in product value due to the 4-hour wait time totals $1,928,765.

TABLE 6.—FRESH PRODUCE IMPORTED FROM CANADA

Perishable Produce from Canada	Total Volume for 2001 (100,000 lb units)	Current Wholesale Price per lb. (Sept. 2002)	Total Revenues Wholesale
Peppers	753	0.30	22,590,000
Cucumbers	627	0.145	9,091,500
Blueberries	401	1.42	56,942,000
Mushrooms	373	1.55	57,815,000
Lettuce-Other	243	0.50	12,150,000
Raspberries	89	2.78	24,742,000
Broccoli	88	0.72	6,336,000
Cherries	37	1.30	4,810,000
Sweet Corn	36	0.22	792,000
Squash	27	0.17	459,000
Spinach	24	1.30	3,120,000
Radishes	11	0.50	550,000
Endive	9	0.17	153,000
Beans	7	0.50	350,000
Strawberries	5	0.575	287,500
Pears	4	0.39	156,000
Green Peas	3	1.60	480,000
Greens	2	0.30	60,000
Eggplant	1	0.29	29,000
Wholesale Value			$200,913,000
Retail Value			$401,826,000
2.4% reduction in value for 20% of the products			$1,928,765

We used the same logic for seafood as we did for produce to account for the possibility of having to resubmit prior notice, i.e., a change in the quantity of seafood in the shipment made after the original notice was submitted, less than 4 hours before scheduled entry. We will use the reduction in the value of perishable imported seafood to account for the cost of a wait at the border while prior notice is resubmitted.

We used information from the annual imported seafood statistics published by the National Marine Fisheries Service (Ref. 8) to estimate the weight and wholesale value in dollars of all fresh, perishable seafood products imported from Mexico and Canada. As we did for fresh produce, we mark-up the wholesale price of the fresh seafood by 100 percent (Ref. 9) to represent the retail value of the products. Then, assuming that perishable seafood will keep for 2 days in a consumer's refrigerator, (Ref. 10) we find that an 4-hour delay in delivery time caused by the prior notice requirement for 20 percent of the products results in a 8.3 percent loss in that seafood's value (4 hours out of 48 hours). Table 7 shows that the lost time results in a $1,863,805 loss on the value of Mexican fresh seafood imports. FDA requests comment on the perishability of the seafood used in tables 7 and 8.

TABLE 7.—FRESH SEAFOOD IMPORTED FROM MEXICO

2001 Fresh Mexican Seafood Products	Pounds	Dollars
Atka Mackerel, fresh	1,995	2,200
Bass, fresh	1,362	2,218
Clam live, fresh	245,498	274,942
Crab live, fresh	405,621	489,856
Crabmeat, fresh	287,531	1,540,130
Flatfish flounder, fresh	1,518	2,199
Flatfish fillet, fresh	1,705	3,100
Flatfish, fresh	678,768	781,883
Groundfish cod, fresh	4,000	2,400
Grouper, fresh	4,056,054	7,399,434
Lobster, live	8,584	50,474
Rock lobster live, fresh	794,224	5,859,260
Mackerel, fresh	147,334	127,873
Marine fish fillet, fresh	2,120,250	7,395,902
Marine fish, fresh	5,448,771	6,681,485
Marine fish scaled, fresh	162,105	125,346
Mollusks live, fresh	2,147	15,272
Octopus live, fresh	31,680	24,214
Oysters live, fresh	39,930	25,040
Salmon Atlantic fillet farmed, fresh	405	2,552
Sardine, sardinella, brisling, sprat, fresh	71,163	7,591
Scallops live, fresh	472,384	1,418,302
Sea Urchin live, fresh	10,501	67,331
Sea Urchin roe, fresh	464,946	4,641,659
Shark, fresh	1,500,877	711,349
Shrimp, shell-on, fresh	452,714	861,897
Snapper, fresh	5,835,775	9,254,300
Squid live, fresh	88,042	39,952
Swordfish, fresh	1,615,546	3,759,096
Trout, fresh	82,958	131,353
Rainbow trout farmed, fresh	80,384	161,526
Bigeye tuna, fresh	9,819	12,200
Bluefin tuna, fresh	82,471	332,250
Tuna, fresh	78,747	155,069
Yellowfin tuna, fresh	2,012,848	3,771,488
Whitefish fillet, fresh	3,590	7,560
Total Wholesale Value	27,302,246	56,138,703

TABLE 7.—FRESH SEAFOOD IMPORTED FROM MEXICO—Continued

2001 Fresh Mexican Seafood Products	Pounds	Dollars
Total Retail Value		$112,277,406
8.3% reduction in value for 20% of products		$1,863,805

Table 8 shows the 4 hours of lost time due to prior notice resubmission for 20 percent of all imported Canadian fresh seafood causes a value loss of $30,929,417.

TABLE 8.—FRESH SEAFOOD IMPORTED FROM CANADA

2001 Fresh Canadian Seafood Products	Pounds	Dollars
Bass, fresh	727,830	740,152
Caviar	20,189	272,770
Clam geoduck live, fresh	155,927	1,097,902
Clam live, fresh	9,144,304	22,064,683
Crab live, fresh	9,479,765	24,066,021
Crabmeat, fresh	27,601	80,431
Crustaceans live, fresh	148,925	574,989
Fish liver and roe, fresh	51,154	229,569
Flatfish flounder fillet, fresh	750,468	1,238,031
Flatfish flounder, fresh	6,264,346	4,367,780
Flatfish halibut Atlantic, fresh	1,948,791	7,542,598
Flatfish halibut Pacific, fresh	12,553,266	39,850,556
Flatfish fillet, fresh	853,224	3,536,120
Flatfish, fresh	1,693,516	796,383
Flatfish sole fillet, fresh	1,099,430	2,968,610
Flatfish sole, fresh	1,062,030	1,096,079
Flatfish turbot Greenland fillet, fresh	700,456	2,069,006
Flatfish turbot Greenland, fresh	862,211	3,146,300
Freshwater fish fillet, fresh	2,824,811	4,970,127
Freshwater fish, fresh	549,956	1,008,302
Groundfish cod Atlantic fillet, fresh	1,646,363	4,489,788
Groundfish cod Atlantic, fresh	4,904,368	5,199,471
Groundfish cod fillet, fresh	107,994	288,644
Groundfish cod, fresh	239,987	249,991
Groundfish cusk, fresh	8,281	22,060
Groundfish cusk, pollock fillet, fresh	218,854	362,293
Groundfish haddock fillet, fresh	708,261	2,109,607
Groundfish haddock, fresh	17,391,202	19,469,582
Groundfish hake fillet, fresh	160,972	93,941
Groundfish hake, fresh	14,070,217	9,182,974

TABLE 8.—FRESH SEAFOOD IMPORTED FROM CANADA—Continued

2001 Fresh Canadian Seafood Products	Pounds	Dollars
Groundfish ocean perch fillet, fresh	5,415,106	10,029,520
Groundfish ocean perch, fresh	898,964	518,431
Groundfish pollock Atlantic, fresh	2,362,637	1,595,615
Groundfish pollock, fresh	161,121	130,308
Herring, fresh	4,009,469	671,338
Lingcod, fresh	612,093	812,597
Lobster, fresh	7,707	60,030
Lobster, live	49,200,925	244,567,173
Rock lobster live, fresh	196,858	1,133,246
Mackerel, fresh	943,155	595,937
Marine fish fillet, fresh	10,272,946	24,235,390
Marine fish, fresh	9,084,029	6,610,870
Mollusks live, fresh	809,461	907,048
Monkfish, fresh	89,861	154,267
Mussels live, fresh farmed	18,545,254	13,693,263
Mussels live, fresh wild	98,842	104,273
Oysters live, fresh farmed	2,918,098	4,378,548
Oysters live, fresh wild	579,011	1,236,868
Perch fillet, fresh	529,366	2,079,677
Perch, fresh	337,273	727,284
Pickerel fillet, fresh	850,256	3,715,248
Pickerel, fresh	1,682,743	3,500,552
Pike, fresh	214,390	395,706
Pike perch, yellow pike, fresh	125,114	197,396
Sablefish, fresh	21,648	48,845
Salmon Atlantic fillet, fresh farmed	28,972,418	97,270,694
Salmon Atlantic fillet, fresh wild	404,012	1,281,582
Atlantic Salmon, fresh farmed	107,101,696	248,809,617
Atlantic Salmon, fresh wild	68,732	84,035
Chinook Salmon, fresh farmed	5,752,197	10,614,163
Chinook Salmon, fresh wild	225,509	530,368
Salmon chum, fresh	1,651,221	1,133,029
Salmon coho, fresh farmed	1,382,572	1,963,499
Salmon coho, fresh wild	183,427	270,138
Salmon fillet, fresh	1,640,485	4,361,707
Salmon, fresh	2,820,957	5,430,272
Pink Salmon, fresh	79,981	60,403

TABLE 8.—FRESH SEAFOOD IMPORTED FROM CANADA—Continued

2001 Fresh Canadian Seafood Products	Pounds	Dollars
Sockeye salmon, fresh	265,505	457,427
Salmonidae, fresh	57,787	149,760
Scallops live, fresh	6,955,476	31,688,064
Sea urchin live, fresh	5,053,710	4,367,434
Sea urchin roe, fresh	11,414	94,706
Dogfish shark, fresh	3,300,398	1,003,294
Shark, fresh	223,788	206,838
Shrimp peeled, fresh	5,401	27,934
Shrimp shell-on, fresh	479,483	1,478,634
Smelts, fresh	509,586	606,463
Snail live, fresh	46,174	121,239
Snapper, fresh	37,316	94,366
Swordfish, fresh	1,809,654	6,488,992
Trout, fresh	1,574,672	2,891,806
Rainbow trout, fresh farmed	361,121 608,347	
Albacore tuna, fresh	25,859	70,076
Bigeye tuna, fresh	426,547	1,448,778
Bluefin tuna, fresh	288,361	2,464,619
Tuna, fresh	13,429	50,299
Yellowfin tuna, fresh	205,812	666,809
Whitefish fillet, fresh	988,816	1,864,542
Whitefish, fresh	8,224,484	11,262,979
Yellow perch fillet, fresh	1,174,798	6,401,844
Total Wholesale Value	382,663,829	931,608,947
Total Retail Value		$1,863,217,894
16.7% reduction in value for 20% of products		$30,929,417

Table 9 presents a summary of the costs associated with option 2. Also presented in table 9 is the present value of the costs associated with this option, calculated using the OMB-recommended discount rate of 7 percent.

TABLE 9.—SUMMARY OF COSTS FOR OPTION 2

Research costs	$4,908,509
Computer acquisition costs	$8,315,755

TABLE 9.—SUMMARY OF COSTS FOR OPTION 2—Continued

Annual costs to fill out prior notice screens (including updates and amendments)	$59,689,990
FDA prior notice system cost	$4,421,176
Lost value for Mexican produce	$16,600,920
Lost value for Canadian produce	$1,928,765

TABLE 9.—SUMMARY OF COSTS FOR OPTION 2—Continued

Lost value for Mexican seafood	$1,863,805
Lost value for Canadian seafood	$30,929,417
Total Costs for Option 2	$128,658,337
Present value of costs	$1,603,543,969

Option three: Minimum prior notice timeframe of 8 hours; electronic submission of information; any change in information requires resubmission.

Option three is to allow the minimum timeframe for prior notices, as dictated by the statute, to take effect. Comments indicated that Canadian and Mexican produce growers and seafood processors are concerned that the longer the minimum time required for the prior notice, the less fresh their products will be when they reach customers. Less-than-optimal fresh (i.e., lower quality) products would result in a lower price paid for the imported produce or seafood shipments, or possibly even the loss of a customer's business to a domestic producer. For importers of perishable products such as seafood and produce, the 8-hour minimum time for prior notice might change business practices in the industry. These changes in business practices would be in addition to the costs of learning about the proposed regulation, submitting forms, and the FDA IT costs outlined in option two.

How much importer, produce grower, and seafood processor business practices will be affected by prior notice requirements again will depend on how early the orders were received compared with how early prior notice must be submitted. If the order for the product was placed more than 8 hours before the truckload is scheduled to arrive at the border, then there should be no delay in the importation of the product.

What is more likely to cause a wait before crossing the border is if the information on the prior notice changes after the prior notice was submitted. For example, if the prior notice is submitted just a few hours before loading the truck, unforeseen factors, including composition of the actual shipment, may cause the prior notice information submitted to not match the actual shipment on the truck. This is just one example of how information on a prior notice submission might change after the prior notice has already been submitted to FDA, thus requiring a cancellation of the prior notice and a resubmission of the corrected information.

Having to resubmit a prior notice to FDA may not cause any delay of the shipment if the original submission was placed early enough. However, it is likely that the necessary corrected prior notice information will be resubmitted not long before the articles start heading for the border. Therefore it is likely that some shipments may have to wait several hours and possibly the full 8-hour minimum for the resubmitted prior notice to be accepted by FDA.

If the prior notice time for submission is 8 hours instead of 4 hours, the probability of having to adjust and resubmit prior notice information will be higher. Now, instead of 20 percent of the importers of perishable products from Canada and Mexico having to resubmit their notices, we will assume that the 8-hour submission timetable means that 25 percent will have to resubmit their notices. We do not expect the number of resubmissions to increase greatly as the minimum timeframe for prior notice is still minimal and FDA expects most orders to be placed well in advance of the 8-hour timeframe. We assume that as the minimum notice time increases, the likelihood of a resubmission also increases, but less than proportionally to the change in minimum notice time.

Carriers of these products may not be able to cross the border for 8 hours instead of 4 hours, which affects 4.8 percent of the produce life span (8 hours out of 168 hours) and 16.7 percent of the seafood life span (8 hours out of 48 hours).

Table 10 shows the loss in value caused by the resubmitted prior notice information for the 25 percent of imported Mexican and Canadian fresh seafood and produce affected.

TABLE 10.—LOSS IN VALUE CAUSED BY RESUBMITTED PRIOR NOTICE UNDER OPTION 3

Perishable Produce	
2001 Imported Mexican Produce Total Retail Value	$3,458,525,000
4.8% reduction in value for 25% of Mexican produce	$41,502,300
2001 Imported Canadian Produce Total Retail Value	$401,826,000
4.8% reduction in value for 25% of Canadian produce	$4,821,912
Perishable Seafood	
2001 Imported Mexican Seafood Total Retail Value	$112,277,406
16.7% reduction in value for 25% of Mexican seafood	$4,687,582
2001 Imported Canadian Seafood Total Retail Value	$1,863,217,894
16.7% reduction in value for 25% of Canadian seafood	$77,789,347

Table 11 presents a summary of the costs associated with option 3. Also presented in table 11 is the present value of the costs associated with this option using the OMB-recommended discount rate of 7 percent.

TABLE 11.—SUMMARY OF COSTS FOR OPTION 3

Research costs	$4,908,509
Computer acquisition costs	$8,315,755
Annual costs to fill out prior notice screens (including updates and amendments)	$59,689,990
FDA prior notice system cost	$4,421,176
Lost value for Mexican produce	$41,502,300
Lost value for Canadian produce	$4,821,912

TABLE 11.—SUMMARY OF COSTS FOR OPTION 3—Continued

Lost value for Mexican seafood	$4,687,582
Lost value for Canadian seafood	$77,789,347
Total Costs for Option 3	$206,136,571
Present value of costs	$2,710,375,883

Option four: prior notice received by noon of the calendar day prior to the day of crossing; electronic submission of information; any change in information requires resubmission.

This option requires that prior notification be submitted no later than noon of the calendar day prior to the expected day of crossing. Under this option, prior notice submitters will have to let FDA know of the incoming food shipment at least 12 hours before the shipment reaches a U.S. point of crossing. This fourth option would likely cause a change in importer business practices and the business practices of their clients in much the same way as option three, but the potential loss of product value is higher because the minimum prior notice time has increased.

Again, how business practices will be affected by prior notice requirements depends on how early the invoice orders are received, the timeframe in which the truck was loaded, and when prior notice is submitted. FDA requests comments on any additional costs that might result from changes in business practices as a result of this proposed rule.

As before, we assume that as the minimum notice time increases, the likelihood of a resubmission also increases, but less than proportionally to the change in minimum notice time. Thus, since the prior notice timeframe for submission is at least 12 hours instead of 8 hours, the probability of having to adjust and resubmit prior notice information is higher. Instead of 25 percent of the importers of perishable products from Canada and Mexico having to resubmit their notices, we will assume that the 12-hour submission timetable means that 40 percent will have to resubmit their notices.

We increase the percentage of resubmission this time by 15 percent because as the prior notice timeframe increases relative to the time of entry, it becomes more likely that the prior notice information will change after the notice is submitted to FDA, thus requiring resubmission. The transporters of products with resubmitted prior notices may then have to wait as long as 12 hours, which affects 7.1 percent of the produce life span (12 hours out of 168 hours) and 25 percent of the seafood life span (12 hours out of 48 hours).

Table 12 shows the loss in value caused by the resubmitted prior notice information for the 40 percent of imported Mexican and Canadian fresh seafood and produce that might be affected. As a result of having to give prior notice by noon the calendar day prior to entry, the Mexican fresh produce industry would lose $98,222,110 and the Canadian fresh produce industry would lose $11,411,858. The Mexican fresh seafood industry would lose $11,227,741 and the Canadian fresh seafood industry would lose $186,321,789 in value.

TABLE 12.—LOSS IN VALUE CAUSED BY RESUBMITTED PRIOR NOTICE UNDER OPTION FOUR

Perishable Produce	
2001 Imported Mexican Produce Total Retail Value	$3,458,525,000
7.1% reduction in value for 40% of Mexican produce	$98,222,110
2001 Imported Canadian Produce Total Retail Value	$401,826,000
7.1% reduction in value for 40% of Canadian produce	$11,411,858
Perishable Seafood	
2001 Imported Mexican Seafood Total Retail Value	$112,277,406
25% reduction in value for 40% of Mexican seafood	$11,227,741
2001 Imported Canadian Seafood Total Retail Value	$1,863,217,894
25% reduction in value for 40% of Canadian seafood	$186,321,789

Table 13 presents a summary of the costs associated with option 4. Also presented in table 13 is the present value of the costs associated with this option using the OMB-recommended discount rate of 7 percent.

TABLE 13.—SUMMARY OF COSTS FOR OPTION 4

Research costs	$4,908,509
Computer acquisition costs	$8,315,755

TABLE 13.—SUMMARY OF COSTS FOR OPTION 4—Continued

Annual costs to fill out prior notice screens (including updates and amendments)	$59,689,990
FDA prior notice system cost	$4,421,176
Lost value for Mexican produce	$98,222,110
Lost value for Canadian produce	$11,411,858

TABLE 13.—SUMMARY OF COSTS FOR OPTION 4—Continued

Lost value for Mexican seafood	$11,227,741
Lost value for Canadian seafood	$186,321,789
Total Costs for Option 4	$384,518,928
Present value of costs	$5,258,695,269

Option five: prior notice received by noon of the calendar day prior to the day of crossing; electronic submission of information; allow changes to the prior notice submission up to two hours prior to entry (proposed option).

We now take the estimates in option 4 and adjust them to account for the effects of allowing changes to the prior notice submission. Since prior notice must be submitted by noon on the calendar day prior to U.S. entry, it is reasonable to expect that not all the information required on a prior notice will be final. Allowing changes to the original submission, in the form of electronic product identity amendments and arrival updates, should improve the flow of import traffic by reducing the number of prior notice resubmissions and thereby reducing the loss of value for perishable foods, since they will not have to wait much extra time, if any at all, before crossing the U.S. border.

The prior notice screen will have required fields for the addresses of the submitter, importer, owner, and consignee, as well as transporter, manufacturer, and grower if known. Required information would also include the identity of the article of food, its originating country, the country from which the food was shipped, its U.S. Customs entry number, and the date, time, and expected port of entry.

Increasing the number of required fields that can be changed on the prior notice screen prior to entry reduces the likelihood that the information would have to be completely resubmitted by importers. This change would lessen the time burden, and therefore the cost, of having to submit prior notice. Allowing a 2 hour amendment and updates to prior notice would provide some flexibility for importers in industries where pieces of information, such as the quantity of the product being imported, time to port of arrival, and the anticipated port may change or is not known until just before shipping.

Assuming that prior notice can be amended and updated would reduce the number of resubmissions that would normally occur. For this option then, with amendment and updates, we will assume that the number of prior notice resubmissions necessitated by changes in information on the notice will be reduced from 40 percent (as in option 4) to 5 percent.

This option lowers the prior notice costs to importers (as compared to option 4) and therefore to Mexican and Canadian fresh produce growers and seafood processors, because they will not have to resubmit their prior notices when importing food to the United States as frequently. Instead they can amend or update the notices. Option 5 would save a minimum of 10 hours wait time per entry that can be amended or updated for the prior notice over the time used in option 4; the maximum time products would have to wait at the border would be 2 hours, or 1.2 percent of the fresh produce life span (2 hours out of 168 hours) and 4.2 percent of the fresh seafood life span (2 hours out of 48 hours). Table 14 shows the costs of submitting prior notice for a 12-hour minimum time, with a 2-hour amendment and updates, for Canadian and Mexican fresh produce and seafood.

TABLE 14.—LOSS IN VALUE CAUSED BY RESUBMITTED PRIOR NOTICE UNDER OPTION FIVE

Perishable Produce	
2001 Imported Mexican Produce Total Retail Value	$3,458,525,000
1.2% reduction in value for 25% of Mexican produce	$2,075,115
2001 Imported Canadian Produce Total Retail Value	$401,826,000
1.2% reduction in value for 25% of Canadian produce	$241,096
Perishable Seafood	
2001 Imported Mexican Seafood Total Retail Value	$112,277,406
4.2% reduction in value for 25% of Mexican seafood	$235,783
2001 Imported Canadian Seafood Total Retail Value	$1,863,217,894
4.2% reduction in value for 25% of Canadian seafood	$3,912,771

Table 15 compares the reduction in the costs of this rule if an amendment and update to prior notice is allowed (option 5) as opposed to the no-amendment option 4.

TABLE 15.—COMPARISON OF OPTION FOUR WITH OPTION FIVE

Perishable Mexican Produce Value loss	
Option 4–12 hour minimum notice	$98,222,110
Option 5–12 hour notice with changes	$2,075,115
Savings with amendment and update	$96,146,995
Perishable Canadian Produce Value loss	
Option 4–12 hour minimum notice	$11,411,858
Option 5–12 hour notice with changes	$241,096

TABLE 15.—COMPARISON OF OPTION FOUR WITH OPTION FIVE—Continued

Perishable Canadian Produce Value loss	
Savings with amendment and update	$11,170,762
Perishable Mexican Seafood Value loss	
Option 4–12 hour minimum notice	$11,227,741
Option 5–12 hour notice with changes	$235,783
Savings with amendment and update	$10,991,985
Perishable Canadian Seafood Value Loss	
Option 4–12 hour minimum notice	$186,321,789
Option 5–12 hour notice with changes	$3,912,758
Savings with amendment and update	$182,409,031

Table 16 presents a summary of the costs associated with option 5. Also presented in table 16 is the present value of the costs associated with this option using the OMB-recommended discount rate of 7 percent.

TABLE 16.—SUMMARY OF COSTS FOR OPTION 5

Research costs	$4,908,509
Computer acquisition costs	$8,315,755
Annual costs to fill out prior notice screens (including updates and amendments)	$59,689,990
FDA prior notice system cost	$4,421,176
Lost value for Mexican produce	$2,075,115
Lost value for Canadian produce	$241,096
Lost value for Mexican seafood	$235,783
Lost value for Canadian seafood	$3,912,758
Total Costs for Option 5	$83,800,182
Present value of costs	$962,713,183

Summary of Options

Table 17 gives a summary of the costs associated with the prior notice rule for each option presented.

TABLE 17.—SUMMARY OF COSTS ASSOCIATED WITH EACH OPTION

Costs	Option 1	Option 2	Option 3	Option 4	Option 5
Research Costs	$0	$4,908,509	$4,908,509	$4,908,509	$4,908,509
Costs of acquiring electronic capacity	$0	$8,315,755	$8,315,755	$8,315,755	$8,315,755
FDA prior notice system cost	$0	$4,421,176	$4,421,176	$4,421,176	$4,421,176
Total annual cost to submit prior notice forms	$0	$59,689,990	$59,689,990	$59,689,990	$59,689,990
Lost value for perishable foods	$0	$51,322,907	$128,801,141	$307,183,498	$6,464,752
First year cost of each option	$0	$128,658,000	$206,137,000	$384,519,000	$83,800,000
Annual cost of each option	$0	$114,656,000	$192,134,000	$370,517,000	$69,798,000
Present value total cost of each option	$0	$1,603,544,000	$2,710,376,000	$5,258,695,000	$962,713,000

Sensitivity Analysis

We estimate that the social costs of the proposed rule (option 5) would be about $84 million in the first year and $70 million in later years. At a 7 percent discount rate, the present value of the costs of the proposed rule, discounted indefinitely into the future, would be about $963 million. These estimates rely on several important assumptions:

- In option 4, forty percent of prior notices will need to be changed if the notice must be submitted by noon on the calendar day prior to entry. (Option 4 is the base for option 5 before amendment.)
- Five percent of prior notices will still need to be changed even when the amendment option is available.
- The amendment option will eliminate all but 1.2 percent of the lost value of imported fresh produce and all but 4.2 percent of the lost value of imported fresh seafood.
- The amendment or update time is two hours before entry.
- The retail value of imported fresh seafood and produce is 100 percent higher than its wholesale value.

• The number of import entries requiring prior notice will not increase over time.

• The discount rate for calculating present value is 7 percent.

We now show how our estimates of costs for the proposed option change under different assumptions. We substitute the following assumptions for those used above:

• In option 4, fifty percent of prior notices will need to be changed if the notice must be submitted by noon on the calendar day prior to entry. (Option 4 is the base for option 5 before amendment.)

• 15 percent of prior notices will still need to be changed even when the amendment option is available.

• The amendment option will eliminate all but 5 percent of the lost value of imported fresh produce and all but 12 percent of lost value of imported fresh seafood.

• The amendment or update time is 4 hours before entry.

• The retail value of imported fresh seafood and produce is 200 percent higher than its wholesale value.

• The number of import entries requiring prior notice will increase 3 percent per year over time.

• The discount rate for calculating present value is 3 percent.

Tables 18 and 19 show the results of the sensitivity analysis. The tables show that the estimated cost of the proposed rule is most sensitive to the assumed fraction of prior notices that will need to be changed. The present value of the proposed rule is most sensitive to the rate of discount.

TABLE 18.—SENSITIVITY ANALYSIS FOR ASSUMPTIONS MADE FOR OPTION 5 (PROPOSED OPTION)

Test	Annual Cost Under Base Assumption	Annual Cost Under Test Assumption	Change in Annual Cost (or Value)	Percent Change in Present Value
50% prior notices changed	$370,516,823	$447,312,699	$76,795,876	21
15% prior notices changed with amendment	$69,798,077	$71,727,578	$1,929,501	3
5% lost value for produce, 12% lost value for seafood	$69,798,077	$84,837,174	$15,039,097	22
Amendment time is 4 hours	$69,789,077	$123,843,623	$54,045,546	77
Retail value is 200% of wholesale value	$69,798,077	$73,030,451	$3,232,374	5
Prior notice entries increase 3% in second year	$69,798,077	$71,588,777	$1,790,700	3

TABLE 19.—PRESENT VALUES FOR SENSITIVITY ANALYSIS FOR ASSUMPTIONS MADE FOR OPTION 5 (PROPOSED OPTION)

Test	Present Value of Base Total Cost	Present Value of New Total Cost Under Test Assumption	Change in Present Value	Percent Change in Present Value
50% prior notices changed	$5,258,695,269	$6,355,779,211	$1,097,083,942	21
15% prior notices changed with amendment	$962,713,183	$1,042,325,126	$79,611,943	8
5% lost value for produce, 12% lost value for seafood	$962,713,183	$1,177,557,426	$214,844,243	22
Amendment time is 4 hours	$962,713,183	$1,786,840,054	$824,126,871	86
Retail value is 200% of wholesale value	$962,713,183	$1,008,889,954	$46,176,771	5
Prior notice entries increase 3% in second year	$962,713,183	$988,294,611	$25,581,428	3
3% Discount rate	$962,713,183	$2,222,803,507	$1,260,090,324	131

Benefits: Requiring prior notice of imported food shipments and defining the required data elements should improve FDA's ability to detect accidental and deliberate contamination of food and deter deliberate contamination. Having notice of an imported food shipment before it reaches a U.S. border would allow FDA personnel to be ready to respond to shipments that appear to be adulterated, whether through intentional or accidental means, as well as when FDA receives credible evidence that an entry represents a serious threat to human or animal health.

Historical evidence suggests that a terrorist or other intentional strike on the food supply is a low-probability, but potentially high-cost event. FDA lacks data to estimate the likelihood and resulting costs of a strike occurring. Without knowing the likelihood or cost of an event, we cannot quantitatively measure the reduction in probability of an event occurring, or the possible reduction in cost of an event associated with each regulatory option. Further hindering any quantification of benefits are the complementary effects of the other regulations that are being developed to implement Title III of the Bioterrorism Act.

To understand possible costs of an intentional strike on the food supply, FDA examined five outbreaks resulting from accidental and deliberate contamination, and from both domestic and imported foods. An intentional attack on the food supply that sought to disrupt the food supply and sicken many U.S. citizens could be much larger than the examples given.

TABLE 20.—SUMMARY OF FIVE FOODBORNE OUTBREAKS

Pathogen	Location and year	Vehicle	Confirmed or reported cases	Estimated number of cases	Total illness cost
Salmonella enteritidis	Minnesota, 1994	Ice cream	150 cases; 30 hospitalizations	29,100 in MN 224,00 Nationwide	$3,187,744,000 to $5,629,792,000
Shigella sonnei	Michigan, 1988	Tofu salad	3,175 cases	Not available	$45,183,000 to $79,795,000

TABLE 20.—SUMMARY OF FIVE FOODBORNE OUTBREAKS—Continued

Pathogen	Location and year	Vehicle	Confirmed or reported cases	Estimated number of cases	Total illness cost
Outbreaks resulting from deliberate contamination					
Salmonella Typhimurium	Dalles, Oregon 1984	Salad bars	751 cases; 45 hospitalizations	Not available	$10,687,000 to $18,875,000
Shigella dysentreriae type 2	Texas, 1996	Muffins and doughnuts	12 cases; 4 hospitalizations	All cases identified	$83,000
Outbreaks resulting from imported foods					
Cyclospora cayaetanensis	United States and Canada, 1996	Raspberries (probably imported from Guatemala)	1465 cases identified, less than 20 hospitalization	Not available	$3,941,000

Salmonella enteritidis in ice cream

In 1994, approximately 224,000 people were sickened by ice cream contaminated with Salmonella enteritidis. The source of the contamination appeared to be pasteurized pre-mix that had been contaminated during transport in tanker trailers that previously had carried non-pasteurized eggs. There were 150 confirmed cases of salmonellosis associated with the outbreak in Minnesota. However, ice cream produced during the contamination period was distributed to 48 states. To calculate the total number of illnesses associated with the outbreak, researchers calculated an attack rate of 6.6 percent. This attack rate was extrapolated to the population that consumed the ice cream, giving a total number sickened of 224,000 (Ref. 11).

Salmonellosis most commonly causes gastrointestinal symptoms. Almost 91 percent of cases are mild and cause one to three days of illness with symptoms including diarrhea, abdominal cramps, and fever. Moderate cases, defined as requiring a trip to a physician, account for 8 percent of the cases. These cases typically have duration of two to 12 days. Severe cases require hospitalization and last 11 to 21 days. In addition to causing gastroenteritis, salmonellosis also can cause reactive arthritis in a small percentage of cases. Reactive arthritis may be short or long term and is characterized by joint pain. Just over one percent of cases develop short-term reactive arthritis and two percent of cases develop chronic, reactive arthritis.

In table 21, FDA estimated the costs associated with salmonellosis, including medical treatment costs and pain and suffering. Pain and suffering is measured by lost quality adjusted life days (QALDs). QALDs measure the loss of utility associated with an illness. A QALD is measured between zero and one, with one being a day in perfect health. The total loss of a Quality Adjusted Life Year (QALY), or the loss of a year of life is valued at $100,000, based on economic studies of how consumers value risks to life (Ref. 12). Thus, an entire lost QALD would be valued at $274 and fractions of QALDs are a fraction of the day's value. FDA presents two estimates of values of pain and suffering associated with arthritis, one based on physician estimates (Ref. 13) and another based on a regression analysis approach (Ref. 14). This gives a range of costs for the average case of salmonellosis between $14,231 and $25,133.

TABLE 21.—THE COST OF AN AVERAGE CASE OF SALMONELLOSIS

Severity	Case Breakdown	Total QALDs Lost per Illness	Health Loss per Case (Discounted)	Medical Costs per Case (Discounted)	Weighted Dollar Loss per Case
Illness					
Mild	90.7%	1.05	$660	$0	$599
Moderate	8.1%	3.68	$2,310	$283	$209
Severe	1.2%	9.99	$6,266	$9,250	$188
Arthritis *Regression Approach*					
Short-Term	1.26%	5.41	$3,391	$100	$44
Long-Term	2.40%	2,613.12	$452,554	$7,322	$11,048
Direct Survey Approach					
Short-Term	1.26%	10.81	$6,778	$100 $87	
Long-Term	2.40%	5,223.15	$904,573	$7,322	$21,906
Death	0.04%		$5,000,000		$2,143
Total Expected Loss per Case				Regression Approach Direct Survey Approach	$14,231 $25,133

To estimate the economic cost due to illness associated with this outbreak, FDA used the range for the average cost per case. For 224,000 people, this is a total cost of between $3,187,744,000 and $5,629,792,000 from this accidental food disaster.

Shigella sonnei in tofu salad

In 1988, a tofu salad at an outdoor music festival was contaminated with Shigella sonnei and sickened an estimated 3,175 people. Over 2,000 volunteer food handlers served communal meals at the festival. (Ref. 15) Shigellosis causes similar symptoms and is of similar duration to salmonellosis. It also is associated with short term and chronic reactive arthritis; thus, FDA assumed the average case of shigellosis has the same cost as salmonellosis. This gives a total cost of $45,183,000 to $79,797,000.

Salmonella typhimirium in salad bars

During September and October of 1984, two outbreaks of Salmonella typhimirium occurred in association with salad bars in restaurants in The Dalles, Oregon. At least 751 people were affected. Members of the local Rajneeshpuram commune intentionally caused the outbreak by spraying Salmonella typhimirium on the salad bars in local restaurants. Their apparent motivation was to influence a local election by decreasing voter turnout. Intentional contamination was not suspected immediately and no charges were brought until a year after the attacks (Ref. 16).

The 751 people affected primarily were identified through passive surveillance: thus the true number of people actually sickened is undoubtedly much higher. The Dalles is located on Interstate 84 in Oregon and is a frequent stop for travelers who were unlikely to be identified by passive or active surveillance for salmonellosis. However, since we do not have any estimates of the true size of the outbreak, we estimated the costs associated with known cases, recognizing this is an underestimate of the true cost of the outbreak. We use the cost estimates for salmonellosis as ranging from $14,231 to $25,133. This gives an estimated cost of known cases for the outbreak of $10,687,000 to $18,875,000.

Shigella dysenteriae type 2 among laboratory workers

Twelve people working in a laboratory who consumed muffins left in the laboratory break room contracted shigellosis in Texas in 1996. Affected workers had diarrhea, nausea, and abdominal discomfort. Investigators concluded that the outbreak likely was the result of deliberate contamination. All twelve affected workers were treated by, or consulted with, a physician. Nine affected workers went to the emergency room, four of whom were hospitalized (Ref. 17).

To estimate the cost of this outbreak, FDA assumed that the eight cases that required consultation with a doctor, but did not require hospitalization, had the same cost as a moderate case of salmonellosis. The four cases requiring hospitalization were estimated to have the same cost as a severe case of gastroenteritis resulting from salmonellosis. This gives a cost of $82,808 for illnesses associated with the event.

TABLE 22.—SUMMARY OF COSTS FOR AN OUTBREAK OF SHIGELLOSIS

Severity	Number of cases	Cost per case	Total cost
Mild	0	$0	$0
Moderate	8	$2,593	$20,744
Severe	4	$15,516	$62,064
Total	12		$82,808

Cyclospora cayatanensis in imported raspberries

In 1996, 1,465 cases of cyclosporiasis were linked to consumption of raspberries imported from Guatemala. Nine hundred and seventy eight of these cases were laboratory confirmed. No deaths were confirmed and less than 20 hospitalizations were reported (Ref. 18). Case control studies indicated that raspberries imported from Guatemala were the source of the illnesses. Fifty-five clusters of cases were reported in 20 states, two Canadian provinces, and the District of Columbia (Ref. 19).

Cyclosporiasis typically causes watery diarrhea, loss of appetite, weight loss, and fatigue. Less common symptoms include fever, chills, nausea, and headache. The median duration of illness associated with the outbreak was more than 14 days and the median duration of diarrheal illness was 10 days (Ref. 20). We estimated the cost of a mild case of cyclosporiasis as two and one half times higher than the cost of a mild case of gastroenteritis from salmonellosis due to the longer duration. The reports of cyclosporiasis outbreaks did not include information on the number of physician visits. We assumed that the percentage of total cases that result in physician visits would be larger than the corresponding percentage for salmonellosis illnesses, due to the longer duration of illnesses. We assumed, therefore, that 40 percent of those infected with cyclosporiasis visited a physician. Less than 20 hospitalizations were reported from the cyclosporiasis outbreak. No deaths were confirmed.

TABLE 23.—SUMMARY OF COSTS OF AN OUTBREAK OF CYCLOSPORIASIS

Severity	Number of cases	Cost per case	Total cost
Mild	879	$1,650	$1,450,000
Moderate	586	$3,748	$2,196,000
Severe	19	$15,516	$294,000
Total	1,465		$3,941,000

B. Small Entity Analysis (or Initial Regulatory Flexibility Analysis)

FDA has examined the economic implications of this proposed rule as required by the Regulatory Flexibility Act (5 U.S.C. 601–612). If a rule has a significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act requires agencies to analyze regulatory options that would lessen the economic effect of the rule on small entities consistent with statutory objectives. The analysis below, together with other relevant sections of this document, serves as the agency's initial regulatory flexibility analysis under the Regulatory Flexibility Act.

1. Number of Establishments Affected

FDA finds that this proposed rule would affect the 77,427 U.S. importers. Most of these importers have fewer than 500 employees, thus making them small businesses according to the definitions of the Small Business Administration. Because most of the importers affected are small, all options considered in the Benefit-Cost Analysis in section IV.A above are regulatory relief options.

2. Costs Per Entity

Small businesses will be affected by this proposed rule in a couple of ways. First, this proposed rule requires importers to notify FDA of incoming products electronically before the food arrives at the U.S. border. The annual cost of doing so is about $770 per importer (see tables 1, 2, and 17 of this document). As discussed above and shown in tables 1 and 2, about 3,100 U.S. importers do not have electronic transmitting capacity and will have to obtain computer equipment (at a cost of about $2,000 per importer) and Internet access (at a cost of about $240 annually) in order to comply with this proposed rule. FDA could not provide flexibility for those importers who do not have electronic transmitting capacity, as paper notices could not be submitted and processed in the proposed prior notice timeframe and would therefore actually be more burdensome to importers because paper notices would need to be submitted earlier.

Second, this proposed rule will potentially cause some loss of product value if the prior notice requirement causes perishable products to have to wait any length of time before crossing the U.S. border. The costs of lost product value vary with the required notice timeframe. We discuss the various costs associated with this possibility in the options previously outlined. FDA requests comments on the effect of this proposed rule on small entities.

3. Additional Flexibility Considered

Because of the requirements of the Bioterrorism Act, FDA is precluded from selecting some of the options that typically would be considered to lessen the economic effect of the rule on small entities, including granting an exemption to small entities. FDA tentatively concludes that it would be inconsistent with section 307 of the Bioterrorism Act to allow small entities a later effective date, since the Bioterrorism Act established a deadline for beginning prior notice that applies to all FDA-regulated imported food. Although the recordkeeping provision of the Bioterrorism Act directs FDA to take into account the size of a business when issuing implementing regulations, the prior notice provision contains no such language. Thus, it appears that Congress intended for all entities to be subject to the effective date established in the Bioterrorism Act. Nonetheless, the agency recognizes that the prior notice requirement will cause an economic burden on small businesses; therefore, we are seeking comment on whether it would be consistent with section 307 for the agency to set staggered effective dates that would give small businesses more time to comply. FDA also seeks comment on how FDA could effectively distinguish between large and small businesses if it considered staggered effective dates.

C. Unfunded Mandates

Title II of the Unfunded Mandates Reform Act of 1995 (Public Law 104–4) requires cost-benefit and other analyses before any rule making if the rule would include a ''Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any 1 year.'' The current inflation-adjusted statutory threshold is $112 million. FDA has determined that this proposed rule does not constitute a significant rule under the Unfunded Mandates Reform Act. See table 17 for the total costs.

V. Paperwork Reduction Act of 1995

This proposed rule contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). A description of these provisions is given 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.

FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Title: Prior Notice of Imported Food

Description: Section 801(m) of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 381(m)) requires prior notification to the Secretary of Health and Human Services of an article of food that is being imported or offered for import into the United States. The purpose of this notification is to enable the food to be inspected at ports of entry into the United States.

Section 801(m) of the Act states that the Secretary shall by regulation identify the parties responsible for providing the notice and explain the information that the prior notice is required to contain, the method of submission of the notice, and the minimum and maximum period of advance notice required. Section 801(m)(1) of the Act states that the Secretary shall require submission of notice providing the identity of each of the following: the article of food; the manufacturer; the shipper; the grower, if known at the time of notification; the originating country; the shipping country; and the anticipated port of entry. Section 801(m)(2)(A) of the Act states that the Secretary shall by regulation prescribe the time of submission of the notification in advance of importation or the offering of the food for import, which period shall be no less than the minimum amount of time necessary for the Secretary to receive, review, and appropriately respond to such notification, but may not exceed five days. FDA's prior notification of imported food shipments proposed regulation would implement these statutory provisions.

FDA estimates the burden for this information collection as follows:

TABLE 24.—ESTIMATED ANNUAL REPORTING BURDEN

21 CFR Part 1, Subpart I	No. Of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Capital Costs	Operating and Maintenance Costs	Total Hours
1.285–1.290, 1.294[1]	77,427	23.3	1,807,692	1–2	$6,194,000	$743,280	1,888,216
1.278(d)[1]	90,385	1	90,385	0.5	$0	$0	45,193
1.278(d), 1.285–1.290, 1.294[2]	77,427	23.8	1,844,116	0.5–1	$620,000	$817,680	1,833,822
Total hours for first year							1,888,216
Total recurring hours							1,833,822

[1] First year burden.
[2] Recurring burden.

Burden Estimate

Number of Establishments Affected

Using 2001 FY information from FDA's OASIS system (industry codes 02 through 52, 54, and 70 through 72), FDA has determined that there are approximately 77,427 importers and consignees who receive shipments of food for human and animal consumption into the United States. It is these 77,427 U.S. importers or U.S. purchasers (or their agents) that will be primarily responsible for submitting the prior notice information.

New and Closing Importers

In addition to the U.S. importers currently in existence, in future years, new import businesses will open and some existing import businesses will close. These new importers would have to become familiar with the FDA prior notice system and possibly obtain computer equipment and Internet access to comply with prior notice requirements.

According to the Small Business Administration Office of Advocacy, in 2001, about 10 percent of all businesses were new and 10 percent of businesses closed. Using the 10 percent opening and closing business statistic, and given that there are currently 77,427 U.S. importers, FDA will assume, then, that on a yearly basis 7,743 importers will leave the market and 7,743 importers will enter the market.

Hour Burden Estimate Researching the Prior Notice Requirement

To become familiar with the requirements for this rule, FDA estimates it will initially take responsible parties with Internet access (74,330 importers) about one hour to research the prior notice requirements and responsible parties without readily available Internet access (3,097 importers) about 2 hours to research the requirements. This one-time search burden for the existing importers is 80,524 hours.

In the years that follow the start-up year for prior notice, it is reasonable to expect a certain percentage of importing firms to enter and leave the market. Thus, in addition to the first year burden to research prior notice, it is expected that 8,053 hours will be spent annually researching the prior notice requirement by the anticipated 7,743 new importers entering the market annually that must learn about prior notice, 7,433 of whom are estimated to have Internet access and 310 of whom do not.

Submitting Prior Notice

To estimate the repetitive effort of submitting a prior notice, and updating and amending the information, as needed, FDA will assume the activity takes one hour each time an entry (based on an average of 2.6 lines, and therefore notices, per entry) must be submitted. This includes 45 minutes of an administrative worker's time to fill out the screen, including updating, and then 15 minutes of the manager's time to verify the information. FDA does not have information on how many prior notices will come from each of the 77,427 importers. However, we assume that 1,807,692 prior notices will be submitted annually (based on FY 2001 OASIS information); we can take this number and divide by the 77,427 importers to get an average response frequency per importer of 23.3 notices.

Secure Storage and Notifying FDA

If an article of food is imported or offered for import with no prior notice or inadequate (e.g. untimely, inaccurate, or incomplete) prior notice, the food must be held at the port of entry or in a secure facility. In these cases, the submitter or carrier must promptly notify FDA of the location where the goods are held.

It is quite likely that more imported products will be held during the first year that the prior notice is required than in subsequent years as importers will learn from experience. Therefore, FDA estimates that imported products with insufficient prior notice will be held or sent to secure storage about 5 percent of the time during the first year and 2 percent of the time thereafter. This means that of the 1,807,692 prior notice entries received annually, in the first year prior notice is in effect we would expect 90,385 of the entries to be held or sent to secure storage; 36,154 entries would be held or sent to secure storage in subsequent years.

Most port storage facilities and secure storage facilities located at or near ports are probably familiar to submitters or carriers; therefore it should only take one-half hour per entry to notify FDA of the shipment's location. Thus, in the first year of the regulation, submitters or carriers will spend 45,193 hours notifying FDA of secure storage locations; 18,077 hours in subsequent years.

Capital Cost and Operating and Maintenance Cost Burden

Since all prior notices must be submitted electronically, we will assume that the 3,097 responsible parties without Internet access will have to purchase the appropriate IT equipment and gain Internet access to actually transmit the information. Assuming computer equipment costs each firm $2,000 and yearly Internet access costs each firm $240 ($20 per month for 12 months), this results in a one-time computer cost for these facilities of $6,194,000 and a recurring Internet access cost of $743,280. For the 7,743 new firms that enter the import market each year, we can expect 310 of them to need to purchase computer equipment and obtain Internet access. Thus, on an annual basis we can expect

new importers to spend $620,000 on computers and $74,400 on Internet access to be able to submit prior notice information.

In compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)), the agency has submitted the information collection provisions of this proposed rule to OMB for review. Interested persons are requested to send comments regarding information collection to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Stuart Shapiro, FDA Desk Officer.

VI. Analysis of Environmental Impact

The agency has carefully considered the potential environmental effects of this action. FDA has concluded under 21 CFR 25.30(h) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VII. Federalism

FDA has analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the proposed rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the agency tentatively concludes that the proposed rule does not contain policies that have federalism implications as defined in the Executive Order and, consequently, a federalism summary impact statement has not been prepared.

VIII. Comments

Interested persons may submit to the Dockets Management Branch (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 hard copies of any written comments, except that individuals may submit one hard copy. Comments are to be identified with the docket number found in brackets in the heading of this document. FDA cannot be responsible for addressing comments submitted to the wrong docket or that do not contain a docket number. Received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

FDA notes that the comment period for this document is shorter than the 75-day period that the agency customarily provides for proposed rules that are technical or sanitary or phytosanitary (SPS) measures. FDA believes that a 60-day comment period is appropriate in this instance. Executive Order 12889, ''Implementation of the North American Free Trade Agreement'' (58 FR 69681, December 30, 1993), states that any agency subject to the Administrative Procedure Act must provide a 75-day comment period for any proposed Federal technical regulation or any Federal SPS measure of general application. Executive Order 12889 provides an exception to the 75-day comment period where the United States considers a technical regulation or SPS measure of general application necessary to address an urgent problem related to the protection of human, plant, or animal health or sanitary or phytosanitary protection. FDA has concluded that this proposed rule is subject to the exception in Executive Order 12889.

The Bioterrorism Act states that it is intended ''[t]o improve the ability of the United States to prevent, prepare for, and respond to bioterrorism and other public health emergencies.'' In order to meet these objectives, section 307 of the Act requires the FDA to propose and issue final regulations requiring prior notice of food imported or offered for import into the United States within 18 months of the Bioterrorism Act's enactment, which is by December 12, 2003. Section 307 also provides that if FDA does not issue final regulations by this date, FDA still must receive prior notice of food imported or offered for import into the United States by December 12, 2002, of no less than 8 hours and no more than 5 days, subject to compliance with the final regulations when the final regulations are made effective. This expedited timeframe reflects the urgency of the United States government's need to prepare to respond to bioterrorism and other food-related emergencies and FDA's need to have the final rule in place, tested, and fully operational by December 12, 2003. This means that the final rule must publish in early October 2003.

FDA will not consider any comments submitted after the 60-day comment period closes and does not intend to grant any requests for extension of the comment period due to the Bioterrorism Act's requirement to have a final regulation in effect by December 12, 2003, which requires publication on or before October 12, 2003.

IX. References

The following references have been placed on display 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. (FDA has verified the Web site address, but FDA is not responsible for any subsequent changes to the nonFDA Web sites after this document publishes in the **Federal Register**.)

1. Compilation of food entry documents, with corresponding invoices and screens, taken from FDA's Operational and Administrative System for Import Support (OASIS).

2. Bureau of Economic Analysis, http://www.bea.doc.gov

3. United States Department of Labor, Bureau of Labor Statistics, National Compensation Survey: Occupation Wages in the United States, 2000, Summary 01–04. Available at http://www.bls.gov/ncs/ocs/sp/ncbl0354.pdf.

4. USDA Agricultural Marketing Service (March 2002) Fresh Fruits and Vegetable Shipments. www.ams.usda.gov

5. Kasmire, Dr. Robert F. Vegetable Marketing Specialist, www.thepacker.com/rbcs/handbookarticles/properis.htm Accessed on September 16, 2002.

6. USDA Agricultural Marketing Service produce point price reports for various border crossings for the dates September 12, 2002 and September 16, 2002. www.ams.usda.gov

7. Florida Department of Agriculture and Consumer Services (FDACS) www.ffva.com/rps.htm.

8. National Marine Fisheries Service, Fisheries Statistics and Economics Division, www.st.nmfs.gov accessed September 2002.

9. Florida Department of Agriculture and Consumer Services, http://doacs.state.fl.us/press/1999/090999.html and www.ffva.com/rps.htm

10. Center for Food Safety and Applied Nutrition, http://www.cfsan.fda.gov/~dms/qa-sto8.html

11. Hennessy T.W., C.W. Hedberg, L. Slutsker, K.E. White, J.M. Besser-Wiek, M.E. Moen, J. Feldman, W.W. Coleman, L.M. Edmonson, K.L. MacDonald, M.T. Osterholm, and the Investigation Team, ''A National Outbreak of Salmonella Enteritidis Infections From Ice Cream,'' *The New England Journal of Medicine*, May 16, 1996, pp. 1281–1286.

12. Cutler, D., E. Richardson, 1999, ''Your Money and Your Life: The Value of Health and What Affects It,'' Working Paper 6895, National Bureau of Economic Research.

13. Zorn, D., K. Klontz, 1998, ''Appendix: The Value of Consumer Loss to Foodborne Reactive Arthritis,'' **Federal Register**, 63 FR 24292–24299, May 1, 1998.

14. Scharff, R., and A. Jessup, ''Valuing Chronic Disease for Heterogenous Populations: the Case of Arthritis,'' 2002, Mimeo.

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American Journal of Epidemiology, 133:6:608–615.

16. Trook, T.J., R.V. Tauxe, R.P. Wise, J.R. Livengood, R. Sokolow, S. Mauvais, K.A. Birkness, M.R. Skeels, J.M. Horan, and L.R. Foster, ''A Large Community Outbreak of Salmonellosis Caused by Intentional Contamination of Restaurant Salad Bars,'' *The Journal of the American Medical Association*, 278:5:389–397.

17. Kolavic, S.A., A. Kimura, S.L. Simons, L. Slusker, S. Barth, and C.E. Haley, ''An Outbreak of Shigella Dysenteriae Type 2 Among Laboratory Workers Due to Intentional Food Contamination,'' *The Journal of the American Medical Association*, 278:5:396–403.

18. Colley, D.G., Widespread Foodborne Cyclosporiasis Outbreaks Present Major Challenges (letter), Emerging Infectious Diseases, 2:4:354–356.

19. Herwaldt, B.L., M.L. Ackers, and Cyclospora Working Group, ''An Outbreak in 1996 of Cyclosporiasis Associated with Imported Raspberries,'' *New England Journal of Medicine*, May 29, 1997, 1548–1556.

20. Small Business Administration Office of Advocacy, ''Small Business By the Numbers,'' May 2002, http://www.sba.gov/advo/.

List of Subjects in 21 CFR Part 1

Cosmetics, Drugs, Exports, Food labeling, Imports, Labeling, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 1 be amended as follows:

PART 1—GENERAL ENFORCEMENT REGULATIONS

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

Authority: 15 U.S.C. 1453, 1454, 1455; 21 U.S.C. 304, 321, 331, 334, 343, 350c, 350d, 352, 355, 360b, 362, 371, 374, 381, 382, 393; 42 U.S.C. 216, 241, 243, 262, 264.

2. Subpart I is added to part 1 to read as follows:

Subpart I—PRIOR NOTICE OF IMPORTED FOOD

General Provisions

Sec.

1.276 What imported food is subject to this subpart?
1.277 What definitions apply to this subpart?
1.278 What are the consequences of failing to submit adequate prior notice or otherwise failing to comply with this subpart?

Requirements to Submit Prior Notice of Imported Food

Sec.

1.285 Who is authorized to submit prior notice for an article of food that is imported or offered for import into the United States?
1.286 When must the prior notice be submitted to FDA?
1.287 How must you submit the prior notice?
1.288 What information must be submitted in the prior notice?
1.289 What changes are allowed to a prior notice after it has been submitted to FDA?
1.290 Under what circumstances must you submit a product identity amendment to your prior notice after you have submitted it to FDA?
1.291 What is the deadline for product identity amendments under § 1.290?
1.292 How do you submit a product identity amendment to a prior notice?
1.293 What are the consequences if you do not submit a product identity amendment to your prior notice?
1.294 What must you do if the anticipated arrival information (required under § 1.288(k)(1)) submitted in your prior notice changes?

General Provisions

§ 1.276 What imported food is subject to this subpart?

(a) This subpart applies to food for humans and other animals that is imported or offered for import into the United States (U.S.), including U.S. foreign trade zones, for consumption, storage, immediate export from the port of entry, transshipment through the United States to another country, or import for export.

(b) This subpart does not apply to:

(1) Food that is carried by an individual entering the United States in that individual's personal baggage for that individual's personal use;

(2) Meat food products that at the time of importation are subject to the exclusive jurisdiction of the U.S. Department of Agriculture (USDA) under the Federal Meat Inspection Act (21 U.S.C. 601 *et seq.*);

(3) Poultry products that at the time of importation are subject to the exclusive jurisdiction of USDA under the Poultry Products Inspection Act (21 U.S.C. 451 *et seq.*); and

(4) Egg products that at the time of importation are subject to the exclusive jurisdiction of USDA under the Egg Products Inspection Act (21 U.S.C. 1031 *et seq.*).

§ 1.277 What definitions apply to this subpart?

(a) The act means the Federal Food, Drug, and Cosmetic Act.

(b) The definitions of terms in section 201 of the act (21 U.S.C. 321) apply when the terms are used in this subpart.

(c) In addition, for the purposes of this subpart:

(1) *Calendar day* means every day shown on the calendar.

(2) *Country from which the article of food was shipped* means the country in which the article of food was loaded onto the conveyance that brings it to the United States.

(3) *Food* has the meaning given in section 201(f) of the act. Examples of food include, but are not limited to, fruits, vegetables, fish, dairy products, eggs, raw agricultural commodities for use as food or components of food, animal feed, including pet food, food and feed ingredients and additives, including substances that migrate into food from food packaging and other articles that contact food, dietary supplements and dietary ingredients, infant formula, beverages, including alcoholic beverages and bottled water, live food animals, bakery goods, snack foods, candy, and canned foods.

(4) *Originating country* means the country from which the article of food originates. If the article of food is fresh produce or fresh aquacultured fish or seafood, the originating country is the country in which it is grown and harvested. If the article of food is wild-caught fish or seafood and it is harvested in the waters of the United States or by a U.S. flagged vessel or processed aboard a U.S. flagged vessel, the originating country is the United States. Otherwise, the originating country is the country in which the article of food is produced.

(5) *Port of entry* means the water, air, or land port at which the article of food is imported or offered for import into the United States, i.e., the port where food first arrives in the United States. This port may be different than the port where the article of food is entered for U.S. Customs Service purposes.

(6) *You* means the purchaser or importer of an article of food who resides or maintains a place of business in the United States, or an agent who resides or maintains a place of business in the United States acting on the behalf of the U.S. purchaser or importer or, if the article of food is imported with the intention of in-bond movement through the United States for export, i.e., Transportation for Exportation or Immediate Export entries, the arriving carrier or, if known, the in-bond carrier.

§ 1.278 What are the consequences of failing to submit adequate prior notice or otherwise failing to comply with this subpart?

(a) If an article of food is imported or offered for import with no prior notice or inadequate (e.g., untimely, inaccurate, or incomplete) prior notice, the food shall be refused admission

under section 801(m)(1) of the act (21 U.S.C. 381(m)(1)).

(b) If an article of food is refused admission under section 801(m)(1), it must be held at the port of entry unless FDA directs its removal to a secure facility in accordance with § 1.278(c).

(c) If FDA determines that removal to a secure facility is appropriate (e.g., due to a concern with the security of the article of food or due to space limitations in the port of entry), FDA may direct that the article of food be removed to a Bonded Warehouse, Container Freight Station, Centralized Examination Station, or another appropriate secure facility that has been approved by FDA.

(d) The person submitting the prior notice or the carrier must arrange for movement of the article of food, under appropriate custodial bond, within the port of entry or to the secure facility and must promptly notify FDA of the location. Transportation and storage expenses shall be borne by the owner, purchaser, importer, or consignee.

(e) (1) The article of food must be held at the port of entry or in the secure facility until prior notice is submitted to FDA in accordance with this subpart, FDA has examined the prior notice, FDA has determined that the prior notice is adequate, and FDA has notified the U.S. Customs Service and the person who submitted the prior notice that the article of food no longer is subject to refusal of admission under section 801(m)(1) of the act.

(2) Notwithstanding section 801(b) of the act (21 U.S.C. 381(b)), while any article of food that has been refused admission under section 801(m)(1) of the act is held at its port of entry or in a secure facility, it may not be delivered to any of its importers, owners, or consignees.

(f) A determination that an article of food is no longer subject to refusal under section 801(m)(1) is different than, and may come before, determinations of admissibility under other provisions of the act or other U.S. laws. A determination that an article of food is no longer subject to refusal under section 801(m)(1) does not mean that it will be granted admission under other provisions of the act or other U.S. laws.

(g) Any person who imports or offers for import an article of food without complying with the requirements of 21 U.S.C. 381(m) as set out in this subpart, or otherwise violates any requirement under 21 U.S.C. 381(m), or any person who causes such an act, commits a prohibited act within the meaning of 21 U.S.C. 331 (ee). Under 21 U.S.C. section 332, the United States can bring a civil action in Federal court to enjoin persons who commit prohibited acts. Under 21 U.S.C. section 333, the United States can bring a criminal action in Federal court to prosecute persons who commit prohibited acts. Under 21 U.S.C. 335a, FDA can seek debarment of any person who has been convicted of a felony relating to importation of food into the United States.

Requirements to Submit Prior Notice of Imported Food

§ 1.285 Who is authorized to submit prior notice for an article of food that is imported or offered for import into the United States?

(a) A purchaser or importer of an article of food who resides or maintains a place of business in the United States, or an agent who resides or maintains a place of business in the United States acting on the behalf of the U.S. purchaser or importer, is authorized to submit to FDA prior notice of the article of food being imported or offered for import into the United States, except as specified in paragraph (b) of this section.

(b) If the article of food is imported for in-bond movement through the United States for export, i.e., Transportation for Exportation or Immediate Export entries, the arriving carrier or, if known, the in-bond carrier is authorized to submit prior notice to FDA.

§ 1.286 When must the prior notice be submitted to FDA?

(a) You must submit the prior notice to FDA no later than noon of the calendar day before the day the article of food will arrive at the border crossing in the port of entry.

(b) You may not submit the prior notice until all of the information required by § 1.288 exists, except as provided in § § 1.288(e)(2) and 1.290, which both relate to product identity amendments. You may not submit prior notice more than 5 days before the anticipated date of arrival of the food at the anticipated port of entry.

§ 1.287 How must you submit the prior notice?

(a) You must submit prior notice, product identity amendments, and arrival updates electronically to FDA through FDA's Prior Notice System at [a Website that will be provided in the final rule], except as provided in paragraph (b) of this section.

(b) If FDA's Prior Notice System is unable to receive prior notice electronically, you must submit prior notice, product identity amendments, and arrival updates using a printed version of the Prior Notice Screen from FDA's Prior Notice System delivered in person, by e-mail, or fax to the FDA field office with responsibility over the geographical area in which the anticipated port of entry identified in your initial prior notice is located.

§ 1.288 What information must be submitted in the prior notice?

For each article of food that is imported or offered for import into the United States, you must submit the information listed in this section. (The Prior Notice Screen of FDA's Prior Notice System also identifies the information that you must submit to FDA.)

(a) The name of the individual submitting the prior notice, the submitting firm's name, address, phone number, fax number, and e-mail address, and, if the firm is required to register for a facility associated with the article of food under 21 CFR part 1, subpart H, the registration number assigned to that facility;

(b) The entry type as designated by the U.S. Customs Service;

(c) The U.S. Customs Service's Automated Commercial System (ACS) entry number, or if the article of food is an import that is not subject to ACS, the other U.S. Customs Service identification number associated with the importation;

(d) If the article of food is under hold under § 1.278, the location where it is being held, the date the article will arrive at that location, and identification of a contact at that location.

(e)(1) The identity of the article of food being imported or offered for import, as follows:

(i) The complete FDA product code;

(ii) The common or usual name or market name;

(iii) The trade or brand name, if different from the common or usual name or market name;

(iv) The quantity of food described from smallest package size to largest container; and

(v) The lot or code numbers or other identifier of the food if applicable.

(2) If all of the information required by this subsection exists by noon of the calendar day before the day the article of food will arrive at the border crossing in the port of entry, you must include it in your prior notice and you may not amend the prior notice under § 1.290. If any of this information does not exist by noon of the calendar day before the day the article of food will arrive at the border crossing in the port of entry, you must give FDA as much information as does exist at that time and tell FDA that you will amend the prior notice as required under § 1.290.

(f) The name, address, phone number, fax number, and e-mail address of the

manufacturer, and if it is required to register for a facility associated with the article of food under 21 CFR part 1, subpart H, the registration number assigned to that facility;

(g) The name, address, phone number, fax number, and e-mail of all growers, and the growing location if different from business address, if known at time of submission of your prior notice;

(h) The originating country of the article of food;

(i) The name, address, phone number, fax number, and e-mail address of the shipper and, if it is required to register under 21 CFR part 1, subpart H, for a facility associated with the article of food, the registration number assigned to that facility;

(j) The country from which the article of food was shipped;

(k) (1) Anticipated arrival information about the article of food being imported or offered for import, as follows:

(i) The anticipated port of entry and, if the anticipated port of entry has more than one border crossing, the specific anticipated border crossing where the food will be brought into the United States;

(ii) The anticipated date on which the article of food will arrive at the anticipated port of entry; and

(iii) The anticipated time of that arrival;

(2) If any of the anticipated arrival information required under this paragraph changes after you submit your prior notice, you must update your notice in accordance with § 1.294.

(l) The port where entry of the article of food will be made for purposes of the U.S. Customs Service;

(m) The anticipated date of entry for purposes of the U.S. Customs Service; and

(n) The name, address, phone number, fax number, and e-mail address of the importer, and, if the importer is required to register for a facility associated with the article of food under 21 CFR part 1, subpart H, the registration number assigned to that facility;

(o) The name, address, phone number, fax number, and e-mail address of the owner, and if the owner is required to register for a facility associated with the article of food under 21 CFR part 1, subpart H, the registration number assigned to that facility;

(p) The name, address, phone number, fax number, and e-mail address of the consignee, and if the consignee is required to register for a facility associated with the article of food under 21 CFR part 1, subpart H, the registration number assigned to that facility; and

(q) The names, addresses, phone numbers, fax numbers and e-mail addresses of all the carriers which are or will be carrying the article of the food from the country from which the article of food was shipped to the United States, and the carriers' Standard Carrier Abbreviation Codes (SCAC) if appropriate.

§ 1.289 What changes are allowed to a prior notice after it has been submitted to FDA?

After a prior notice has been submitted to FDA, it may only be changed as set out in § 1.290 which relates to product identity amendments or § 1.294 which relates to arrival updates. If other information provided in the prior notice changes, you must cancel the prior notice in the FDA Prior Notice System and submit a new prior notice to FDA.

§ 1.290 Under what circumstances must you submit a product identity amendment to your prior notice after you have submitted it to FDA?

(a) If any of the information required by § 1.288(e)(1) did not exist at the time you submitted your prior notice and the prior notice you submitted was therefore incomplete, you must amend your prior notice with complete product identity information by the deadline specified in § 1.291.

(b) You may only amend your prior notice once.

(c) You may not change the general identity of the article of food that is the subject of the prior notice by amendment. However, if the article is fresh produce or fresh, wild-caught fish, you may amend the last two digits of the product code when you do not know the specific identity of the article at the time of initial prior notice. If your initial prior notice submission identifies the product by the FDA product code for ''fresh peppers, refrigerated,'' when you amend your submission, you must give the product code that identifies with specificity the type of pepper—''fresh green bell peppers, refrigerated.'' You may also include more than one article in your amendment if the industry and class and process (of the FDA product code) are the same. A prior notice for ''refrigerated fresh fish'' may be amended as ''refrigerated fresh cod'' and ''refrigerated fresh salmon,'' but not ''refrigerated fresh cod'' and ''canned shrimp.'' You may not amend the product identity to refer to another food, e.g., apples, or another process, e.g., canned.

(d) If you did not provide grower identity at the time you submitted your prior notice under this subpart, but you know the identity of the grower when you submit a product identity amendment to your prior notice, you must include in your amendment: the name, address, phone number, fax number, and e-mail of all growers, and growing location if different from business address.

§ 1.291 What is the deadline for product identity amendments under § 1.290?

Your product identity amendment must be submitted no later than 2 hours prior to the time of arrival.

§ 1.292 How do you submit a product identity amendment to a prior notice?

You must submit product identity amendments in accordance with § 1.287.

§ 1.293 What are the consequences if you do not submit a product identity amendment to your prior notice?

(a) If you informed FDA in your prior notice that you would be submitting a product identity amendment but you do not amend your prior notice completely, the prior notice is inadequate for the purposes of § 1.278(a).

(b) If you informed FDA in your prior notice that you would be submitting a product identity amendment and you submit your amendment after the deadline provided in section 1.291, the prior notice is inadequate for the purpose of § 1.278(a).

§ 1.294 What must you do if the anticipated arrival information (required under § 1.288(k)(1)) submitted in your prior notice changes?

(a) If any of the anticipated arrival information required under § 1.288(k)(1) changes after you submit a prior notice to FDA, you must submit an arrival update updating the information in your prior notice in accordance with § 1.287. Your arrival update must provide the following information:

(1) If the anticipated port of entry changes, provide the updated port of entry;

(2) If the time of arrival is expected to be more than 3 hours later than the anticipated time of arrival, provide the updated time of arrival;

(3) If the time of arrival is expected to be more than 1 hour earlier than the anticipated time of arrival, provide the updated time of arrival.

(b) If you did not provide grower identity at the time you submitted your prior notice under this subpart, but you know the identity of the grower when you update your prior notice, you must include in your update: the name, address, phone number, fax number, and e-mail of all growers, and growing location if different from business address.

(c) You must update the information in accordance with the requirements of § § 1.291 and 1.292.

(d) If you do not submit an arrival update when one is required by paragraph (a) of this section, the prior notice is inadequate for the purposes of § 1.278(a).

Dated: January 27, 2003.

Tommy G. Thompson,

Secretary of Health and Human Services.

Dated: January 27, 2003.

Kenneth W. Dam,

Acting Secretary of the Treasury.

Note: The following form is an appendix that will not appear in the Code of Federal Regulations.

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES Food and Drug Administration **PRIOR NOTICE SUBMISSION**	**Form Approved: OMB No. 0910-____** **Expiration Date: _____**
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❑ Initial	❑ Held	❑ Amendment Product Identity	❑ Update Arrival Info	❑ Cancel

Mandatory Information	Mandatory if applicable

Submitter

First Name	
Last Name	

Submitting Firm

❑ U.S. Purchaser	❑ U.S. Importer
❑ U.S. Agent of Purchaser	❑ U.S. Agent of Importer
❑ Carrier	❑ In-bond Carrier

Name of Firm		
FDA Registration Number	❑ N/A	#
Street Address		
City		
State		
Zip		
Phone		
FAX		
E-mail address		

Entry Type

❑ Consumption	❑ T & E	❑ IE	❑ Mail	❑ Trade Fair
❑ Warehouse	❑ TIB		❑ Baggage	❑ Other

Entry Type Customs Code

Customs Entry Number/Customs Line Number/FDA Line Number

Article held under FDA direction	❑ No	❑ Yes

Name of Location			
Street Address			
City			
State		Zip	
Contact Name		Phone	

FORM FDA 3540 (01/03)

Date available at Location mm/dd/yy						
Product Identity						
FDA Product Code						
Common/usual/market name						
Trade/brand name						
Quantity	Number		Measure			
Identifiers		☐ Lot number		☐ Production Code		
1						
2						
3						
4						
Manufacturer						
Name of Firm						
FDA Registration Number		☐ N/A	#			
Street Address						
City						
State/Province						
Country						
Zip/Mail code						
Phone						
FAX						
E-mail address						
Grower						
Name of Firm						
Street Address						
City						
State/Province						
Country						
Zip/Mail code						
Phone						
FAX						
E-mail address						
Growing Location street						
Growing Location City						
Growing Location State/Province						
Growing Location Country						
Growing Location Zip/Mail code						
ADDITIONAL GROWERS	☐ No	☐ Yes	How Many?			
GROWER 2						
Name of Firm						
Street Address						
City						

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State/Province	
Country	
Zip/Mail code	
Phone	
FAX	
E-mail address	
Growing Location street	
Growing Location City	
Growing Location State/Province	
Growing Location Country	
Growing Location Zip/Mail code	
GROWER 3	
Name of Firm	
Street Address	
City	
State/Province	
Country	
Zip/Mail code	
Phone	
FAX	
E-mail address	
Growing Location street	
Growing Location City	
Growing Location State/Province	
Growing Location Country	
Growing Location Zip/Mail code	
Originating Country	ISO code
Shipper	
Name of Firm	
FDA Registration Number	❑ N/A #
Street Address	
City	
State/Province	
Country	
Zip/Mail code	
Phone	
FAX	
E-mail address	
Country from which the article was shipped	ISO code
Anticipated Arrival Information	
Name of Crossing	

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City of Crossing			
State of Crossing		Port of Entry Code	
Anticipated Date of Crossing mm/dd/yy			
Anticipated Time of Crossing		☐ am	☐ pm
Port of Entry for Customs Purposes (port code)			
Date of Entry for Customs Purposes mm/dd/yy			
Importer			
Name of Firm			
FDA Registration Number	☐ N/A	#	
Street Address			
City			
State			
Zip			
Phone			
FAX			
E-mail address			
Owner			
Name of Firm			
FDA Registration Number	☐ N/A	#	
Street Address			
City			
State			
Zip			
Phone			
FAX			
E-mail address			
Consignee			
Name of Firm			
FDA Registration Number	☐ N/A	#	
Street Address			
City			
State			
Zip			
Phone			
FAX			
E-mail address			
Carrier 1			
Standard Carrier Abbreviation Code			
Name of Firm			
Street Address			

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City				
State/Province				
Zip/mail code				
Country				
Phone				
FAX				
E-mail address				
Additional Carriers	❑ No	❑ Yes	How Many?	
Carrier 2				
Standard **C**arrier **A**bbreviation **C**ode				
Name of Firm				
Street Address				
City				
State/Province				
Country				
Zip/Mail code				
Phone				
FAX				
E-mail address				
Carrier 3				
Standard **C**arrier **A**bbreviation **C**ode				
Name of Firm				
Street Address				
City				
State/Province				
Country				
Zip/Mail code				
Phone				
FAX				
E-mail address				
Amendment to follow	❑ Yes	❑ No		
Cancel this submission	❑ Yes	❑ No		
This form must be submitted by the U.S. Importer or U.S. Purchaser, or U.S. Agent of the importer or purchaser, of the article of food being imported or offered for import. Under 18 U.S.C. 1001, anyone who makes a materially false, fictitious, or fraudulent statement to the U.S. Government is subject to criminal penalties.				

FORM FDA 3540 (01/03)

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Federal Register

Monday,
February 3, 2003

Part V

Office of Personnel Management

5 CFR Part 890

Debarments and Suspensions of Health Care Providers From the Federal Employees Health Benefits Program; Final Rule

OFFICE OF PERSONNEL MANAGEMENT

5 CFR Part 890

RIN 3206–AD76

Debarments and Suspensions of Health Care Providers From the Federal Employees Health Benefits Program

AGENCY: Office of Personnel Management.

ACTION: Final rule.

SUMMARY: The Office of Personnel Management (OPM) is amending its regulations regarding administrative sanctions of health care providers participating in the Federal Employees Health Benefits Program (FEHBP). These regulations implement the suspension and debarment provisions of section 2 of the Federal Employees Health Care Protection Act of 1998 (Pub. L. 105–266). That statute modified both the substantive and procedural requirements for FEHBP administrative sanctions. These regulations supersede interim final regulations issued in 1989 to implement the earlier sanctions legislation that was amended by Public Law 105–266. They will promote quicker, more uniform decisionmaking for suspensions and debarments, and will enhance protection against unfit providers for both the FEHBP and the individuals who receive health insurance coverage through the Program.

DATES: Effective February 3, 2003.

FOR FURTHER INFORMATION CONTACT: David Cope, by telephone at 202–606–2851; by FAX at 202–606–2153; or by e-mail at *debar@opm.gov.*

SUPPLEMENTARY INFORMATION:

Background

This rule was issued as a notice of proposed rulemaking in the December 12, 2001, **Federal Register** (66 FR 64160). During the 60-day public comment period, OPM received written comments from two professional organizations representing health care providers, an industry association of health insurance plans, and an FEHBP carrier. Oral comments were received from an FEHBP carrier and from OPM employees. This regulatory preamble addresses all of the comments from each source, many of which were incorporated into the final rule.

After the public comment period closed, we rewrote the proposed rule to improve its clarity and to reduce what we, as well as some of the commenters, believed to be the unnecessary wordiness associated with the ''question and answer'' format. This resulted in wording, formatting, and structural changes in virtually every section of the regulatory text. However, in no case has the meaning or effect of any regulatory material changed simply as a function of our rewriting. Because they do not reflect substantive modifications to the proposed rule, we have not identified each individual wording or format change. However, all such changes fall into one or more of the following categories:

(1) The proposed rule was written in a ''question and answer'' format in which the title of each section was phrased as a question and the body of the section constituted a response to that question. However, because the regulation is intended to apply to four different groups with divergent interests—the debarring official, the presiding official, health care providers, and health insurance carriers participating in FEHBP—in many passages the format created uncertainty as to the group or groups to which the regulatory material pertained. Therefore, we converted the regulation from ''question and answer'' to a third-person narrative format.

(2) In the proposed rule, the pronouns ''we'' or ''us'' were frequently used to denote the U.S. Office of Personnel Management, within the context of the ''question and answer'' regulatory format. We have since concluded that such references were not appropriate to denote a Federal agency, and may have created uncertainty among some readers about their meaning. As rewritten, the final rule refers to the agency solely as ''OPM,'' except in a very few instances where the context and antecedent unambiguously support use of the pronoun ''it.''

(3) As part of the ''question and answer'' format, the proposed rule used the pronoun ''you'' to denote a health care provider(s). In narrative format of the final rule, we replaced those references with ''health care provider'' or ''provider.''

(4) We have uniformly rendered references to the United States Code as (title number) U.S.C. (section number) and references to the Code of Federal Regulations as (title number) CFR (part number and/or letter designating subpart) (section number).

(5) In the definitions section (890.1003), we deleted subsection designations ((a), (b), *etc.*). The defined terms continue to be listed in alphabetic order.

(6) We replaced every passage that consisted of a direct restatement of a statutory provision with a citation to the applicable statutory provision. In most cases, this eliminated an appreciable amount of text and substantially shortened the regulatory provision. Because such sections had been intended simply to restate a statutory passage, there was no change of regulatory effect. Further, this type of rewriting improved the precision of the regulatory content by making it clear that the regulation intends to apply the cited statutory language exactly as written.

(7) Several sections or passages in the proposed rule contained citations to other regulatory sections as an authority for taking regulatory action. In every case where the cited regulatory passage had a direct underlying statutory authority, we have replaced the regulatory citation with a citation to the applicable statutory provision as the authority for regulatory action.

(8) In addition to rewriting the proposed rule from ''question and answer'' to narrative format, we attempted to simplify and shorten both the language and structure of the regulation wherever possible. We made wording changes throughout the regulation to introduce nontechnical terminology, and we sought to insure that each paragraph addresses only a single concept. In this process, we noted that the proposed § 890.1009(b) contained two distinctly separate concepts (contesting the length of a proposed debarment and requesting a personal appearance before the debarring official). Therefore, we created a new § 890.1009(c) to address the personal appearance, leaving § 890.1009(b) to address only contests of proposed debarments. Similarly, we noted that §§ 890.1013(a) and 1016(a) and (b) contained both a list of decisional factors and a statement as to how the absence of a decisional factor would be treated. Therefore, we created new §§ 890.1013(b) and 1016(c) to address the impact of an absence of decisional factors, leaving §§ 890.1013(a) and 1016(a) and (b) to contain solely a list of factors. To accommodate pre-existing sections, we renumbered the former § 890.1013(b) as 1013(c).

Purpose and Effect of Administrative Sanctions

Before analyzing the public comments that focused on specific sections of the proposed rule, we want to address several generalized concerns expressed by the professional organizations regarding the overall intent and possible effect of the FEHBP administrative sanctions program. Both of the organizations indicated that their

membership would consider administrative sanctions as ''punitive'' measures. They further commented that the statutory sanctions authority would ''perpetuate a gotcha [sic] mentality'' on OPM's part toward health care providers, leading to severe penalties for essentially innocent matters such as inadvertent billing errors or similar mistakes resulting from lack of knowledge of FEHBP program requirements.

We understand that health care providers may inevitably view administrative sanctions with some level of concern. However, there is simply no factual basis for the belief that OPM will operate any aspect of the sanctions program in a manner that would be confrontational or hostile toward providers. OPM has conducted an administrative sanctions program under the authority of the Governmentwide Nonprocurement Debarment and Suspension Common Rule (''common rule'') since May 1993. During these 9 years, OPM has debarred over 21,000 health care providers, and has maintained a professional and impartial approach to sanctions operations.

While the statutory sanctions authority being implemented by these regulations is broader than the common rule, the actual approach to sanctions decisionmaking is more objective and offers greater procedural protections to the affected health care providers. The FEHBP administrative sanctions law contains 18 bases for debarment, each involving either a previously adjudicated violation, an association between a provider and a previously-sanctioned person or entity, or specific actionable conduct by a provider. Sanctions based on conduct that has not been previously adjudicated carry a statutory requirement that the provider knew or should have known the wrongfulness of his or her actions. In this context, we believe it is clear that OPM cannot impose sanctions for *bona fide* errors or mistakes.

The sanctions that may be imposed under these regulations do not constitute punishment as that term is recognized by the law. A line of Supreme Court cases has definitively established that administrative sanctions such as debarment and civil monetary penalties are not ''punitive'' for Eighth Amendment or double jeopardy purposes unless the legislature intended them to be criminal measures. The leading current case in this line, *Hudson* v. *United States,* 522 U.S. 93 (1997), notes that even sanctions that might, ''in common parlance, be described as punishment,'' are appropriately characterized as administrative in nature if Congress enacted them to be civil, rather than criminal, remedies. There is no question that the FEHBP administrative sanctions law was intended to be a civil statute, and in fact the administrative sanctions it authorizes are no more severe—and in some contexts are less stringent—than the corresponding health care provider sanctions under Medicare law.

Further, OPM's responsibility is to implement the statute consistent with the legislative intent and purpose. In this context, OPM's principal operating challenge—as is the case for other Federal agencies using sanctions authorities—will be to focus its efforts so as to afford an optimal level of protection to FEHBP in the most efficient manner possible. Hostile, antagonistic, or confrontational activities aimed at providers would clearly be improper, incompatible with the statute and these regulations, and detrimental to the intended protective purposes of the sanctions themselves. We expect that our implementation of these regulations will demonstrate that administrative sanctions in fact support high standards of professional conduct and ethical business practices by holding those who commit violations accountable for their actions.

Suggestions Regarding Unrelated Legislation

One of the professional organizations suggested that we rewrite the proposed regulations to incorporate the principles of the Medicare Education and Regulatory Fairness Act of 2001 (MERPA), introduced in the 107th Congress as H.R. 868 and S. 452, and reissue the resultant product as a proposed regulation for further comment. As characterized by the professional organization, MERPA would require the Department of Health and Human Services (DHHS) to emphasize educating health care providers about program requirements and to simplify ''complex legal and regulatory requirements'' rather than imposing ''punitive enforcement actions'' against providers. MERPA's preamble indicates that many physicians are leaving the Medicare program, due to the risks of ''aggressive government investigation,'' thus compromising the availability of health care for Medicare patients.

We believe the professional organization's suggestion is inappropriate in the context of these regulations. Congress enacted the administrative sanctions provisions of Pub. L. 105–266 to meet the needs of the FEHBP for an effective and efficient means of addressing integrity issues associated with certain types of provider-related violations. We note that MERPA's stated objectives do not appear to be germane to FEHBP operations. For example, Medicare's regulatory and billing practices do not apply to FEHBP, and FEHBP has not experienced declining provider participation. In this context, we do not believe that MERPA's principal ''instructional'' feature—a system of binding advisory opinions on the allowability of specific claims—would be necessary or relevant to providers' relationships with the FEHBP claims system.

The remainder of the comments we received dealt with specific regulatory provisions or issues. We address each of them in the following sections of this preamble.

Informing Providers of Sanctions Action

The health care provider professional organizations suggested that the proposed § 890.1006(c)(2) and (3), authorizing OPM to issue notices of proposed debarment via facsimile transmission (fax) or e-mail, were not in compliance with the terms of 5 U.S.C. 8902a. The same commenters also remarked that the provisions of the proposed § 890.1006(e), authorizing OPM to presume that providers have received a notice 5 days after it was sent, are ''irresponsible'' and deprive providers of their due process entitlement to adequate notice. The commenters recommended that § 890.1006(e) be changed to require OPM to obtain actual proof that a provider has received notice before taking debarment action.

The intent of the proposed § 890.1006(c)(2) and (3) was to make communication with persons affected by sanctions actions faster and more reliable, especially as heightened security measures have slowed the delivery of postal mail to many Federal agencies. Similar electronic notification provisions appear in the proposed revision to the common rule, which was issued as a notice of proposed rulemaking in the January 23, 2002, **Federal Register** (67 FR 3266). The common rule revision was developed by the Interagency Suspension and Debarment Committee at the request of the Office of Management and Budget. However, as reflected by the commenter's concerns, questions remain as to the acceptability of electronic media for communicating official notices. After consultation with the Interagency Suspension and Debarment Committee, we concluded

that this issue would be more appropriately determined in the Governmentwide forum of the proposed common rule. Therefore, we modified the proposed § 890.1006(c) to delete any mention of electronic transmission of notice, and we have specifically reserved a new section § 890.1006(g) to address the ''e-notices'' if they are ultimately adopted in the final version of the revised common rule. In the interim, we intend to continue our practice of using electronic means to communicate material other than official debarment notices when providers furnish us a fax number or e-mail address.

In regard to the comments on the proposed § 890.1006(e), presumption of receipt of official notice is a well-established aspect of Federal regulatory practice. For example, the common rule has contained such a provision since it was first issued in 1988. In addition, the Department of Health and Human Services (DHHS) relies upon 5-day presumption of receipt provisions for its official notices of provider exclusions in the Medicare program (see 42 CFR 1001.2001). Further, the burden of operating an ''actual notice'' system, in terms of cost, staff time, and prolonged processing timeframes for debarments, is highly problematic. Given these factors, we believe that a notice system based on regular first class mail with a regulatory presumption of receipt represents a reasonable model for transmitting debarment notices to providers. We would also point out that § 890.1006(e) should be read in conjunction with § 890.1006(f), which requires OPM to make appropriate followup efforts to secure delivery of notice if it learns that a notice cannot be delivered as originally addressed. Taken together, these provisions offer a high level of assurance that providers will receive notices in a timely manner, while permitting OPM the flexibility to implement debarments promptly.

Effective Date of Debarment Orders

The health care provider professional associations expressed concern that the proposed § 890.1009 specified that debarments taken under mandatory debarment authorities would go into effect when issued by OPM, and remain in effect during the pendency of judicial appeals. They characterized this provision as ''a severe penalty'' for health care providers whose debarments may be reversed on appeal, and suggested that OPM defer the effective date of debarments until after all administrative and judicial appeals have been completed.

The commenters' concerns touch upon two separate but related issues that we believe are essential to effective implementation of the statutory debarment authorities. The first of these involves OPM's ability to effectuate debarments in a timely manner. As noted in the ''Background'' section of the Supplementary Information accompanying the proposed rule (66 FR 64160), Pub. L. 105–266 amended an earlier (1988) FEHBP sanctions statute that had proved to be ''costly and unworkable,'' primarily because of its requirement that OPM debarment orders not go into effect until all administrative and judicial appeal avenues to challenge those debarments had been exhausted. This deprived OPM's sanctions decisions of meaningful finality and invited delay and expense through protracted litigation. Pub. L. 105–266 addressed the problem by providing OPM with regulatory authority to establish effective dates of debarments. In implementing this authority (§ 890.1009 for mandatory debarments and § 890.1026 for permissive debarments), OPM decided to make debarments effective immediately upon completion of the administrative appeals process, or, if a provider does not file an administrative appeal, immediately upon expiration of the 30-day notice period for a proposed debarment. OPM will keep debarments in effect while providers exercise their statutory right of appeal to U.S. district court. OPM would, of course, stay the implementation of a debarment during a judicial appeal if ordered to do so by the court.

The other issue raised by this comment is whether a basis for debarment that involves a conviction is affected by a provider's appeal of the conviction. The FEHBP debarment statute addresses this in 5 U.S.C. 8902a(a)(1)(C), which specifies that a ''conviction'' exists ''without regard to the pendency or outcome of any appeal (other than a judgment of acquittal based on innocence) or request for relief.'' The purpose of this provision is to keep a mandatory debarment continuously in effect during subsequent litigation unless a final appellate ruling reverses or vacates the conviction and there is no longer a possibility of a retrial.

As part of our overall rewriting of the regulation, we replaced the definition of ''conviction'' in § 890.1003, which was a direct restatement of the statutory language of 5 U.S.C. 8902a(a)(1)(C), with a citation to the statutory provision. This means that a conviction, as a basis for a mandatory debarment, comes into effect immediately upon adjudication and remains in effect during all subsequent litigation. To reflect the impact of 5 U.S.C. 8902a(a)(1)(C) on reinstatement of a provider, we have also added a citation to this provision in § 890.1052(a).

Inasmuch as the regulatory provisions criticized by the commenters directly implement the provisions of Public Law 105—266 that authorize OPM to effectuate debarments, notwithstanding the pendency of judicial appeals, we are not adopting the commenters' recommendations.

Aggravating and Mitigating Factors

One of the professional associations observed that a serious inequity appears to exist between the respective lists of aggravating and mitigating factors in the proposed §§ 890.1008 and 1016. The commenter stated that the aggravating factors are ''open-ended,'' while the mitigating factors are strictly limited to the items listed. Further, the commenter noted that neither the aggravating nor mitigating factors recognize restitution a provider may have made for incorrect, improper, or wrongful receipt of Federal funds.

The proposed § 890.1008 identifies the aggravating and mitigating factors that the debarring official must consider in determining the proposed length of a mandatory debarment. The proposed § 890.1016 contains an essentially identical list for permissive debarments. We believe the aggravating and mitigating factors identified in the regulation are equitable and appropriately recognize matters relevant to the violation for which a sanction is being proposed. In our estimation, a reasonable reading of §§ 890.1008 and 1016 simply does not support the commenter's interpretation that the aggravating factors are broad and ambiguous while the mitigating factors are narrowly drawn. The lists of factors in each regulatory provision represent the factors that the debarring official may consider as aggravating and mitigating, respectively, in determining the proposed length of a proposed debarment. Neither list contains a ''catch-all'' provision to authorize consideration of other factors on an *ad hoc* basis.

It should be noted, moreover, that the final length of a debarment is not based solely on these factors. After being notified of a proposed debarment and its proposed length, the provider has the opportunity to challenge them in an administrative proceeding under the provisions of §§ 890.1022—1029. Decisions regarding the length of debarments are discretionary with the debarring official in every case, and a

provider's ability to contest the proposed length of his or her debarment is not limited in any way by the aggravating and mitigating factors listed in §§ 890.1008 and 1016.

In regard to the treatment of restitution by these regulations, the professional organization posed a hypothetical example involving restitution of amounts received by a provider because of a ''billing error.'' This example reflects an inaccurate premise. In fact, receipt of an incorrect payment of FEHBP funds due to a *bona fide* billing error is not a sanctionable violation, and these regulations would not apply in such a situation. However, if a provider receives payments of FEHBP funds because of false, fraudulent, deceptive, or otherwise wrongful claims that form the basis for a debarment, §§ 890.1008 and 1016 authorize the debarring official to consider the resultant financial loss to the Government as an aggravating factor. Because the actual amount of the improper payments reflects the seriousness of the provider's violation, the regulations do not provide for crediting any post-violation restitution in calculating the amount of the financial loss. However, it is appropriate to recognize restitution made as part of a provider's post-violation cooperation with law enforcement authorities under the mitigating factors in §§ 890.1008(b)(3) and 1016(b)(1). To the extent that the proposed regulation may not have clearly conveyed this meaning, we have reworded both §§ 890.1008 and 1016 to reflect unambiguously that restitution is an aspect of cooperation with law enforcement authorities that may be considered mitigating for purposes of computing a proposed period of debarment.

Length of Permissive Debarments

One of the professional organizations commented that the wording of the proposed 890.1015 was inconsistent with the underlying statutory provisions, to the extent that it could restrict the discretion of the debarring official in setting the length of debarments under permissive debarment authorities. In every case based on a permissive debarment authority, Public Law 105–266 allows the debarring official full discretion to debar or not debar, and, if he elects to debar, to set the period of the debarment without limitations as to length.

While we did not intend the proposed § 890.1015 to establish a mandatory minimum debarment period for permissive debarments, nor to limit the debarring official's discretion in any other way, we agree with the commenter's observation that the proposed wording invited such an interpretation. Accordingly, we have revised § 890.1015 to clarify that the debarring official possesses full discretionary decisionmaking authority to establish the length of permissive debarments in every case.

Matters To Be Treated as Prior Adjudications

The proposed § 890.1025 sets forth the criteria which the debarring official will use to determine if OPM must conduct a fact-finding hearing to resolve a provider's administrative appeal of a debarment. Public Law 105–266 requires that every material fact on which a debarment is based be adjudicated in an appropriate administrative proceeding. However, OPM will not readjudicate facts determined in prior due process proceedings, such as criminal or civil actions or professional licensure actions, or facts to which the provider stipulated. Both professional associations objected to the wording of the proposed § 890.1025(a)(4), which would treat settlement agreements entered into by a provider to resolve civil or administrative actions as tantamount to adjudications, even if they contain no factual stipulations or admissions. Although the commenters did not so indicate, identical language also appeared in the proposed § 890.1037(a), regarding prior adjudications in the context of administrative appeals of suspensions. We agree with the commenters that these passages are inconsistent with the current state of the law. Therefore, we have modified the final text of both § § 890.1025(a)(4) and 890.1037(a) to indicate that settlement agreements may be deemed to be waivers of adjudication only if they contain stipulations of facts establishing that a sanctionable violation occurred.

Informing FEHBP Enrollees about Provider Debarments

The proposed § 890.1045 required FEHBP carriers to notify their enrollees who have previously obtained items or services from a debarred provider of the provider's debarment, and specified certain items of information that must be included in the notification. An FEHBP carrier and the health insurance industry association both suggested that this section be modified to require debarred providers to notify the FEHBP enrollees with whom they deal of their debarment. This would relieve the carriers of the effort and cost associated with the notification responsibility.

OPM does not have statutory authority to directly regulate provider conduct in this manner. In fact, the proposed § 890.1045 was drawn directly from 5 U.S.C. 8902a(j), which requires OPM to issue regulations placing responsibility on the FEHBP carriers for informing enrollees of provider debarments. Therefore, we are not adopting this recommendation.

As an alternate suggestion, the health insurance industry association recommended that, if carriers must inform enrollees of provider debarments, the proposed § 890.1045 be modified to permit carriers to target their notifications in some manner. The literal wording of § 890.1045 would have required carriers to notify all enrollees who had ever received items or services from a debarred provider, but the commenter suggested that such a practice would involve excessive time and expense. Instead, the industry association suggested targeting notices to enrollees who have (1) incurred claims with providers that OPM deemed to present a risk to FEHBP members or (2) recently received services from debarred providers.

We believe this comment is well-founded. Our experience under the common rule has revealed that early enrollee notification is absolutely vital to carrying out the purpose of debarments. This is even more clearly the case under these regulations, because 5 U.S.C. 8902a(j) requires enrollee claims for items or services furnished by a debarred provider to be paid by FEHBP carriers if the enrollee was unaware of the provider's debarment. Since FEHBP enrollees generally need no prior approval or clearance to obtain covered services from a health care provider, they create an obligation on the part of their FEHBP carrier to pay claims simply by receiving such services. Well-targeted notice to potential patients regarding the debarment of a provider appears to be the most efficient means of reducing the incidence of enrollee contact with debarred providers.

Of the targeting criteria suggested by the industry association, we do not believe that we would consistently have sufficient information to reliably designate certain providers as ''high risk.'' Further, such a practice could be perceived by providers as carrying a potentially stigmatizing effect beyond the reasonable needs of the sanctions process. In contrast, notifying enrollees who have recently obtained items and services from debarred providers appears to offer a reasonable approach to diminishing FEHBP payments to those providers, without the risk of

prejudicially labeling them. Accordingly, we have accepted this aspect of the industry association's suggestion—including the one year recency criterion—and have reworded § 890.1045 to require FEHBP carriers to notify enrollees who have obtained items or services from a debarred provider within one year prior to the provider's debarment.

The insurance industry association further suggested that we create a website to provide FEHBP carriers and enrollees with up-to-date information on provider debarments, and that we reflect this action in the proposed § 890.1044. For nearly 2 years, OPM's Office of the Inspector General has used a secure Internet webpage to make debarment data available to FEHBP carriers. We update the page regularly, according to a schedule known to the carriers. Because of the extensive amount of Privacy Act-protected information about providers that we furnish to carriers, this webpage cannot be publicly accessible. However, the function of making debarment information from all agencies available to the public in an automated, searchable format is met by the General Services Administration's Governmentwide debarment list (''GSA List''), which is on the Internet at www.epls.com. There are links directly to the GSA List from OPM's website (www.opm.gov). In its present form, § 890.1044 accurately reflects OPM's responsibilities to make debarment-related information available both to carriers and to the GSA List. Therefore, while we will not be adopting this suggestion, information about OPM debarments is readily available online for both FEHBP carriers and the public.

Authority to Issue Suspensions

One of the professional associations commented that Public Law 105–266 did not appear to provide OPM the authority to suspend health care providers. Therefore, the commenter recommended that all of the proposed provisions regarding suspension (proposed §§ 890.1030–1041) be removed from the final rule.

While Public Law 105–266 does not contain the term ''suspension,'' it does provide authority for OPM to issue the type of sanctions that are characterized as suspensions in the proposed 890.1030–1041. We designated these actions ''suspensions'' because that terminology is widely used among Federal agencies—including OPM under the common rule authority—to connote sanctions with certain effects. As used in these regulations, ''suspension'' connotes a short-term action with the force of a debarment that is (1) effective immediately upon issuance of notice by OPM, (2) predicated on one or more of the bases for debarment identified in Public Law 105–266, and (3) necessitated by the existence of a sufficiently serious risk to warrant removing a provider from participating in FEHBP in the most expeditious manner possible. OPM's ability to regulate in this area is based on 5 U.S.C. 8902a(g)(1)(A), authorizing the agency to set reasonable conditions regarding notice to providers and effective dates of debarments, and 5 U.S.C. 8902a(g)(1)(B), authorizing OPM to establish effective dates in advance of process if warranted by the ''health or safety of individuals receiving health care services.''

In drafting the sections of these regulations implementing the provider suspension authority, we attempted to incorporate existing Governmentwide practices as extensively as possible. The two most frequently used suspension models are represented by the Federal Acquisition Regulation (FAR) and the common rule. However, the FAR approach, providing for automatic and immediate suspension upon issuance of every notice of proposed debarment, is clearly beyond the scope of the authority granted by 5 U.S.C. 8902a. In contrast, the common rule approach, selectively limiting suspension to situations where there is a tangible need to protect a program or program participants, closely tracks the provisions of the FEHBP sanctions statute that authorize suspension. Therefore, §§ 890.1030 through 1041 set forth procedures which generally mirror the corresponding common rule practices for suspensions. The administrative appeal provisions of §§ 890.1035–1041 offer greater procedural protections to affected providers than those contained in the common rule. Their purpose is to assure that all suspended providers have the right to contest the suspension promptly, as required by 5 U.S.C. 8902a(h)(1), including a personal appearance before the suspending official and a separate hearing on any facts material to the suspension that have not previously been adjudicated.

Based on the commenter's observations, we have also revised the wording of § 890.1031(c) to conform more closely to the terms of 5 U.S.C. 8902a(g)(1)(B), limiting suspensions to cases of risk to the health or safety of FEHBP enrollees. However, we will construe such risk to include not only physical harm resulting from a provider's maltreatment or abuse, but also the more generalized risks inherent in receiving health care from a provider who has committed any sort of sanctionable violations that reflect on his or her trustworthiness.

Miscellaneous Provisions Addressed by Outside Commenters

The health care provider professional associations expressed concerns that several provisions of the proposed regulations broadened the reach of OPM's administrative sanctions authority in a manner that was unfair to health care providers. The commenters suggested that these provisions be deleted from the proposed regulations.

In fact, each of the proposed regulatory sections identified by the commenters is based directly on a provision of the FEHBP sanctions statute. Collectively, their placement in these regulations is necessary to assure full implementation of the statute. Therefore, we are retaining all of these sections in the final regulation. However, our overall rewriting of the regulatory text has substantially altered their wording and format. As they appeared in the proposed rule, each of the regulatory sections cited by the commenters comprised a restatement of a statutory provision. As rewritten in the final rule, each section simply provides a citation to the corresponding section of the statute. The regulatory provisions in question are as follows:

(1) Proposed § 890.1003(e)(4), defining ''conviction'' to include an individual's participation in first offender, pre-trial diversion, or other programs under which a formal adjudication of an offense is withheld. The commenters considered this definition to be ''overly broad,'' so as to include any infraction, including an inadvertent billing error. As we have previously noted in this preamble, we intended the regulatory definition of ''conviction'' to correspond precisely to the statutory definition of that term set forth in 5 U.S.C. 8902a(a)(1)(C). As now rewritten, the definition of ''conviction'' appearing in § 890.1003 of the final rule simply cites to 5 U.S.C. 8902a(a)(1)(C). The exact wording identified as objectionable by the commenter is contained in 8902a(a)(1)(C)(iv). Further, as we have stated elsewhere in this preamble, we do not believe that a reasonable reading of the statutory definition of ''conviction,'' or indeed any other provision of the FEHBP sanctions statute, would support the conclusion that a truly inadvertent provider error could be the basis of a sanctions action.

(2) Proposed § 890.1011(b)(1)(iii), authorizing permissive debarment of an entity based on an ownership or control interest by a provider who has been

assessed a civil monetary penalty under the FEHBP sanctions statute. One commenter expressed the belief that this provision ''creates serious opportunities for abuse.'' However, this proposed regulatory section directly restated the provisions of 5 U.S.C. 8902a(c)(2). The rewritten § 890.1011(b) simply cites the statutory provisions authorizing debarment based on ownership or control interests—5 U.S.C. 8902a(c)(2) and (3)—thus removing a substantial amount of unnecessary text without altering the intent or effect of the provision.

(3) Proposed § 890.1011(b)(2), authorizing permissive debarment of an individual provider who holds an ownership or control interest in an entity that has been debarred, convicted of a sanctionable offense, or assessed a civil monetary penalty under the FEHBP provider sanctions statute, if the individual knew or should have known of the entity's violations. One commenter characterized this provision as ''even more offensive'' than the proposed § 890.1011(b)(1). In fact, this regulatory provision directly restates the provisions of 5 U.S.C. 8902a(c)(3). As noted in the preceding paragraph, we have revised the proposed § 890.1011(b) to consist simply of a reference to the statutory provisions authorizing debarment based on ownership and control interests, without restating the rather lengthy statutory text.

(4) Proposed § 890.1011(c), authorizing permissive debarment for certain enumerated claims-related violations. One commenter suggested that this provision would permit debarment based on ''a single billing error.'' In the proposed rule, § 890.1011(c) restated the statutory wording of the seven bases for permissive debarment established by 5 U.S.C. 8902a(c)(4) and (5) and (d)(1) and (2). As reworded in the final rule, § 890.1011(c) consists simply of a citation to those sections of the statute. Once again, we would note that a careful reading of these regulations and FEHBP sanctions law does not support the conclusion that a good faith error could be the basis for a sanctions action.

(5) Proposed § 890.1011(d), authorizing permissive debarment for a provider's failure to furnish claims-related information requested by OPM or an FEHBP carrier. While the commenter did not indicate the precise nature of its objection to this provision, in fact the cited passage in the proposed rule directly restated 5 U.S.C. 8902a(d)(3). As it appears in the final rule, § 890.1011(d) consists only of a citation to that statutory provision.

Miscellaneous Revisions Identified by OPM Comments

As the result of comments from OPM sources, we have slightly modified the following sections of the regulatory package.

(1) The proposed §§ 890.1005 and 1012 address implementation of the 6-year statutory limitations period for mandatory and permissive debarments, respectively. In each section, we have replaced every instance of the phrase ''issue * * * a notice of proposed debarment'' with ''send * * * a notice of proposed debarment.'' The term ''send'' is used uniformly in proposed § 890.1006 to denote transmission of official notice, and its corresponding use in §§ 890.1005 and 1012 clarifies that the limitations period is tolled when OPM places a notice of proposed debarment into the transmission channels authorized by § 890.1006.

(2) The proposed § 890.1028(d) describes the manner in which OPM will create an official record of fact-finding hearings associated with permissive debarments. In preparing the regulatory text for the proposed rule, we inadvertently omitted from this section a phrase requiring OPM to furnish the provider with a free copy of an audio recording of the hearing. We have restored that intended wording in the final rule. Further, we have changed the final sentence of § 890.1028(d) to indicate that OPM will arrange for transcription of the recording if the provider requests it, but that the provider must pay the cost of the transcription.

(3) The proposed § 890.1052(a) addressed the procedures for reinstating providers whose debarments were based on convictions that have been reversed on appeal. An OPM reviewer noted that the proposed wording of this section did not account for the full statutory definition of ''conviction'' in 5 U.S.C. 8902a(a)(1)(C), which indicates that a provider is considered to have been convicted ''without regard to the pendency or outcome of any appeal.'' Upon a literal reading, this passage would seem to support the interpretation that a provider remains convicted—and thus debarred—even if an appeals court reverses or vacates the conviction on which the debarment is based. However, such an interpretation would clearly produce anomalous results.

The actual intent of the statutory wording is to permit a mandatory debarment to remain in effect until the appeals process, including possible retrials, has concluded. This avoids the possibility of sequential retractions and reinstatements of debarments which could result from differing appeals court rulings as a case progresses through the appeals process. Therefore, as noted elsewhere in this preamble, we have expanded the wording of § 890.1052(a) to reflect that OPM will reinstate a provider on the basis of a reversed conviction only if a final appeals ruling has been issued and there is no further possibility of a retrial or if an appeals court enters a judgment of acquittal based on the provider's innocence.

(4) We added a definition of ''days'' in § 890.1003 to support the distinction between the ''calendar day'' timeframes applied to most deadlines established by the regulation and the ''business day'' timeframe associated with presumed receipt of notices of proposed sanctions under § 890.1006(e)(2).

Regulatory Flexibility Act

I certify that this regulation will not have a significant economic impact on a substantial number of small entities, because it affects only health care providers' transactions with the Federal Employees Health Benefits Program.

Executive Order 12866, Regulatory Review

This rule has been reviewed by the Office of Management and Budget in accordance with Executive Order 12866.

List of Subjects in 5 CFR Part 890

Administrative practice and procedure, Government employees, Health facilities, Health insurance, Health professions, Hostages, Iraq, Kuwait, Lebanon.

Office of Personnel Management.

Kay Coles James,

Director.

Accordingly, OPM is amending part 890 of title 5, Code of Federal Regulations as follows:

PART 890—FEDERAL EMPLOYEES HEALTH BENEFITS PROGRAM

1. The authority citation for part 890 is revised to read as follows:

Authority: 5 U.S.C. 8913; § 890.803 also issued under 50 U.S.C. 403(p), 22 U.S.C. 4069c and 4069c–1; subpart L also issued under sec. 599C of Pub. L. 101–513, 104 Stat. 2064, as amended; § 890.102 also issued under sections 11202(f), 11232(e), 11246(b) and (c) of Pub. L. 105–33, 111 Stat. 251; and section 721 of Pub. L. 105–261, 112 Stat. 2061, unless otherwise noted.

2. Subpart J of part 890 is revised to read as follows:

Subpart J—Administrative Sanctions Imposed Against Health Care Providers

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[Reserved]

Subpart J—Administrative Sanctions Imposed Against Health Care Providers

Authority: 5 U.S.C. 8902a.

General Provisions and Definitions

§ 890.1001 Scope and purpose.

(a) *Scope.* This subpart implements 5 U.S.C. 8902a, as amended by Public Law 105–266 (October 19, 1998). It establishes a system of administrative sanctions that OPM may, or in some cases, must apply to health care providers who have committed certain violations. The sanctions include debarment, suspension, civil monetary penalties, and financial assessments.

(b) *Purpose.* OPM uses the authorities in this subpart to protect the health and safety of the persons who obtain their health insurance coverage through the FEHBP and to assure the financial and programmatic integrity of FEHBP transactions.

§ 890.1002 Use of terminology.

Unless otherwise indicated, within this subpart the words ''health care provider,'' ''provider,'' and ''he'' mean a health care provider(s) of either gender or as a business entity, in either the singular or plural. The acronym ''OPM'' and the pronoun ''it'' connote the U.S. Office of Personnel Management.

§ 890.1003 Definitions.

In this subpart:

Carrier means an entity responsible for operating a health benefits plan described by 5 U.S.C. 8903 or 8903a.

Community means a geographically-defined area in which a provider furnishes health care services or supplies and for which he may request a limited waiver of debarment in accordance with this subpart. *Defined service area* has the same meaning as community.

Contest means a health care provider's request for the debarring or suspending official to reconsider a proposed sanction or the length or amount of a proposed sanction.

Control interest means that a health care provider:

(1) Has a direct and/or indirect ownership interest of 5 percent or more in an entity;

(2) Owns a whole or part interest in a mortgage, deed of trust, note, or other obligation secured by the entity or the entity's property or assets, equating to a direct interest of 5 percent or more of the total property or assets of the entity;

(3) Serves as an officer or director of the entity, if the entity is organized as a corporation;

(4) Is a partner in the entity, if the entity is organized as a partnership;

(5) Serves as a managing employee of the entity, including but not limited to employment as a general manager, business manager, administrator, or other position exercising, either directly or through other employees, operational or managerial control over the activities of the entity or any portion of the entity;

(6) Exercises substantive control over an entity or a critical influence over the activities of the entity or some portion of thereof, whether or not employed by the entity; or

(7) Acts as an agent of the entity.

Conviction or *convicted* has the meaning set forth in 5 U.S.C. 8902a(a)(1)(C).

Covered individual means an employee, annuitant, family member, or former spouse covered by a health benefits plan described by 5 U.S.C. 8903 or 8903a or an individual eligible to be covered by such a plan under 5 U.S.C. 8905(d).

Days means calendar days, unless specifically indicated otherwise.

Debarment means a decision by OPM's debarring official to prohibit payment of FEHBP funds to a health care provider, based on 5 U.S.C. 8902a (b), (c), or (d) and this subpart.

Debarring official means an OPM employee authorized to issue debarments and financial sanctions under this subpart.

FEHBP means the Federal Employees Health Benefits Program.

Health care services or supplies means health care or services and supplies such as diagnosis and treatment; drugs and biologicals; supplies, appliances and equipment; and hospitals, clinics, or other institutional entities that furnish supplies and services.

Incarceration means imprisonment, or any type of confinement with or without supervised release, including but not limited to home detention, community confinement, house arrest, or similar arrangements.

Limited waiver means an approval by the debarring official of a health care provider's request to receive payments of FEHBP funds for items or services rendered in a defined geographical area, notwithstanding debarment, because the provider is the sole community provider or sole source of essential specialized services in a community.

Mandatory debarment means a debarment based on 5 U.S.C. 8902a(b).

Office or *OPM* means the United States Office of Personnel Management or the component thereof responsible for conducting the administrative sanctions program described by this subpart.

Permissive debarment means a debarment based on 5 U.S.C. 8902a(c) or (d).

Provider or *provider of health care services or supplies* means a physician, hospital, clinic, or other individual or entity that, directly or indirectly, furnishes health care services or supplies.

Reinstatement means a decision by OPM to terminate a health care provider's debarment and to restore his eligibility to receive payment of FEHBP funds.

Sanction or *administrative sanction* means any administrative action authorized by 5 U.S.C. 8902a or this subpart, including debarment, suspension, civil monetary penalties, and financial assessments.

Should know or *should have known* has the meaning set forth in 5 U.S.C. 8902a(a)(1)(D).

Sole community provider means a provider who is the only source of primary medical care within a defined service area.

Sole source of essential specialized services in a community means a health care provider who is the only source of specialized health care items or services in a defined service area and that items or services furnished by a non-specialist cannot be substituted without jeopardizing the health or safety of covered individuals.

Suspending official means an OPM employee authorized to issue suspensions under 5 U.S.C. 8902a and this subpart.

Mandatory Debarments

§ 890.1004 Bases for mandatory debarments.

(a) *Debarment required.* OPM shall debar a provider who is described by any category of offense set forth in 5 U.S.C. 8902a(b).

(b) *Direct involvement with an OPM program unnecessary.* The conduct underlying the basis for a provider's mandatory debarment need not have involved an FEHBP covered individual or transaction, or any other OPM program.

§ 890.1005 Time limits for OPM to initiate mandatory debarments.

OPM shall send a provider a written notice of a proposed mandatory debarment within 6 years of the event that forms the basis for the debarment. If the basis for the proposed debarment is a conviction, the notice shall be sent within 6 years of the date of the conviction. If the basis is another agency's suspension, debarment, or exclusion, the OPM notice shall be sent within 6 years of the effective date of the other agency's action.

§ 890.1006 Notice of proposed mandatory debarment.

(a) *Written notice.* OPM shall inform a provider of his proposed debarment by written notice sent not less than 30 days prior to the proposed effective date.

(b) *Contents of the notice.* The notice shall contain information indicating the:

(1) Effective date of the debarment;

(2) Minimum length of the debarment;

(3) Basis for the debarment;

(4) Provisions of law and regulation authorizing the debarment;

(5) Effect of the debarment;

(6) Provider's right to contest the debarment to the debarring official;

(7) Provider's right to request OPM to reduce the length of debarment, if it exceeds the minimum period required by law or this subpart; and

(8) Procedures the provider shall be required to follow to apply for reinstatement at the end of his period of debarment, and to seek a waiver of the debarment on the basis that he is the sole health care provider or the sole source of essential specialized services in a community.

(c) *Methods of sending notice.* OPM shall send the notice of proposed debarment and the final decision notice (if a contest is filed) to the provider's last known address by first class mail, or, at OPM's option, by express delivery service.

(d) *Delivery to attorney, agent, or representatives.* (1) If OPM proposes to debar an individual health care provider, it may send the notice of proposed debarment directly to the provider or to any other person designated by the provider to act as a representative in debarment proceedings.

(2) In the case of a health care provider that is an entity, OPM shall deem notice sent to any owner, partner, director, officer, registered agent for service of process, attorney, or managing employee as constituting notice to the entity.

(e) *Presumed timeframes for receipt of notice.* OPM computes timeframes associated with the delivery notices described in paragraph (c) of this section so that:

(1) When OPM sends notice by a method that provides a confirmation of receipt, OPM deems that the provider received the notice at the time indicated in the confirmation; and

(2) When OPM sends notice by a method that does not provide a confirmation of receipt, OPM deems that the provider received the notice 5 business days after it was sent.

(f) *Procedures if notice cannot be delivered.* (1) If OPM learns that a notice was undeliverable as addressed or routed, OPM shall make reasonable efforts to obtain a current and accurate address, and to resend the notice to that address, or it shall use alternative methods of sending the notice, in accordance with paragraph (c) of this section.

(2) If a notice cannot be delivered after reasonable followup efforts as described in paragraph (f)(1) of this section, OPM shall presume that the provider received notice 5 days after the latest date on which a notice was sent.

(g) *Use of electronic means to transmit notice.* [Reserved]

§ 890.1007 Minimum length of mandatory debarments.

(a) *Debarment based on a conviction.* The statutory minimum period of debarment for a mandatory debarment based on a conviction is 3 years.

(b) *Debarment based on another agency's action.* A debarment based on another Federal agency's debarment, suspension, or exclusion remains in effect until the originating agency terminates its sanction.

§ 890.1008 Mandatory debarment for longer than the minimum length.

(a) *Aggravating factors.* OPM may debar a provider for longer than the 3-year minimum period for mandatory debarments if aggravating factors are associated with the basis for the debarment. The factors OPM considers to be aggravating are:

(1) Whether the FEHBP incurred a financial loss as the result of the acts underlying the conviction, or similar acts that were not adjudicated, and the level of such loss. In determining the amount of financial loss, OPM shall not consider any amounts of restitution that a provider may have paid;

(2) Whether the sentence imposed by the court included incarceration;

(3) Whether the underlying offense(s), or similar acts not adjudicated, occurred repeatedly over a period of time, and whether there is evidence that the offense(s) was planned in advance;

(4) Whether the provider has a prior record of criminal, civil, or administrative adjudication of related offenses or similar acts; or

(5) Whether the actions underlying the conviction, or similar acts that were not adjudicated, adversely affected the physical, mental, or financial well-being of one or more covered individuals or other persons.

(b) *Mitigating factors.* If the aggravating factors justify a debarment longer than the 3 year minimum period for mandatory debarments, OPM shall also consider whether mitigating factors may justify reducing the debarment period to not less than 3 years. The factors that OPM considers to be mitigating are:

(1) Whether the conviction(s) on which the debarment is based consist entirely or primarily of misdemeanor offenses;

(2) Whether court records, including associated sentencing reports, contain an official determination that the provider had a physical, mental, or emotional condition before or during the commission of the offenses underlying the conviction that reduced his level of culpability; or

(3) Whether the provider's cooperation with Federal and/or State investigative officials resulted in criminal convictions, civil recoveries, or administrative actions against other individuals, or served as the basis for identifying program weaknesses. Restitution made by the provider for funds wrongfully, improperly, or illegally received from Federal or State programs may also be considered as a mitigating circumstance.

(c) *Maximum period of debarment.* There is no limit on the maximum period of a mandatory debarment based on a conviction.

§ 890.1009 Contesting proposed mandatory debarments.

(a) *Contesting the debarment.* Within 30 days after receiving OPM's notice of proposed mandatory debarment, a provider may submit information, documents, and written arguments in opposition to the proposed debarment. OPM's notice shall contain specific information about where and how to submit this material. If a timely contest is not filed, the proposed debarment shall become effective as stated in the notice, without further action by OPM.

(b) *Requesting a reduction of the debarment period.* If OPM proposes a mandatory debarment for a period longer than the 3-year minimum required by 5 U.S.C. 8902a(g)(3), the provider may request a reduction of the debarment period to not less than 3 years, without contesting the debarment itself.

(c) *Personal appearance before the debarring official.* In addition to providing written material, the provider may appear before the debarring official personally or through a representative to present oral arguments in support of his contest. OPM's notice shall contain specific information about arranging an in-person presentation.

§ 890.1010 Debarring official's decision of contest.

(a) *Prior adjudication is dispositive.* Evidence indicating that a provider was formally adjudicated for a violation of any type set forth in 5 U.S.C. 8902a(b) fully satisfies the standard of proof for a mandatory debarment.

(b) *Debarring official's decision.* The debarring official shall issue a written decision, based on the entire administrative record, within 30 days after the record closes to receipt of information. The debarring official may extend this decision period for good cause.

(c) *No further administrative proceedings.* The debarring official's decisions regarding mandatory debarment and the period of debarment are final and are not subject to further administrative review.

Permissive Debarments

§ 890.1011 Bases for permissive debarments.

(a) *Licensure actions.* OPM may debar a health care provider to whom the provisions of 5 U.S.C. 8902a(c)(1) apply. OPM may take this action even if the provider retains current and valid professional licensure in another State(s).

(b) *Ownership or control interests.* OPM may debar a health care provider based on ownership or control of or by a debarred provider, as set forth in 5 U.S.C. 8902a(c)(2) and (3).

(c) *False, deceptive, or wrongful claims practices.* OPM may debar a provider who commits claims-related violations as set forth in 5 U.S.C. 8902a(c)(4) and (5) and 5 U.S.C. 8902a(d)(1) and (2).

(d) *Failure to furnish required information.* OPM may debar a provider who knowingly fails to provide information requested by an FEHBP carrier or OPM, as set forth in 5 U.S.C. 8902a(d)(3).

§ 890.1012 Time limits for OPM to initiate permissive debarments.

(a) *Licensure cases.* If the basis for the proposed debarment is a licensure action, OPM shall send the provider a notice of proposed debarment within 6 years of the effective date of the State licensing authority's revocation, suspension, restriction, or nonrenewal action, or the date on which the provider surrendered his license to the State authority.

(b) *Ownership or control.* If the basis for the proposed debarment is ownership or control of an entity by a sanctioned person, or ownership or control of a sanctioned entity by a person who knew or should have known of the basis for the entity's sanction, OPM shall send a notice of proposed debarment within 6 years of the effective date of the sanction on which the proposed debarment is based.

(c) *False, deceptive, or wrongful claims practices.* If the basis for the proposed debarment involves a claim filed with a FEHBP carrier, OPM shall send the provider a notice of proposed debarment within 6 years of the date he presented the claim for payment to the covered person's FEHBP carrier.

(d) *Failure to furnish requested information.* If the basis for the proposed debarment involves a provider's failure to furnish information requested by OPM or an FEHBP carrier,

OPM shall send the notice of proposed debarment within 6 years of the date on which the carrier or OPM requested the provider to furnish the information in question.

§ 890.1013 Deciding whether to propose a permissive debarment.

(a) *Review factors.* The factors OPM shall consider in deciding whether to propose a provider's debarment under a permissive debarment authority are:

(1) The nature of any claims involved in the basis for the proposed debarment and the circumstances under which they were presented to FEHBP carriers;

(2) The improper conduct involved in the basis for the proposed debarment, and the provider's degree of culpability and history of prior offenses;

(3) The extent to which the provider poses or may pose a risk to the health and safety of FEHBP-covered individuals or to the integrity of FEHBP transactions; and

(4) Other factors specifically relevant to the provider's debarment that shall be considered in the interests of fairness.

(b) *Absence of a factor.* The absence of a factor shall be considered neutral, and shall have no effect on OPM's decision.

(c) *Specialized review in certain cases.* In determining whether to propose debarment under 5 U.S.C 8902a(c)(4) for providing items or services substantially in excess of the needs of a covered individual or for providing items or services that fail to meet professionally-recognized quality standards, OPM shall obtain the input of trained reviewers, based on written medical protocols developed by physicians. If OPM cannot reach a decision on this basis, it shall consult with a physician in an appropriate specialty area.

§ 890.1014 Notice of proposed permissive debarment.

Notice of a proposed permissive debarment shall contain the information set forth in § 890.1006.

§ 890.1015 Minimum and maximum length of permissive debarments.

(a) *No mandatory minimum or upper limit on length of permissive debarment.* There is neither a mandatory minimum debarment period nor a limitation on the maximum length of a debarment under any permissive debarment authority.

(b) *Debarring official's process in setting period of permissive debarment.* The debarring official shall set the period of each debarment issued under a permissive debarment authority after considering the factors set forth in § 890.1016 and the factors set forth in the applicable section from among §§ 890.1017 through 890.1021.

§ 890.1016 Aggravating and mitigating factors used to determine the length of permissive debarments.

(a) *Aggravating factors.* The presence of aggravating circumstances may support an OPM determination to increase the length of a debarment beyond the nominal periods set forth in §§ 890.1017 through 890.1021. The factors that OPM considers as aggravating are:

(1) Whether the provider's actions underlying the basis for the debarment, or similar acts, had an adverse impact on the physical or mental health or well-being of one or more FEHBP-covered individuals or other persons.

(2) Whether the provider has a documented history of prior criminal wrongdoing; civil violations related to health care items or services; improper conduct; or administrative violations addressed by a Federal or State agency. OPM may consider matters involving violence, patient abuse, drug abuse, or controlled substances convictions or violations to be particularly serious.

(3) Whether the provider's actions underlying the basis for the debarment, or similar acts, resulted in financial loss to the FEHBP, FEHBP-covered individuals, or other persons. In determining whether, or to what extent, a financial loss occurred, OPM shall not consider any amounts of restitution that the provider may have paid.

(4) Whether the provider's false, wrongful, or improper claims to FEHBP carriers were numerous, submitted over a prolonged period of time, or part of an on-going pattern of wrongful acts.

(5) Whether the provider was specifically aware of or directly responsible for the acts constituting the basis for the debarment.

(6) Whether the provider attempted to obstruct, hinder, or impede official inquiries into the wrongful conduct underlying the debarment.

(b) *Mitigating factors.* The presence of mitigating circumstances may support an OPM determination to shorten the length of a debarment below the nominal periods set forth in §§ 890.1017 through 890.1021, respectively. The factors that OPM considers as mitigating are:

(1) Whether the provider's cooperation with Federal, State, or local authorities resulted in criminal convictions, civil recoveries, or administrative actions against other violators, or served as the basis for official determinations of program weaknesses or vulnerabilities. Restitution that the provider made for funds wrongfully, improperly, or illegally received from Federal or State programs may also be considered as a mitigating factor.

(2) Whether official records of judicial proceedings or the proceedings of State licensing authorities contain a formal determination that the provider had a physical, mental, or emotional condition that reduced his level of culpability before or during the period in which he committed the violations in question.

(c) *Absence of factors.* The absence of aggravating or mitigating factors shall have no effect to either increase or lower the nominal period of debarment.

§ 890.1017 Determining length of debarment based on revocation or suspension of a provider's professional licensure.

(a) *Indefinite term of debarment.* Subject to the exceptions set forth in paragraph (b) of this section, debarment under 5 U.S.C. 8902a(c)(1) shall be for an indefinite period coinciding with the period during which the provider's license is revoked, suspended, restricted, surrendered, or otherwise not in effect in the State whose action formed the basis for OPM's debarment.

(b) *Aggravating circumstances.* If any of the aggravating circumstances set forth in § 890.1016 apply, OPM may debar the provider for an additional period beyond the duration of the licensure revocation or suspension.

§ 890.1018 Determining length of debarment for an entity owned or controlled by a sanctioned provider.

OPM shall determine the length of debarments of entities under 5 U.S.C. 8902a(c)(2) based on the type of violation committed by the person with an ownership or control interest. The types of violations actionable under this provision are:

(a) *Owner/controller's debarment.* The debarment of an entity based on debarment of an individual with an ownership or control interest shall be for a period concurrent with the individual's debarment. If any aggravating or mitigating circumstances set forth in § 890.1016 apply solely to the entity and were not considered in setting the period of the individual's debarment, OPM may debar the entity for a period longer or shorter than the individual's debarment.

(b) *Owner/controller's conviction.* The debarment of an entity based on the criminal conviction of a person with an ownership or control interest for an offense listed in 5 U.S.C. 8902a(b)(1)–(4) shall be for a period of not less than 3 years, subject to adjustment for any aggravating or mitigating circumstances

set forth in § 890.1016 applying solely to the entity.

(c) *Owner/controller's civil monetary penalty.* The debarment of an entity based on a civil monetary penalty imposed on a person with an ownership or control interest, shall be for a period of not less than 3 years, subject to adjustment for any aggravating or mitigating circumstances set forth in § 890.1016 applying solely to the entity.

§ 890.1019 Determining length of debarment based on ownership or control of a sanctioned entity.

OPM shall determine the length of debarments of individual providers under 5 U.S.C. 8902a(c)(3) based on the type of violation committed by the sanctioned entity owned or controlled by the person with an ownership or control interest. The types of violations actionable under this provision are:

(a) *Entity's debarment.* If a provider's debarment is based on his ownership or control of a debarred entity, the debarment shall be concurrent with the entity's debarment. If any of the aggravating or mitigating circumstances identified in § 890.1016 applies directly to the provider that owns or controls the debarred entity and was not considered in setting the period of the entity's debarment, OPM may debar the provider for a period longer or shorter, respectively, than the entity's debarment.

(b) *Entity's conviction.* If a provider's debarment is based on the criminal conviction of an entity he owns or controls for an offense listed in 5 U.S.C. 8902a(b)(1)–(4), OPM shall debar the provider for a period of no less than 3 years, subject to adjustment for any aggravating or mitigating circumstances identified in § 890.1016 that apply to the provider as an individual.

(c) *Entity's civil monetary penalty.* If a provider's debarment is based on a civil monetary penalty imposed on an entity he owns or controls, OPM shall debar him for 3 years, subject to adjustment on the basis of the aggravating and mitigating circumstances listed in § 890.1016 that apply to the provider as an individual.

§ 890.1020 Determining length of debarment based on false, wrongful, or deceptive claims.

Debarments under 5 U.S.C. 8902a(c)(4) and (5) and 5 U.S.C. 8902a(d)(1) and (2) shall be for a period of 3 years, subject to adjustment based on the aggravating and mitigating factors listed in § 890.1016.

§ 890.1021 Determining length of debarment based on failure to furnish information needed to resolve claims.

Debarments under 5 U.S.C. 8902a(d)(3) shall be for a period of 3 years, subject to adjustment based on the aggravating and mitigating factors listed in § 890.1016.

§ 890.1022 Contesting proposed permissive debarments.

(a) *Right to contest a proposed debarment.* A provider proposed for debarment under a permissive debarment authority may challenge the debarment by filing a written contest with the debarring official during the 30-day notice period indicated in the notice of proposed debarment. In the absence of a timely contest, the debarment shall become effective as stated in the notice, without further action by OPM.

(b) *Challenging the length of a proposed debarment.* A provider may contest the length of the proposed debarment, while not challenging the debarment itself, or may contest both the length of a debarment and the debarment itself in the same contest.

§ 890.1023 Information considered in deciding a contest.

(a) *Documents and oral and written arguments.* A provider may submit documents and written arguments in opposition to the proposed debarment and/or the length of the proposed debarment, and may appear personally or through a representative before the debarring official to provide other relevant information.

(b) *Specific factual basis for contesting the proposed debarment.* A provider's oral and written arguments shall identify the specific facts that contradict the basis for the proposed debarment as stated in the notice of proposed debarment. A general or unsupported denial of the basis for debarment does not raise a genuine dispute over facts material to the debarment, and the debarring official shall not give such a denial any probative weight.

(c) *Mandatory disclosures.* Regardless of the basis for the contest, providers are required to disclose certain types of background information, in addition to any other information submitted during the contest. Failure to provide such information completely and accurately may be a basis for OPM to initiate further legal or administrative action against the provider. The specific items of information that shall be furnished to OPM are:

(1) Any existing, proposed, or prior exclusion, debarment, penalty, or other sanction imposed on the provider by a Federal, State, or local government agency, including any administrative agreement that purports to affect only a single agency;

(2) Any criminal or civil legal proceeding not referenced in the notice of proposed debarment that arose from facts relevant to the basis for debarment stated in the notice; and

(3) Any entity in which the provider has a control interest, as that term is defined in § 890.1003.

§ 890.1024 Standard and burden of proof for deciding contests.

OPM shall demonstrate, by a preponderance of the evidence in the administrative record as a whole, that a provider has committed a sanctionable violation.

§ 890.1025 Cases where additional fact-finding is not required.

In each contest, the debarring official shall determine whether a further fact-finding proceeding is required in addition to presentation of arguments, documents, and information. An additional fact-finding proceeding is not required when:

(a) *Prior adjudication.* The proposed debarment is based on facts determined in a prior due process adjudication. Examples of prior due process proceedings include, but are not limited to, the adjudication procedures associated with:

(1) Licensure revocation, suspension, restriction, or nonrenewal by a State licensing authority;

(2) Debarment, exclusion, suspension, civil monetary penalties, or similar legal or administrative adjudications by Federal, State, or local agencies;

(3) A criminal conviction or civil judgment; or

(4) An action by a provider that constitutes a waiver of his right to a due process adjudication, such as surrender of professional license during the pendency of a disciplinary hearing, entering a guilty plea or confession of judgment in a judicial proceeding, or signing a settlement agreement stipulating facts that constitute a sanctionable violation.

(b) *Material facts not in dispute.* The provider's contest does not identify a bona fide dispute concerning facts material to the basis for the proposed debarment.

§ 890.1026 Procedures if a fact-finding proceeding is not required.

(a) *Debarring official's procedures.* If a fact-finding proceeding is not required, the debarring official shall issue a final decision of a provider's contest within 30 days after the record

closes for submitting evidence, arguments, and information as part of the contest. The debarring official may extend this timeframe for good cause.

(b) *No further administrative review available.* There are no further OPM administrative proceedings after the presiding official's final decision. A provider adversely affected by the decision may appeal under 5 U.S.C. 8902a(h)(2) to the appropriate U.S. district court.

§ 890.1027 Cases where an additional fact-finding proceeding is required.

(a) *Criteria for holding fact-finding proceeding.* The debarring official shall request another OPM official (''presiding official'') to hold an additional fact-finding proceeding if:

(1) Facts material to the proposed debarment have not been adjudicated in a prior due process proceeding; and

(2) These facts are genuinely in dispute, based on the entire administrative record available to the debarring official.

(b) *Qualification to serve as presiding official.* The presiding official is designated by the OPM Director or another OPM official authorized by the Director to make such designations. The presiding official shall be a senior official who is qualified to conduct informal adjudicative proceedings and who has had no previous contact with the proposed debarment or the contest.

(c) *Effect on contest.* The debarring official shall defer a final decision on the contest pending the results of the fact-finding proceeding.

§ 890.1028 Conducting a fact-finding proceeding.

(a) *Informal proceeding.* The presiding official may conduct the fact-finding proceedings as informally as practicable, consistent with principles of fundamental fairness. Formal rules of evidence or procedure do not apply to these proceedings.

(b) *Proceeding limited to disputed material facts.* The presiding official shall consider only the genuinely disputed facts identified by the debarring official as material to the basis for the debarment. Matters that have been previously adjudicated or that are not in bona fide dispute within the administrative record shall not be considered by presiding official.

(c) *Provider's right to present information, evidence, and arguments.* A provider may appear before the presiding official with counsel, submit oral and written arguments and documentary evidence, present witnesses on his own behalf, question any witnesses testifying in support of the debarment, and challenge the accuracy of any other evidence that the agency offers as a basis for the debarment.

(d) *Record of proceedings.* The presiding official shall make an audio recording of the proceedings and shall provide a copy to the provider at no charge. If the provider wishes to have a transcribed record, OPM shall arrange for production of one which may be purchased at cost.

(e) *Presiding official's findings.* The presiding official shall resolve all of the disputed facts identified by the debarring official, on the basis of a preponderance of the evidence contained within the entire administrative record. The presiding official shall issue a written report of all findings of fact to the debarring official within 30 days after the record of the fact-finding proceeding closes.

§ 890.1029 Deciding a contest after a fact-finding proceeding.

(a) *Findings shall be accepted.* The debarring official shall accept the presiding official's findings of fact, unless they are arbitrary, capricious, or clearly erroneous. If the debarring official concludes that the factual findings are not acceptable, they may be remanded to the presiding official for additional proceedings in accordance with § 890.1028.

(b) *Timeframe for final decision.* The debarring official shall issue a final written decision on a contest within 30 days after receiving the presiding official's findings. The debarring official may extend this decision period for good cause.

(c) *Debarring official's final decision.* (1)The debarring official shall observe the evidentiary standards and burdens of proof stated in § 890.1024 in reaching a final decision.

(2) In any case where a final decision is made to debar a provider, the debarring official has the discretion to set the period of debarment, subject to the factors identified in §§ 890.1016 through 1021.

(3) The debarring official has the discretion to decide not to impose debarment in any case involving a permissive debarment authority.

(d) *No further administrative proceedings.* No further administrative proceedings shall be conducted after the debarring official's final decision in a contest involving an additional fact-finding hearing. A provider adversely affected by the debarring official's final decision in a contested case may appeal under 5 U.S.C. 8902a(h)(2) to the appropriate U. S. district court.

Suspension

§ 890.1030 Effect of a suspension.

(a) *Temporary action pending formal proceedings.* Suspension is a temporary action pending completion of an investigation or ensuing criminal, civil, or administrative proceedings.

(b) *Immediate effect.* Suspension is effective immediately upon the suspending official's decision, without prior notice to the provider.

(c) *Effect equivalent to debarment.* The effect of a suspension is the same as the effect of a debarment. A suspended provider may not receive payment from FEHBP funds for items or services furnished to FEHBP-covered persons while suspended.

§ 890.1031 Grounds for suspension.

(a) *Basis for suspension.* OPM may suspend a provider if:

(1) OPM obtains reliable evidence indicating that one of the grounds for suspension listed in paragraph (b) of this section applies to the provider; and

(2) The suspending official determines under paragraph (c) of this section that immediate action to suspend the provider is necessary to protect the health and safety of persons covered by FEHBP.

(b) *Grounds for suspension.* Evidence constituting grounds for a suspension may include, but is not limited to:

(1) Indictment or conviction of a provider for a criminal offense that is a basis for mandatory debarment under this subpart;

(2) Indictment or conviction of a provider for a criminal offense that reflects a risk to the health, safety, or well-being of FEHBP-covered individuals;

(3) Other credible evidence indicating, in the judgment of the suspending official, that a provider has committed a violation that would warrant debarment under this subpart. This may include, but is not limited to:

(i) Civil judgments;

(ii) Notice that a Federal, State, or local government agency has debarred, suspended, or excluded a provider from participating in a program or revoked or declined to renew a professional license; or

(iii) Other official findings by Federal, State, or local bodies that determine factual or legal matters.

(c) *Determining need for immediate action.* Suspension is intended to protect the public interest, including the health and safety of covered individuals or the integrity of FEHBP funds. The suspending official has wide discretion to decide whether to suspend a provider. A specific finding of

immediacy or necessity is not required to issue a suspension. The suspending official may draw reasonable inferences from the nature of the alleged misconduct and from a provider's actual or potential transactions with the FEHBP.

§ 890.1032 Length of suspension.

(a) *Initial period.* The initial term of all suspensions shall be an indefinite period not to exceed 12 months.

(b) *Formal legal proceedings not initiated.* If formal legal or administrative proceedings have not begun against a provider within 12 months after the effective date of his suspension, the suspending official may:

(1) Terminate the suspension; or

(2) If requested by the Department of Justice, the cognizant United States Attorney's Office, or other responsible Federal, State, or local prosecuting official, extend the suspension for an additional period, not to exceed 6 months.

(c) *Formal proceedings initiated.* If formal criminal, civil, or administrative proceedings are initiated against a suspended provider, the suspension may continue indefinitely, pending the outcome of those proceedings.

(d) *Terminating the suspension.* The suspending official may terminate a suspension at any time, and shall terminate it after 18 months, unless formal proceedings have begun within that period.

§ 890.1033 Notice of suspension.

(a) *Written notice.* OPM shall send written notice of suspension according to the procedures and methods described in § 890.1006(c)–(f).

(b) *Contents of notice.* The suspension notice shall contain information indicating that:

(1) The provider has been suspended, effective on the date of the notice;

(2) The initial period of the suspension;

(3) The basis for the suspension;

(4) The provisions of law and regulation authorizing the suspension;

(5) The effect of the suspension; and

(6) The provider's rights to contest the suspension.

§ 890.1034 Counting a period of suspension as part of a subsequent debarment.

The debarring official may consider the provider's contiguous period of suspension when determining the length of a debarment.

§ 890.1035 Provider contests of suspensions.

(a) *Filing a contest of the suspension.* A provider may challenge a suspension by filing a contest, in writing, with the suspending official not later than 30 days after receiving notice of suspension. The suspension shall remain in effect during the contest, unless rescinded by the suspending official.

(b) *Informal proceeding.* The suspending official shall use informal, flexible procedures to conduct the contest. Formal rules of evidence and procedure do not apply to this proceeding.

§ 890.1036 Information considered in deciding a contest.

(a) *Presenting information and arguments to the suspending official.* A provider may submit documents and written arguments in opposition to the suspension, and may appear personally, or through a representative, before the suspending official to provide any other relevant information.

(b) *Specific factual basis for contesting the suspension.* The provider shall identify specific facts that contradict the basis for the suspension as stated in the suspension notice. A general denial of the basis for suspension does not raise a genuine dispute over facts material to the suspension, and the suspending official shall not give such a denial any probative weight.

(c) *Mandatory disclosures.* Any provider contesting a suspension shall disclose the items of information set forth in § 890.1023(c). Failure to provide such information completely and accurately may be a basis for OPM to initiate further legal or administrative action against the provider.

§ 890.1037 Cases where additional fact-finding is not required.

The suspending official may decide a contest without an additional fact-finding process if:

(a) *Previously adjudicated facts.* The suspension is based on an indictment or on facts determined by a prior adjudication in which the provider was afforded due process rights. Examples of due process proceedings include, but are not limited to, the adjudication procedures associated with licensure revocation, suspension, restriction, or nonrenewal by a State licensing authority; similar administrative adjudications by Federal, State, or local agencies; a criminal conviction or civil judgment; or an action by the provider that constitutes a waiver of his right to a due process adjudication, such as surrender of professional licensure during the pendency of a disciplinary hearing, entering a guilty plea or confession of judgment in a judicial proceeding, or signing a settlement agreement stipulating facts that constitute a sanctionable violation. Neither the existence of the prior adjudication nor any of the underlying circumstances are considered to be subject to genuine factual dispute as part of the suspension proceeding.

(b) *Advisory by law enforcement officials.* OPM is advised by the Department of Justice, the appropriate U.S. Attorney's Office, a State attorney general's office, or a State or local prosecutor's office that proceedings before a presiding official would prejudice the substantial interests of the Government in pending or contemplated legal proceedings based on the same facts as the suspension.

(c) *No bona fide dispute of material facts.* The information, arguments, and documents submitted to the suspending official do not establish that there is a *bona fide* factual dispute regarding facts material to the suspension.

§ 890.1038 Deciding a contest without additional fact-finding.

(a) *Written decision.* The suspending official shall issue a written decision on the contest within 30 days after the record closes for submitting evidence, arguments, and information. The suspending official may extend this timeframe for good cause.

(b) *No further administrative review available.* The suspending official's decision is final and is not subject to further administrative review.

§ 890.1039 Cases where additional fact-finding is required.

(a) *Criteria for holding fact-finding proceeding.* The debarring official shall request another OPM official (''presiding official'') to hold an additional fact-finding proceeding if:

(1) Facts material to the suspension have not been adjudicated in a prior due process proceeding; and

(2) These facts are genuinely in dispute, based on the entire administrative record available to the debarring official.

(b) *Qualification to serve as presiding official.* The presiding official is designated by the OPM Director or another OPM official authorized by the Director to make such designations. The presiding official shall be a senior official who is qualified to conduct informal adjudicative proceedings and who has had no previous contact with the suspension or the contest.

(c) *Effect on contest.* The suspending official shall defer a final decision on the contest pending the results of the fact-finding proceeding.

§ 890.1040 Conducting a fact-finding proceeding.

(a) *Informal proceeding.* The presiding official may conduct the fact-finding proceedings as informally as practicable, consistent with principles of fundamental fairness. Specific rules of evidence or procedure do not apply to these proceedings.

(b) *Proceeding limited to disputed material facts.* The presiding official shall consider only the genuinely disputed facts identified by the suspending official as relevant to the basis for the suspension. Matters that have been previously adjudicated or which are not in bona fide dispute within the record shall not be considered by the presiding official.

(c) *Right to present information, evidence, and arguments.* A provider may appear before the presiding official with counsel, submit oral and written arguments and documentary evidence, present witnesses, question any witnesses testifying in support of the suspension, and challenge the accuracy of any other evidence that the agency offers as a basis for the suspension.

(d) *Record of proceedings.* The presiding official shall make an audio recording of the proceedings and shall provide a copy to the provider at no charge. If the provider wishes to have a transcribed record, OPM shall arrange for production of one which may be purchased at cost.

(e) *Presiding official's findings.* The presiding official shall resolve all of the disputed facts identified by the suspending official, on the basis of a preponderance of the evidence in the entire administrative record. Within 30 days after the record of the proceeding closes, the presiding official shall issue a written report of all findings of fact to the suspending official.

§ 890.1041 Deciding a contest after a fact-finding proceeding.

(a) *Presiding official's findings shall be accepted.* The suspending official shall accept the presiding official's findings, unless they are arbitrary, capricious, or clearly erroneous.

(b) *Suspending official's decision.* Within 30 days after receiving the presiding official's report, the suspending official shall issue a final written decision that either sustains, modifies, or terminates the suspension. The suspending official may extend this period for good cause.

(c) *Effect on subsequent debarment or suspension proceedings.* A decision by the suspending official to modify or terminate a suspension shall not prevent OPM from subsequently debarring the same provider, or any other Federal agency from either suspending or debarring the provider, based on the same facts.

Effect of Debarment

§ 890.1042 Effective dates of debarments.

(a) *Minimum notice period.* A debarment shall take effect not sooner than 30 days after the date of OPM's notice of proposed debarment, unless the debarring official specifically determines that the health or safety of covered individuals or the integrity of the FEHBP warrants an earlier effective date. In such a situation, the notice shall specifically inform the provider that the debarring official decided to shorten or eliminate the 30-day notice period.

(b) *Uncontested debarments.* If a provider does not file a contest within the 30-day notice period, the proposed debarment shall take effect on the date stated in the notice of proposed debarment, without further procedures, actions, or notice by OPM.

(c) *Contested debarments and requests for reducing the period of debarment.* If a provider files a contest within the 30-day notice period, the proposed debarment shall not go into effect until the debarring official issues a final written decision, unless the health or safety of covered individuals or the integrity of the FEHBP requires the debarment to be effective while the contest is pending.

§ 890.1043 Effect of debarment on a provider.

(a) *FEHBP payments prohibited.* A debarred provider is not eligible to receive payment, directly or indirectly, from FEHBP funds for items or services furnished to a covered individual on or after the effective date of the debarment. Also, a provider shall not accept an assignment of a claim for items or services furnished to a covered individual during the period of debarment. These restrictions shall remain in effect until the provider is reinstated by OPM.

(b) *Governmentwide effect.* Debarment precludes a provider from participating in all other Federal agencies' procurement and nonprocurement programs and activities, as required by section 2455 of the Federal Acquisition Streamlining Act of 1994 (Pub. L. 103—355). Other agencies may grant a waiver or exception under their own regulations, to permit a provider to participate in their programs, notwithstanding the OPM debarment.

(c) *Civil or criminal liability.* A provider may be subject to civil monetary penalties under this subpart or criminal liability under other Federal statutes for knowingly filing claims, causing claims to be filed, or accepting payment from FEHBP carriers for items or services furnished to a covered individual during a period of debarment .

Notifying Outside Parties About Debarment and Suspension Actions

§ 890.1044 Entities notified of OPM-issued debarments and suspensions.

When OPM debars or suspends a provider under this subpart, OPM shall notify:

(a) All FEHBP carriers;

(b) The General Services Administration, for publication in the comprehensive Governmentwide list of Federal agency exclusions;

(c) Other Federal agencies that administer health care or health benefits programs; and

(d) State and local agencies, authorities, boards, or other organizations with health care licensing or certification responsibilities.

§ 890.1045 Informing persons covered by FEHBP about debarment or suspension of their provider.

FEHBP carriers are required to notify covered individuals who have obtained items or services from a debarred or suspended provider within one year of the date of the debarment or suspension of:

(a) The existence of the provider's debarment or suspension;

(b) The minimum period remaining in the provider's period of debarment; and

(c) The requirement that OPM terminate the debarment or suspension before FEHBP funds can be paid for items or services the provider furnishes to covered individuals.

Exceptions to the Effect of Debarments

§ 890.1046 Effect of debarment on payments for services furnished in emergency situations.

A debarred health care provider may receive FEHBP funds paid for items or services furnished on an emergency basis if the FEHBP carrier serving the covered individual determines that:

(a) The provider's treatment was essential to the health and safety of the covered individual; and

(b) No other source of equivalent treatment was reasonably available.

§ 890.1047 Special rules for institutional providers.

(a) *Covered individual admitted before debarment.* If a covered person is admitted as an impatient before the effective date of an institutional provider's debarment, that provider may continue to receive payment of FEHBP funds for inpatient institutional services

until the covered person is released or transferred, unless the debarring official terminates payments under paragraph (b) of this section.

(b) *Health and safety of covered individuals.* If the debarring official determines that the health and safety of covered persons would be at risk if they remain in a debarred institution, OPM may terminate FEHBP payments at any time.

(c) *Notice of payment limitations.* If OPM limits any payment under paragraph (b) of this section, it shall immediately send written notice of its action to the institutional provider.

(d) *Finality of debarring official's decision.* The debarring official's decision to limit or deny payments under paragraph (b) of this section is not subject to further administrative review or reconsideration.

§ 890.1048 Waiver of debarment for a provider that is the sole source of health care services in a community.

(a) *Application required.* A provider may apply for a limited waiver of debarment at any time after receiving OPM's notice of proposed debarment. Suspended providers are not eligible to request a waiver of suspension.

(b) *Criteria for granting waiver.* To receive a waiver, a provider shall clearly demonstrate that:

(1) The provider is the *sole community provider* or the *sole source of essential specialized services in a community;*

(2) A limited waiver of debarment would be in the best interests of covered individuals in the defined service area;

(3) There are reasonable assurances that the actions which formed the basis for the debarment shall not recur; and

(4) There is no basis under this subpart for continuing the debarment.

(c) *Waiver applies only in the defined service area.* A limited waiver applies only to items or services provided within the defined service area where a provider is the *sole community provider* or *sole source of essential specialized services.*

(d) *Governmentwide effect continues.* A limited waiver applies only to a provider's FEHBP transactions. Even if OPM waives a debarment for FEHBP purposes, the governmentwide effect under section 2455 of the Federal Acquisition Streamlining Act of 1994 (Pub. L. 103–355) continues for all other Federal agencies' procurement and nonprocurement programs and activities.

(e) *Waiver rescinded if circumstances change.* OPM shall rescind the limited waiver when any of its underlying bases no longer apply. If OPM rescinds the limited waiver, the provider's debarment shall resume full effect for all FEHBP transactions. Events warranting rescission include, but are not limited to:

(1) The provider ceases to furnish items or services in the defined service area;

(2) Another provider begins to furnish equivalent items or services in the defined service area, so that the provider who received a waiver is no longer the sole provider or sole source; or

(3) The actions that formed the basis for the provider's debarment, or similar acts, recur.

(f) *Effect on period of debarment.* The minimum period of debarment is established when the debarment is initially imposed. A subsequent decision to grant, deny, or rescind a limited waiver shall not change that period.

(g) *Application is necessary for reinstatement.* A provider who has received a limited waiver shall apply for reinstatement at the end of the debarment period, even if a limited waiver is in effect when the debarment expires.

(h) *Finality of debarring official's decision.* The debarring official's decision to grant or deny a limited waiver is final and not subject to further administrative review or reconsideration.

Special Exceptions to Protect Covered Persons

§ 890.1049 Claims for non-emergency items or services furnished by a debarred provider.

(a) *Covered individual unaware of debarment.* FEHBP funds may be paid for items and services furnished by a debarred provider if, at the time the items or services were furnished, the covered individual did not know, and could not reasonably be expected to know, that the provider was debarred. This provision is intended solely to protect the interests of FEHBP covered persons who obtain services from a debarred or suspended provider in good faith and without knowledge that the provider has been sanctioned. It does not authorize debarred or suspended providers to submit claims for payment to FEHBP carriers.

(b) *Notice sent by carrier.* When paying a claim under the authority of paragraph (a) of this section, an FEHBP carrier shall send a written notice to the covered individual, stating that:

(1) The provider is debarred and prohibited from receiving payment of FEHBP funds for items or services furnished after the debarment date;

(2) Claims shall not be paid for items or services furnished by the debarred provider after the covered individual receives notice of the debarment;

(3) The current claim is being paid as a legally-authorized exception to the effect of the debarment in order to protect covered individuals who obtain items or services without knowledge of the provider's debarment;

(4) FEHBP carriers are required to deny payment of any claim for items or services rendered by a debarred provider 15 days or longer after the date of the notice described in paragraph (b) of this section, unless the covered individual had no knowledge of the provider's debarment when the items or services were rendered;

(5) The minimum period remaining in the provider's debarment; and

(6) FEHBP funds cannot be paid to the provider until OPM terminates the debarment.

§ 890.1050 Exception to a provider's debarment for an individual enrollee.

(a) *Request by a covered individual.* Any individual enrolled in FEHBP may submit a request through their FEHBP carrier for continued payment of items or services furnished by a debarred provider to any person covered under the enrollment. Requests shall not be accepted for continued payments to suspended providers.

(b) *OPM action on the request.* OPM shall consider the recommendation of the FEHBP carrier before acting on the request. To be approved, the request shall demonstrate that:

(1) Interrupting an existing, ongoing course of treatment by the provider would have a detrimental effect on the covered individual's health or safety; or

(2) The covered individual does not have access to an alternative source of the same or equivalent health care items or services within a reasonably accessible service area.

(c) *Scope of the exception.* An approved exception applies only to the covered individual(s) who requested it, or on whose behalf it was requested. The governmentwide effect of the provider's debarment under section 2455 of the Federal Acquisition Streamlining Act (Pub. L. 103–355) is not altered by an exception.

(d) *Provider requests not allowed.* OPM shall not consider an exception request submitted by a provider on behalf of a covered individual.

(e) *Debarring official's decision is final.* The debarring official's decision on an exception request is not subject to further administrative review or reconsideration.

Reinstatement

§ 890.1051 Applying for reinstatement when period of debarment expires.

(a) *Application required.* Reinstatement is not automatic when the minimum period of a provider's debarment expires. The provider shall apply in writing to OPM, supplying specific information about the reinstatement criteria outlined in paragraph (c) of this section.

(b) *Reinstatement date.* A debarred provider may submit a reinstatement application not earlier than 60 days before the nominal expiration date of the debarment. However, in no case shall OPM reinstate a provider before the minimum period of debarment expires.

(c) *Reinstatement criteria.* To be approved, the provider's reinstatement application shall clearly demonstrate that:

(1) There are reasonable assurances that the actions resulting in the provider's debarment have not recurred and will not recur;

(2) There is no basis under this subpart for continuing the provider's debarment; and

(3) There is no pending criminal, civil, or administrative action that would subject the provider to debarment by OPM.

(d) *Written notice of OPM action.* OPM shall inform the provider in writing of its decision regarding the reinstatement application.

(e) *Limitation on reapplication.* If OPM denies a provider's reinstatement application, the provider is not eligible to reapply for 1 year after the date of the denial.

§ 890.1052 Reinstatements without application.

OPM shall reinstate a provider without a reinstatement application if:

(a) *Conviction reversed.* The conviction on which the provider's debarment was based is reversed or vacated by a final decision of the highest appeals court with jurisdiction over the case; and the prosecutorial authority with jurisdiction over the case has declined to retry it, or the deadline for retrial has expired without action by the prosecutor.

(b) *Sanction terminated.* A sanction imposed by another Federal agency, on which the debarment was based, is terminated by that agency.

(c) *Court order.* A Federal court orders OPM to stay, rescind, or terminate a provider's debarment.

(d) *Written notice.* When reinstating a provider without an application, OPM shall send the provider written notice of the basis and effective date of his reinstatement.

§ 890.1053 Table of procedures and effective dates for reinstatements.

The procedures and effective dates for reinstatements under this subpart are:

Basis for debarment	Application required?	Effective date
Period of debarment expires	Yes	After debarment expires.
Conviction reversed on final appeal/no retrial possible.	No	Retroactive (start of debarment).
Other agency sanction ends	No	Ending date of sanction.
Court orders reinstatement	No	Retroactive (start of debarment).

§ 890.1054 Agencies and entities to be notified of reinstatements.

OPM shall inform the FEHBP carriers, Government agencies and other organizations that were originally notified of a provider's debarment when a provider is reinstated under § 890.1051 or § 890.1052.

§ 890.1055 Contesting a denial of reinstatement.

(a) *Obtaining reconsideration of the initial decision.* A provider may contest OPM's decision to deny a reinstatement application by submitting documents and written arguments to the debarring official within 30 days of receiving the notice described in § 890.1051(d). In addition, the provider may request to appear in person to present oral arguments to the debarring official. The provider may be accompanied by counsel when making a personal appearance.

(b) *Debarring official's final decision on reinstatement.* The debarring official shall issue a final written decision, based on the entire administrative record, within 30 days after the record closes to receipt of information. The debarring official may extend the decision period for good cause.

(c) *Finality of debarring official's decision.* The debarring official's final decision regarding a provider's reinstatement is not subject to further administrative review or reconsideration.

Civil Monetary Penalties and Financial Assessments [Reserved]

[FR Doc. 03–2398 Filed 1–31–03; 8:45 am]

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Federal Register

Monday,
February 3, 2003

Part VI

Department of Transportation

Federal Aviation Administration

14 CFR Parts 125 and 135

Notice of Regulatory Review; Proposed Rule

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Parts 125 and 135

Notice of Regulatory Review

AGENCY: Federal Aviation Administration.

ACTION: Notice and request for comments.

SUMMARY: By this document, the Federal Aviation Administration (FAA) announces a comprehensive regulatory review of 14 CFR parts 135 and 125. This review will also encompass related portions of parts 91, 119, 121, and other regulations, as appropriate. The FAA will establish a part 135/125 Aviation Rulemaking Committee to conduct this review and provide advice and recommendations to:

a. Resolve current issues affecting this part of the industry.

b. Enable new aircraft types, size and design and new technologies in air transportation operations.

c. Provide safety and applicability standards that reflect the current industry, industry trends and emerging technologies and operations.

d. Address international harmonization and ICAO standards.

e. Potentially, rescind part 125 from 14 Code of Federal Regulations.

The FAA invites persons interested in serving on this committee or work groups to request membership in accordance with this document. The FAA will select members to provide a balance of viewpoints, interests, and expertise. Membership on the committee may be limited to facilitate discussions and to maintain a balance of interests.

In addition, the FAA invites interested persons to submit specific, detailed written comments, or provide input on the affected regulatory sections. These comments will be considered in the committee discussions and will assist in determining future regulatory action.

DATES: *Membership:* Persons interested in participating on committees or work groups should submit their request on or before March 5, 2003. Selected members will be advised in writing of their participation and meeting details. In addition meeting information will be posted on the Office of Rulemaking's web site under the heading of ''Advisory Committees.''

Comments: The FAA will consider all comments on this regulatory review filed on or before June 3, 2003. We will consider comments filed late if it is possible to do so without incurring expense or delay.

ADDRESSES: *Membership:* Persons requesting membership or participation on the part 135/125 Aviation Rulemaking Committee and/or associated work groups should make the request in writing to the person listed below under **FOR FURTHER INFORMATION CONTACT**.

Comments: Address your comments to the Docket Management System, U.S. Department of Transportation, Room Plaza 401, 400 Seventh Street, SW. Washington, DC 20590–0001. You must identify docket number FAA–2002–13923 at the beginning of your comments, and you should submit two copies of your comments. If you wish to receive confirmation that FAA received your comments, include a self-addressed, stamped postcard on which the docket number appears. We will stamp the date on the postcard and mail it to you.

You may also submit comments through the Internet to *http://dms.dot.gov*. You may review the public docket containing comments to these proposed regulations in person in the Dockets Office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The Dockets Office is on the plaza level of the NASSIF Building at the Department of Transportation at the above address. Also, you may review comments made to this public docket on the Internet at *http://dms.dot.gov*.

FOR FURTHER INFORMATION CONTACT: Katherine Perfetti, AFS–200, 800 Independence Ave. SW., Washington, DC 20591 (202) 267–3760, facsimile at (202) 267–5229, or by email: *Katherine.Perfetti@faa.gov*

SUPPLEMENTARY INFORMATION:

Background

Industry dynamics, new technologies, new aircraft types and configurations, and current operating issues and environment mandate a comprehensive review and rewrite of parts 135 and 125. This review will also include related portions of parts 91, 119, 121, and other regulations. Issues under review include:

a. Design and manufacture of new aircraft that current regulations do not address adequately (for example, large airships, powered lift aircraft).

b. Certain large airplanes with modifications to payload capacity and passenger seat configuration operating under part 91 or 135.

c. New equipment and technologies not adequately addressed in current regulations.

d. International harmonization, ICAO commercial standards, and increased international operations.

Public Participation in the Regulatory Review Process

Membership. The FAA invites members of the public to serve on the part 135/125 Aviation Rulemaking Committee and/or work groups. The committee will provide advice and recommendations to the FAA to assist the agency in establishing a regulatory framework that will address industry trends and dynamics and issues, and to enhance safety in this segment of the industry. The committee acts solely in an advisory capacity. The committee will discuss and present whatever input, guidance, and recommendations considered relevant to the ultimate disposition of issues.

Because of the diversity and complexities of the part 135/125 industry and issues, the committee will be structured with a steering committee and specialized work groups. The steering committee will consist of approximately 25 members selected by the FAA representing aviation associations, industry representatives, employee groups, FAA and other government entities, and other participants to provide a balance of views, interests, and expertise. Membership on the steering committee will be limited to facilitate discussions. Priority will be given to those applicants representing an identified part of the aviation community who are empowered to speak for those interests.

Additional participation is provided through the specialized work groups. At this time, the FAA is considering the establishment of work groups comprised of subject matter experts, in the following subject areas:

—Operations
—Maintenance
—International operations
—Training
—Part 119 Applicability and Definitions
—Equipment and New Technologies
—Rotorcraft
—New aircraft (*e.g.*, powered lift aircraft, airships)
—Other work groups may be established if required.

All non-government representatives serve without government compensation and bear all costs related to their participation on the steering committee or work groups. Members and participants should be available to attend all scheduled committee or work group meetings for the duration of the review.

It is anticipated that this committee will meet approximately 3–5 times a

year, for 2–3 days for each meeting. Work groups will be scheduled as determined by the steering committee and work group members to provide information and meet schedule requirements.

Make your request to participate on the steering committee or specialized work groups in writing on or before March 5, 2003. Your request should provide the following information:

—Contact information (name, company and position, address, phone, facsimile, and email)
—Segment(s) of the industry or organization/association you represent
—Experience, subject expertise or other background information

The FAA will notify all selected members and participants in writing in advance of the first meeting. Additional information on the committee, membership, dates, and other information may be obtained on the Office of Rulemaking web site under the heading ''Advisory Committees''.

Comments. As noted above, persons wishing to comment on this review may do so until June 3, 2003. In order to proceed with rulemaking, the FAA requests that commenters be timely in their comments.

Commenters should be as specific as possible and provide as much detail in comments as necessary to facilitate regulatory decision making. Comments should address the specific section of the regulation at issue, a detailed explanation of what needs to be changed and why, and the proposed regulatory change. Information on costs and benefits of the proposed change are particularly helpful.

Comments provided in response to this review will assist the FAA and committee in their review and deliberation.

Issued in Washington, DC on January 27, 2003.

Louis C. Cusimano,

Acting Director, Flight Standards Service.

[FR Doc. 03–2416 Filed 1–31–03; 8:45 am]

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Federal Register

Monday,
February 3, 2003

Part VII

Office of Management and Budget

Draft 2003 Report to Congress on the Costs and Benefits of Federal Regulations; Notice

OFFICE OF MANAGEMENT AND BUDGET

Draft 2003 Report to Congress on the Costs and Benefits of Federal Regulations

AGENCY: Office of Management and Budget, Executive Office of the President.

ACTION: Notice and request for comments.

SUMMARY: OMB requests comments on the attached Draft Report to Congress on the Costs and Benefits of Federal Regulation. The Draft Report is divided into two chapters. Chapter I presents estimates of the costs and benefits of Federal regulation and paperwork with an emphasis on the major regulations issued between October 1, 2001 and September 31, 2002. Chapter II requests comments from the public in three areas: (1) Guidelines for regulatory analysis; (2) Analysis and management of emerging risks; and (3) Improving analysis of regulations to homeland security.

DATES: To ensure consideration of comments as OMB prepares this Draft Report for submission to Congress, comments must be in writing and received by OMB no later than April 3, 2003.

ADDRESSES: We are still experiencing delays in the regular mail, including first class and express mail. To ensure that your comments are received, we recommend that comments on this draft report be electronically mailed to *OIRA_BC_RPT@omb.eop.gov,* or faxed to (202) 395–7245. Comments on the OMB Draft Guidelines for the Conduct of Regulatory Analysis and the Format of Accounting Statements (Appendix C) should be e-mailed to *OIRA_ECON_GUIDE@omb.eop.gov*, or faxed, with the title ''Comments on Draft Guidelines'' identified in the transmittal page, to (202) 395–7245.

You may also submit comments to Lorraine Hunt, Office of Information and Regulatory Affairs, Office of Management and Budget, NEOB, Room 10202, 725 17th Street, NW., Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Lorraine Hunt, Office of Information and Regulatory Affairs, Office of Management and Budget, NEOB, Room 10202, 725 17th Street, NW., Washington, DC 20503. Telephone: (202) 395–3084.

SUPPLEMENTARY INFORMATION: Congress directed the Office of Management and Budget (OMB) to prepare an annual Report to Congress on the Costs and Benefits of Federal Regulations. Specifically, Section 624 of the FY2001 Treasury and General Government Appropriations Act, also know as the ''Regulatory Right-to-Know Act,'' (the Act) requires OMB to submit a report on the costs and benefits of Federal regulations together with recommendation for reform. The Act says that the report should contain estimates of the costs and benefits of regulations in the aggregate, by agency and agency program, and by major rule, as well as an analysis of impacts of Federal regulation on State, local, and tribal government, small business, wages, and economic growth. The Act also states that the report should go through notice and comment and peer review.

John D. Graham,

Administrator, Office of Information and Regulatory Affairs.

Draft 2003 Report to Congress on the Costs and Benefits of Federal Regulation

Executive Summary

This Draft Report to Congress on regulatory policy was prepared pursuant to the Regulatory Right-to-Know Act (Section 624 of the Treasury and General Government Appropriations Act, 2001), which requires such an account each year. It provides a statement of the costs and benefits of federal regulations and recommendations for regulatory reforms. The report will be published in its final form after revisions to this draft are made based on public comment, external peer review, and interagency review.

The major feature of this report is the estimates of the total costs and benefits of regulations reviewed by OMB. Major federal regulations reviewed by OMB from October 1, 1992 to September 30, 2002 were examined to determine their quantifiable benefits and costs. The estimated annual benefits range from $135 billion to $218 billion while the estimated annual costs range from $38 billion to $44 billion.

OMB seeks public comment on all aspects of this Draft Report. OMB is specifically interested in public comment in the following three areas:

• Guidelines for regulatory analysis. In order to make continued improvements in the quality of the regulatory analyses prepared by agencies, OIRA initiated in 2002 a process to refine the OMB guidelines for regulatory analysis. The OIRA Administrator and a member of the Council of Economic Advisers (CEA) are serving as co-chairs of this effort. OMB and CEA staff have drafted proposed revised guidelines which are presented in Appendix C of this report. We are requesting comment on these draft guidelines for regulatory analysis.

• Analysis and management of emerging risks. An Interagency Work Group on Risk Management, co-chaired by the OIRA Administrator and the Chairman of the White House Council on Environmental Quality has been formed to foster Administration-wide dialogue and coordination on the management of emerging risks to public health, safety and the environment. To assist in the Work Group's efforts, OMB requests comments on current U.S. approaches to analysis and management of emerging risks.

• Improving analysis of regulations related to homeland security. In light of the significant interest in regulations related to homeland security, OMB is seeking public comment on how to more effectively evaluate the benefits and costs of these proposals, including how agencies might better forecast the anti-terrorism benefits and the direct and indirect costs of such rules, including time, convenience, privacy, and economic productivity.

Chapter I: The Costs and Benefits of Federal Regulations

Section 624 of the FY 2001 Treasury and General Government Appropriations Act, the ''Regulatory Right-to-Know Act,'' [1] requires OMB to submit ''an accounting statement and associated report'' including:

(1) An estimate of the total annual costs and benefits (including quantifiable and nonquantifiable effects) of Federal rules and paperwork, to the extent feasible:

(A) In the aggregate;

(B) By agency and agency program; and

(C) By major rule;

(2) An analysis of impacts of Federal regulation on State, local, and tribal government, small business, wages, and economic growth; and

(3) Recommendations for reform.[2]

This chapter presents the accounting statement. It revises the benefit-cost estimates in last year's report by updating the estimates to the end of fiscal year 2002 (September 30, 2002) and including new estimates from Ocotober 1, 1992 to March 31, 1995. Our new estimates are now based on the major regulations reviewed by OMB over the last ten years. All of the

[1] 31 U.S.C. 1105 note, Pub. L. 106–554, Section 1(a)(3) [Title VI, section 624], Dec. 21, 2000, 114 Stat. 2763, 2763A–161 (see Appendix F).

[2] Recommendations for reform are discussed in Chapter II.

estimates presented in this chapter are based on agency information or transparent modifications of agency information performed by OIRA. We have not provided new information on the impacts of Federal regulation on State, local, and tribal government, small businesses, wages, and economic growth in this draft report. The 2002 Report issued in December 2002 includes discussions of these issues (see pages 41 to 46). We request public comment and any additional information on these impacts for this year's final report.

We also include in this chapter a discussion of major rules issued by independent regulatory agencies, although OMB does not review these rules under Executive Order 12866. This discussion is based on data provided by these agencies to the General Accounting Office (GAO) under the Congressional Review Act.

A. Estimates of the Total Benefits and Costs of Regulations Reviewed by OMB [3]

Table 1 presents estimates by agency of the costs and benefits of major rules reviewed by OMB over the period October 1, 2001 to September 30, 2002. We reviewed 31 final major rules over that period. These 31 rules represent less than ten percent of the 330 final rules reviewed by OMB and less than one percent of the 4,153 final rules documents published in the **Federal Register** during this 12-month period. However, OIRA believes that the costs and benefits of major rules are quantitatively more important than all other rules combined.

Of the 31 rules, 25 implemented Federal budgetary programs, which caused income transfers from one group to another. The remaining six regulations were ''social regulations'', requiring substantial additional private expenditures and/or providing new social benefits.[4] Four of these six ''social regulations'' imposed mandates on State and local entities or the private sector. The other two ''social regulations'' were enabling regulations that did not impose mandates.

Of the six ''social regulations,'' we are able to present estimates of both monetized costs and benefits for three rules.[5] We did not include the 3 other rules that did not have monetized estimates for either costs or benefits or both. Three agencies, DOE, DOT, and EPA issued 3 major regulations adding a combined $2.0 billion to $6.5 billion in annual benefits and $1.6 billion to $2.0 billion in annual costs.

TABLE 1.—ESTIMATES OF THE ANNUAL BENEFITS AND COSTS OF MAJOR FEDERAL RULES, OCTOBER 1, 2001 TO SEPTEMBER 30, 2002

[Millions of 2001 dollars]

Agency	Benefits	Costs
Energy	710	636.
Transportation	409 to 944	749 to 1,206.
Environmental Protection Agency	913 to 4,818	192.
Total	2,032 to 6,472	1,577 to 2,034.

Table 2 presents an estimate of the total costs and benefits of all regulations reviewed by OMB over the ten-year period from October 1, 1992 to September 30, 2002 that met two conditions.[6] Each rule generated costs or benefits of at least $100 million annually, and a substantial portion of its costs and benefits were quantified and monetized by the agency or, in some cases, monetized by OMB. The estimates are therefore not a complete accounting of all the costs and benefits of all regulations issued by the Federal government during this period. We have expanded the number of years covered by our estimates to ten from the six and half years presented in last year's report. We provide estimates of the cost and benefits of social regulation (health, safety and environmental regulation) for each rule for the periods covering October 1, 1992 to March 31, 1995 and October 1, 2001 to September 30, 2002 in Appendix A.[7] OMB has chosen a 10-year period for aggregation because pre-regulation estimates prepared for rules adopted more than ten years ago are of questionable relevance today. The estimates of the costs and benefits of Federal regulations over the period October 1, 1992 to September 30, 2002 are based on agency analyses subject to public notice and comments and OMB review under E.O. 12866.

In last year's report, the aggregate costs of regulations fell within the range of the estimated benefits—albeit at the lower end of the range. The aggregate benefits reported in Table 2, however, are roughly three to five times the aggregate costs and are substantially larger than the aggregate benefits reported in our 2002 report. There are two reasons for this. First, the additional rules added to cover a 10-year period included EPA's rule implementing the sulfur dioxide limits of the acid rain provisions in the 1990 Amendments to the Clean Air Act. This rule adds calculated benefits of over $70 billion per year to the aggregate benefits estimate. Second, in reviewing our estimates, we inadvertently subtracted incorrect cost estimates for EPA's rules establishing National Ambient Air Quality Standards for Ozone and Particulate Matter. This correction reduces the aggregate cost of the rules covered over the 10-year period by roughly $20 billion per year.

It is important to note that four EPA rules—two rules limiting particulate matter and NO_X emissions from heavy duty highway engines, the Tier 2 rule limiting the emissions from light duty vehicles, and the Acid Rain rule cited above—account for a substantial fraction of the aggregate benefits reported in Table 2. These four EPA rules have estimated benefits of $96 to $113 billion per year and costs of $8 to

[3] In previous reports, we presented detailed discussions about the difficulty of estimating and aggregating the costs and benefits of different regulations over long time periods and across many agencies. We do not repeat those discussions here. Our previous reports are on our Web site at <*http://www.whitehouse.gov/omb/inforeg/regpol.html*>.

[4] Rules that transfer Federal dollars among parties are not included because transfers are not social costs or benefits. If included, they would add equal amounts to benefits and costs.

[5] We used agency estimates where available. If an agency quantified estimates but did not monetize, we used standard assumptions to monetize as explained in Appendix A.

[6] We calculated Table 2 estimates by adding the estimates in Table 1 above and the estimates from Table 6 in Appendix A to Table 8 of the 2002 OMB report.

[7] Agency estimates of the cost and benefits of major regulations for October 1, 1992 to March 31, 1995 are provided in Appendix B. Appendix A contains revised estimates.

$8.8 billion per year.[8] The aggregate benefits and costs for the other 103 rules are $38 to $104 billion and $30 to $35 billion, respectively. Table 3 provides additional information on aggregate benefits and costs for select agency programs.

Based on the information released in previous reports, the total costs and benefits of all Federal rules now in effect (major and non-major, including those adopted more than 10 years ago) could easily be a factor of ten or more larger than the sum of the costs and benefits reported in Table 2. More research is necessary to provide a stronger analytic foundation for comprehensive estimates of total costs and benefits by agency and program. OMB's examination of the benefits and costs of Federal regulation supports the need for a common-sense approach to modernizing Federal regulation that involves the expansion, modification, and rescission of regulatory programs as appropriate.

TABLE 2.—ESTIMATES OF THE ANNUAL BENEFITS AND COSTS OF MAJOR FEDERAL RULES, OCTOBER 1, 1992 TO SEPTEMBER 30, 2002

[Millions of 2001 dollars]

Agency	Benefits	Costs
Agriculture	3,108 to 6,203	1,649 to 1,679.
Education	658 to 816	363 to 612.
Energy	4,704 to 4,722	2,473.
Health & Human Services	8,733 to 11,724	3,168 to 3,337.
Housing & Urban Development	527 to 601	796.
Labor	1,808 to 4,200	1,057.
Transportation	6,150 to 9,465	4,313 to 6,812.
Environmental Protection Agency	108,858 to 179,757	23,867 to 27,028.
Total	134,547 to 217,539	37,686 to 43,794.

TABLE 3.—ESTIMATES OF ANNUAL BENEFITS AND COSTS OF MAJOR FEDERAL RULES: SELECT PROGRAMS AND AGENCIES, OCTOBER 1, 1992–SEPTEMBER 30, 2002

[Millions of 2001 dollars]

Agency	Benefits	Costs
Energy: Energy Efficiency and Renewable Energy	4,704 to 4,772	2,473.
Health & Human Services: Food and Drug Administration	2,021 to 4,558	482 to 651.
Labor: Occupational Safety and Health Administration	1,808 to 4,200	1,057.
Transportation:		
National Highway Traffic Safety Administration	4,330 to 7,645	2,795 to 5,295.
Coast Guard	68	1,282.
Environmental Protection Agency:		
Office of Air	106,010 to 163,893	18,362 to 20,978.
Office of Water	891 to 8,103	2,424 to 2,937.

In order for comparisons or aggregation to be meaningful, benefit and cost estimates should correctly account for all substantial effects of regulatory actions, including potentially offsetting effects, which may or may not be reflected in the available data. We have not made any changes to agency monetized estimates other than connecting them to annual equivalents. Any comparison or aggregation across rules should also consider a number of factors which our presentation does not address. To the extent that agencies have adopted different methodologies—for example, different monetized values for effects, different baselines in terms of the regulations and controls already in place, different treatments of uncertainty—these differences remain embedded in the table 2. While we have relied in many instances on agency practices in monetizing costs and benefits, our citation of or reliance on agency data in this report should not be taken as an endorsement of all the

[8] These four EPA rules will reduce ambient levels of fine particulate matter by reducing direct PM emissions and/or the emissions of precursor pollutants like SO_2 and NO_x that contribute to the formation of fine PM. Many studies show an association between both short- and long-term exposure to fine PM and a variety of adverse health effects ranging from increases in the frequency of hospital admissions to premature mortality. There are, however, important uncertainties associated with these benefit estimates. For example key assumptions underlying the benefit estimates associated with premature mortality include the following: (1) The benefits analysis assumes there is a causal association between inhalation of fine particles and such health effects as premature mortality at exposure levels near those experienced by most Americans on a daily basis. While the biological mechanisms for this effect have not yet been definitively established, EPA has concluded that the weight of the available epidemiological and toxicological evidence supports an assumption of causality; (2) The benefits analysis assumes that all fine particles, regardless of their chemical composition, are equally toxic. This is an important assumption because fine particles from power plant emissions are chemically different from those emitted from both mobile sources and other industrial facilities. However, no clear scientific grounds exist for supporting differential effects estimates by particle type; (3) The benefits analysis assumes that the concentration-response function for fine particles is approximately linear within the range of ambient concentrations under consideration. Thus, the estimates include health benefits from reducing fine particles in areas that are in attainment with the fine particle standard and those that do not meet the standard; (4) The benefits analysis assumes that the forecasts for future emissions and associated air quality modeling are valid. The EPA's analyses are based on peer-reviewed scientific literature and up-to-date assessment tools. However such models are themselves based on an evolving understanding and research continues to provide the data necessary for model evaluation; and (5) The valuation of estimated reduction in mortality risk is largely taken from studies of the tradeoff associated with the willingness to accept risk in labor markets. Alternative estimates may, however, be more relevant for rules addressing air pollution. Further information on these benefits estimates can be found at *http://www.epa.gov/air/clearskies/tech_adden.pdf*, *http://www.whitehouse.gov/omb/inforeg/costbenefitreport1998.pdf*, *http://www.whitehouse.gov/omb/inforeg/2000fedreg-report.pdf*.

varied methodologies used to derive benefits and cost estimates.

B. Estimates of Benefits and Costs of This Year's ''Major'' Rules

In this section, we examine in detail the benefits and costs of each ''major'' rule, as required by section 624(a)(1)(C). We have included in our review those final regulations on which OMB concluded review during the 12-month period October 1, 2001 through September 30, 2002.

The statutory language that categorizes the rules we consider for this report differs from the definition of ''economically significant'' in Executive Order 12866 (section 3(f)(1)). It also differs from similar statutory definitions in the Unfunded Mandates Reform Act and subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996—Congressional Review of Agency Rulemaking. Given these varying definitions, we interpreted section 624(a)(1)(C) broadly to include all final rules promulgated by an Executive branch agency that meet any one of the following three measures:

- Rules designated as ''economically significant'' under section 3(f)(1) of Executive Order 12866;
- Rules designated as ''major'' under 5 U.S.C. 804(2) (Congressional Review Act); and
- Rules designated as meeting the threshold under Title II of the Unfunded Mandates Reform Act (2 U.S.C. 1531–1538)

Of the 31 rules received by OMB, USDA submitted four; the Veterans Administration, DOE, EPA, OMB, the Social Security Administration, and SBA each submitted one; HHS eight; The Departments of Interior, Justice, Defense, and FEMA each submitted two; and DOT five.

Social Regulation

Of the 31 economically significant rules reviewed by OMB, six are regulations requiring substantial additional private expenditures and/or providing new social benefits. Table 4 summarizes the costs and benefits of these rules and provides other information taken from rule preambles and agency RIAs. Of the six regulations received by OMB, EPA and DOE each submitted one, and DOI and DOT each submitted two. Agency estimates and discussion are presented in a variety of ways, ranging from a mostly qualitative discussion—for example, the NHTSA light truck corporate average fuel economy (CAFE) standard—to a more complete benefit-cost analysis, such as DOE's central air conditioner rule.

1. Benefits Analysis

Agencies monetized at least some benefit estimates for five of the six rules. In the case of EPA's recreational engines rule, the agency provides some monetized benefit estimates, but discusses other benefits qualitatively. In one case—NHTSA's tire pressure monitoring systems (TPMS) rule—the agency did not monetize all of the quantified benefits. In another case—NHTSA's CAFE rule—the agency did not report any quantified or monetized benefit estimates.

2. Cost Analysis

For three of the six rules, agencies provided monetized cost estimates. These include DOE's air conditioner rule, NHTSA's TPMS rule and EPA's recreational vehicle rule. For the remaining three rules, both DOI migratory bird hunting rules and NHTSA's CAFE rule, the agencies did not estimate costs.

3. Net Monetized Benefits

Three of the six rules provided at least some monetized estimates of both benefits and costs. Of these, the estimated monetized benefits of both the DOE air conditioner rule and the EPA recreational engine rule exceed the estimated monetized costs. The magnitude of the net benefits varies from $75 million per year for the air conditioner rule to as much as $4.6 billion for the recreational engine rule. One rule, NHTSA's TPMS rule, has negative net monetized benefits ranging from approximately $706 to $862 million per year.

4. Rules Without Quantified Effects

One rule, NHTSA's CAFE rule, is classified as economically significant even though the agency did not provide any quantified estimates of their effects.

TABLE 4.—SUMMARY OF AGENCY ESTIMATES FOR FINAL RULES 10/01/2001–9/30/02

[As of Date of Completion of OMB Review]

Agency	Rule	Benefits	Costs	Other Information
DOE	Energy Conservation Standards for Central Air Conditions and Heat Pumps.	$9.1 billion (present value) in energy savings between 2006 and 2030.	$7.3 billion (present value) for purchases between 2006 and 2030.	Monetized benefit and cost values are obtained from the ''National Energy Savings/Net Present Value/Shipments'' spreadsheet, available on DOE's web site: *http://www.eren.doe.gov/buildings/codes_standards/applbrf/central_air_conditioner_3.html* DOE projects a cumulative reduction in nitrogen oxide emissions of 119.3 thousand metric tons (undiscounted) over the period 2006–2030 and a cumulative reduction in carbon dioxide equivalent emissions of 53.8 million metric tons (undiscounted) over the period 2006–2030 [DOE Technical Support Document Appendix M, Table M.9].
DOI	Early Season Migratory Bird Hunting Regulations 2002–2003.	$50 million to $192 million/yr.	Not estimated	The analysis was based on the 1996 National Hunting and Fishing Survey and the U.S. Department of Commerce's County Business Patterns, from which it was estimated that migratory bird hunters would spend between $429 million and $1,084 million at small businesses [67 FR 54704]. The listed benefits represent estimated consumer.
DOI	Late-Season Migratory Bird Hunting Regulations 2002–2003.	$50 million to $192 million/yr.	Not estimated	The analysis was based on the 1996 National Hunting and Fishing Survey and the U.S. Department of Commerce's County Business Patterns, from which it was estimated that migratory bird hunters would spend between $429 million and $1,084 million at small businesses [67 FR 54704]. The listed benefits represent estimated consumer.

TABLE 4.—SUMMARY OF AGENCY ESTIMATES FOR FINAL RULES 10/01/2001–9/30/02—Continued

[As of Date of Completion of OMB Review]

Agency	Rule	Benefits	Costs	Other Information
DOT	Light Truck Average Fuel Economy Standard, Model Year 2004.	Not estimated	Not estimated	''* * * [T]he agency has been operating under a restriction on the use of appropriations for the last six fiscal years. The restriction has prevented the agency from gathering and analyzing data relating to fuel economy capabilities and the costs and benefits of improving the level of fuel economy. Particularly since that restriction was lifted only on December 18, 2001, the agency has been unable to prepare a separate economic analysis for this rulemaking. The agency notes, however, that the standard it is setting for the 2004 model year will not make it necessary for the manufacturers with a substantial share of the market to change their product plans.'' [67 FR 16059]
DOT	Tire Pressure Monitoring Systems (TPMS).	79–124 fatalities and 5,176– 8,722 injuries prevented per year; $43–$344 million per year in fuel savings and reduced tire wear.	$749–$1,206 million/yr	Unquantified Benefits: ''The agency cannot quantify the benefits from a reduction in crashes associated with hydroplaning and overloading vehicles. The primary reason that the agency has been unable to quantify these benefits is the lack of crash data indicating tire pressure and how often these conditions are the cause or contributing factors in a crash. The agency does not collect tire pressure in its crash investigations. NHTSA also has not been able to quantify the benefits associated with reductions in property damage and travel delays that will result from fewer crashes or reductions in the severity of crashes.'' [67 FR 38739] Unquantified Costs: ''The agency anticipates that there may be other maintenance costs for both direct and indirect TPMS. For example, with indirect TPMSs, there may be problems with wheel speed sensors and component failures. With direct TPMSs, the pressure sensors may be broken off when tires are changed. The agency requested comments on this issue in the NPRM, but received none. Without estimates of these maintenance problems and costs, the agency is unable to quantify their impact. The agency also notes that in order to benefit from the TPMS, drivers must respond to a warning by re-inflating their tires. To accomplish this, most drivers will either make a separate trip to a service station or take additional time to inflate their tires when they are at a service station for fuel. The process of checking and re-inflating tires is relatively simple, and probably would take from three to five minutes. The time it would take to make a separate trip to a service station would vary depending on the driver's proximity to a station at the time he or she was notified.'' 67 FR 38741]
EPA	Control of Emissions From Nonroad Large Spark-Ignition Engines, and Recreational Engines.	$410 million/yr. in reduced engine operation costs; $900 million to $7.88 billion in air quality benefits in calendar year 2030.	$192 million/yr	EPA also lists a variety of other benefit categories which it was not able to quantify or monetize, ranging from infant mortality to damage to urban ornamental plants. [67 FR 68328].

Transfer Regulations

Of the 31 economically significant rules reviewed by OMB, Table 5 lists the 25 that implement Federal budgetary programs. The budget outlays associated with these rules are ''transfers'' to program beneficiaries. Of the transfer rules, HHS promulgated eight rules, most of which implement Medicare and Medicaid policy. Four are USDA rules. Of the four, three are crop assistance and disaster aids for farmers and one is a food stamp program rule. The Department of Transportation issued three transfer rules. The Departments of Defense, Justice, and the Federal Emergency Management Administration issued two each. The Social Security Administration, Veterans Administration, Small Business Administration and Office of Management and Budget each promulgated one rule.

TABLE 5.—AGENCY TRANSFER RULES: 10/01/01 TO 9/30/02

[As of date of completion of OMB review]

Office of Management and Budget (OMB)

Regulation for Air Carrier Guaranteed Loan Program.

Dept. of Agriculture (USDA)

2000 Crop Agricultural Disaster and Market Assistance.
2002 Farm Bill Regulations: Sugar Program.
Peanut Quota Buyout Program.
Work Provisions of the PRWORA of 1996 and the Food Stamp Provisions of the Balance Budget Act of 1997.

Dept. of Defense

CHAMPUS/TRICARE: Partial Implementation of Pharmacy Benefits Programs; NDAA for FY 2001.
TRICARE: Sub-Acute Care Program; Uniform Skilled Nursing Benefit; Home Healthcare Benefit; Medicare Payment Methods for Skilled Nursing Facilities.

Dept. of Health and Human Services (HHS)

Contraception and Infertility Research Loan Repayment Program.
Medicare Program: Revisions to Payment Policies and 5-Year Review and Adjustments to the Relative Value Units Under the Physician Fee Schedule for CY 2002.
Medicare Program: Prospective Payment System for Hospital Outpatient Services for CY 2002 and Pro Rata Reduction on Transitional Pass-Through Payments.
Medicaid Program: Modification of the Medicaid Upper Payment Limit for Non-State, Government-Owned or Operated Hospitals.
Medicare Program: Modifications to Managed Care Rules Based on Payment Provisions in BIPA and Technical Corrections.
Medicare Program: Notice of Modification of Beneficiary Assessment Requirements for Skilled Nursing Facilities.
Changes to Hospital Inpatient Prospective Payment Systems and FY 2003 Rate.
Medicaid Managed Care; New Provisions.

Social Security Administration

Revised Medical Criteria for Determination of Disability Musculoskeletal System and Related Criteria.

Department of Justice

Claims Under the Radiation Exposure Compensation Act Amendments of 2000.
September 11 Victim Compensation Fund of 2001.

Dept. of Transportation

Procedures for Compensation of Air Carriers.
Imposition and Collection of Passenger Civil Aviation Security Fees in the Wake of September 11.
Aviation Security Infrastructure Fees.

Veterans Administration

Diseases Specific to Radiation-Exposed Veterans.

Federal Emergency Management Administration

Assistance to Firefighters Grant Program.
Disaster Assistance; Federal Assistance to Individuals and Households.

Small Business Administration

Disaster Loan Program.

Major Rules for Independent Agencies

The congressional review provisions of the Small Business Regulatory Enforcement Fairness Act (SBREFA) require the General Accounting Office (GAO) to submit reports on major rules to the committees of jurisdiction, including rules issued by agencies not subject to Executive Order 12866 (the ''independent'' agencies). We reviewed the information on the costs and benefits of major rules contained in GAO reports for the period of October 1, 2001 to September 30, 2002. GAO reported that three independent agencies issued eight major rules during this period. Two agencies did not conduct benefit-cost analyses. One agency considered benefits and costs of the rules. OIRA lists the agencies and the type of information provided by them (as summarized by GAO) in Table 6. The Securities and Exchange Commission consistently considered benefits and costs in their rulemaking processes while the Federal Communications Commission and the Nuclear Regulatory Commission did not prepare benefit-cost analyses.

In comparison to the agencies subject to E.O. 12866, the independent agencies provided relatively little quantitative information on the costs and benefits of the major rules. As Table 6 indicates, three of the eight rules included some discussion of benefits and costs. Three of the eight regulations had monetized cost information; one regulation monetized benefits. It is difficult to discern, however, whether the rigor and the extent of the analyses conducted by the independent agencies are similar to those of the analyses performed by agencies subject to the Executive Order.

TABLE 6.—RULES FOR INDEPENDENT AGENCIES (OCTOBER, 2001–SEPTEMBER, 2002)

Agency	Rule	Information on benefits or costs	Monetized benefits	Monetized Costs
FCC	Broadcast Services; Digital Television	No	No	No.

TABLE 6.—RULES FOR INDEPENDENT AGENCIES (OCTOBER, 2001–SEPTEMBER, 2002)—Continued

Agency	Rule	Information on benefits or costs	Monetized benefits	Monetized Costs
FCC	Ultra-Wideband Transmission Systems	No	No	No.
FCC	Assessment and Collection of Regulatory Fees for Fiscal Year 2002	No	No	No.
FCC	Order to Permit Operation of NGSO FSS Systems Co-Frequency with GSO and Terrestrial Systems in the Ku-Band Frequency Range; Authorize Subsidiary Terrestrial Use of the 12.2–12.7 GHz Band by Direct Broadcast Satellite Licensees and Their Affiliates; and in Re-Applications of Broadwave USA, PDC Broadband Corporation, and Satellite Receivers, Ltd. in the 12.2–12.7 GHz Band.	No	No	No.
NRC	Revision of Fee Schedules; Fee Recovery for FY 2002	No	No	No.
SEC	Books and Records Requirements for Brokers and Dealers Under the Securities Exchange Act of 1934.	Yes	Yes	Yes.
SEC	Certification of Disclosure in Companies' Quarterly and Annual Reports	Yes	No	Yes.
SEC	Acceleration of Periodic Report Filing Dates and Disclosure Concerning Web Site Access to Reports.	Yes	No	Yes.

Chapter II. Developing Better Regulation

In addition to estimates of the cost and benefits of Federal rules and paperwork, the Regulatory Right-to-Know Act requires OMB to publish ''recommendations for reform.'' In response to this requirement, OMB seeks public comment in the following three areas.

A. Guidelines for Regulatory Analysis

The evaluation of both the benefits and costs of alternative options through regulatory analysis helps agency policymakers arrive at sound regulatory decisions and also helps the public, Congress, and the courts understand those decisions. Although the preparation of such an analysis may require significant investments of agency staff and resources, carefully completed analyses will result in well-designed regulations and larger net benefits to society as a whole. To help support the development of better analysis, OMB has provided guidance to the agencies since the 1980s on how to conduct regulatory analysis. The current OMB guidelines were issued in 1996 as a ''best practices'' document and were revised and issued as guidance in 2000.

In order to make continued improvements in the quality of the regulatory analyses prepared by agencies, OIRA initiated in 2002 a process to refine these guidance documents. The OIRA Administrator and a member of the Council of Economic Advisers (CEA) are serving as co-chairs of this effort. OMB and CEA staff have drafted proposed revised guidelines which are presented in Appendix C. Through these proposed guidelines, we seek to establish more uniform analytic guidance for the agencies to follow in preparing their regulatory analysis. We will also incorporate new insights and recent innovations in what constitutes a good analysis. Finally, we expect the guidelines to increase the transparency of the analysis of prospective regulations to both technical and nontechnical readers.

While these proposed guidelines include some additional requirements on the agencies in performing RIAs, we believe that adherence to the proposed revisions will yield improvements in the information provided by these analyses. Improved analyses will strengthen the regulatory development process, resulting in better designed regulations and potentially large net benefits to society as a whole.

The key changes in the proposed guidelines include the following:

- The proposal encourages agencies to perform both cost-effectiveness analysis and benefit-cost analysis of major rules because the two techniques offer regulators somewhat different but useful perspectives. In addition, however, we recognize that cost-effectiveness analysis will be feasible in certain situations where a benefit-cost analysis may not be feasible.
- The proposal recommends that agencies report analytic results based on two discount rates—3 percent and 7 percent—for major rules whose effects will be felt primarily within this generation (*i.e.*, the next 20 or 30 years). If benefits and costs are expected to last beyond the current generation, the proposal permits additional sensitivity analysis with discount rates as low as 1 percent.
- The proposal requires agencies to support rulemakings with formal probabilistic analysis of the key scientific and economic uncertainties regarding costs and benefits for rules with economic effects that exceed more than $1 billion per year. In particular, the analysis must present a probability distribution for the estimated benefits and costs, unless the benefits and costs are known with a high degree of certainty.

The draft guidelines are being released today for a 60-day public comment period as well as independent peer review by leading academic experts in the field of regulatory analysis. We also plan to conduct an interagency review of the draft guidelines following public and peer review comments.

We will continue to use our current guidance until we complete this review process and publish revised guidelines.

B. Request for Comment on U.S. Approaches to Analysis and Management of Emerging Risks

Regulators often must decide on an appropriate course of action to protect public health, safety or the environment before science has resolved all the key factual questions about a potential hazard. The appropriate level of precaution in risk assessment and management is complicated by the need to balance efforts to mitigate these potential risks with countervailing risks that may arise from other sources. For example, policies to facilitate the growth of the diesel-engine market may be desirable from a global environmental and energy security perspective since diesel offers significant fuel efficiency advantages over gasoline-powered vehicles, and would likely lead to less reliance on importation of foreign oil and reduce the emission of greenhouse gases. However, diesel fuels pose greater risk to public health and environment from smog and soot caused by relatively higher emission of particles and nitrogen dioxide than conventional gasoline.

U.S. regulators rely on various science-based precautionary approaches in assessing potential hazards and taking protective actions. These

approaches have evolved over time and reflect statutory requirements, agency specific policy decisions, and advancements in scientific understanding. For purposes of collecting and analyzing current risk assessment and management practices in federal agencies, with an emphasis on the role of precaution in risk policy and regulation, the Administration has formed an Interagency Work Group on Risk Management co-chaired by James L. Connaughton, Chairman of the White House Council on Environmental Quality and John D. Graham, Administrator, Office of Information and Regulatory Affairs, Office of Management and Budget. The Work Group includes representatives from the Department of Agriculture, the Department of Commerce, the Department of Health and Human Services, the Department of Interior, the Environmental Protection Agency, and the Office of Science and Technology Policy.

To assist in the Work Groups efforts, OMB requests comments for the next 60 days on current U.S. approaches to analysis and management of emerging risks. Specifically, we seek public input on:

- Ways in which ''precaution'' is embedded in current risk assessment procedures through ''conservative'' assumptions in estimation of risk, or through explicit ''protective'' measures in management decisions as required by statutory requirements as well as agency judgments.
- Examples of approaches in human and ecological risk assessment and management methods addressed by U.S. regulatory agencies (*e.g.*, consumer product safety, drug approval, pesticide registration, protection of endangered species) which appear unbalanced.
- How the U.S. balances precautionary approaches to health, safety and environmental risks with other interests such as economic growth and technological innovation.

C. Request for Comment on Improving the Analysis of Regulations Related to Homeland Security

In last year's final Report to Congress, OMB noted that 58 significant new federal regulations had been enacted in the aftermath of September 11th to protect national security and provide post-attack assistance. As an integral part of the expedited issuance of these rules, OIRA conducted its full regulatory review and coordination function under Executive Order 12866. These efforts made sure that all the rules related to September 11th received priority attention from the appropriate reviewers, and that the Administration's best solutions to respond to potential terrorist attacks were implemented.

Looking to the future, OMB expects additional homeland-security proposals from federal agencies covering concerns ranging from airline safety and immigration to food safety. For example, USDA and HHS will propose new regulations required to implement the Bioterrorism Preparedness and Control Act of 2002. Similarly, the Department of Homeland Security will face major challenges in developing sensible regulations covering many facets of American society. In light of the significant interest in these regulations, OMB is seeking public comment for the next 60 days on how to more effectively evaluate the benefits and costs of these proposals. OMB seeks comment on how agencies might assess the probability of future terrorist attacks and the likely damages, and the resulting effectiveness of new federal regulations in preventing future attacks, reducing America's vulnerability, or mitigating the damage of attacks which do occur. OMB seeks comment on how agencies might better identify, quantify and weigh the direct and indirect costs of such rules, including impacts on time, convenience, privacy and economic productivity. OMB also seeks comment on how evaluation of such regulation could include auxiliary benefits not directly related to the homeland security purpose of the regulation. OMB's request for comment is concerned with these issues as they apply to future rulemakings and is not intended to address a specific rulemaking.

Appendix A.—Calculations of Benefits and Costs: Explanation

Chapter I presents estimates of the annual costs and benefits of selected final major regulations reviewed by OMB between October 1, 1992 and September 30, 2002. The explanation of the calculations for the major rules reviewed by OMB between April 1, 1995 and March 31, 1999 can be found in Chapter IV of our 2000 report (OMB 2000). Table 19, Appendix E, of the 2002 Report presents OIRA's estimates of the benefits and costs of the 20 individual rules reviewed between April 1, 1999 and September 30, 2001. All benefit and cost estimates were adjusted to 2001 dollars.

In assembling estimates of benefits and costs, OIRA has:

(1) Applied a uniform format for the presentation of benefit and cost estimates in order to make agency estimates more closely comparable with each other (for example, annualizing benefit and cost estimates); and

(2) Monetized quantitative estimates where the agency has not done so (for example, converting Agency projections of quantified benefits, such as, estimated injuries avoided per year or tons of pollutant reductions per year to dollars using the valuation estimates discussed below).

The adoption of a uniform format for annualizing agency estimates allows, at least for purposes of illustration, the aggregation of benefit and cost estimates across rules. While OIRA has attempted to be faithful to the respective agency approaches, the reader should be cautioned that agencies have used different methodologies and valuations in quantifying and monetizing effects. Thus, this aggregation involves the assemblage of benefit and cost estimates that are not comparable.

TABLE 7.—ESTIMATE OF BENEFITS AND COSTS OF 47 MAJOR RULES OCTOBER 1, 1992 TO MARCH 31, 1995

[Millions of 2001 dollars]

Regulation	Agency	Benefits	Costs	Explanation
Nutrition Labeling of Meat and Poultry Products.	USDA—FSIS	205	25–32	Present value estimates amortized over 20 years.
Food Labeling (combined analysis of 23 individual rules).	HHS—FDA	438–2,637	159–249	Present value estimates amortized over 20 years.
Real Estate Settlement Procedures	HUD	258–332	135	
Manufactured Housing Wind Standards ...	HUD	79	511	
Confined Spaces	DOL–OSHA	540	250	We valued each fatality at $5 million and each lost-workday injury at $50,000. We did not value non-lost-workday injuries.

TABLE 7.—ESTIMATE OF BENEFITS AND COSTS OF 47 MAJOR RULES OCTOBER 1, 1992 TO MARCH 31, 1995—Continued

[Millions of 2001 dollars]

Regulation	Agency	Benefits	Costs	Explanation
Occupational Exposure to Asbestos	DOL–OSHA	92	448	We assumed a 20-year latency period between exposure and the onset of cancer or asbestosis and valued each death and each case of asbestosis at $5 million.
Vessel Response Plans	DOT–Coast Guard.	8	324	Present values amortized over 30 years. We valued each barrel of oil not spilled at $2,000.
Double-Hull Standards	DOT–Coast Guard.	15	641	Present values amortized over 30 years. We valued each barrel of oil not spilled at $2,000.
Controlled Substances and Alcohol Use and Testing.	DOT–FHWA	1,539	114	
Prevention of Prohibited Drug Use in Transit Operations.	DOT	107	37	Present values amortized over 10 years.
Stability Control of Medium and Heavy Vehicles During Braking.	DOT–NHTSA	1,650–2,539	694	We valued each ''equivalent fatality'' at $3 million.
Oil and Gas Extraction	EPA	35–129	35	First-year costs amortized costs over 15 years and added to annual (15th year) costs.
Acid Rain Permits Regulations	EPA	76,854–77,206	1,109–1,871	We valued SO_2 reductions at $7,300 per ton.
Vehicle Inspection and Maintenance (I/M)	EPA	219–992	671	We used the estimates of and cost and emission reductions of the new I/M program compared to the baseline of no I/M program. We valued VOC reductions at $520–$2360 per ton. We did not assign a value to CO reductions.
Evaporative Emissions from Light-Duty Vehicles, Light-Duty Trucks, and Heavy-Duty Vehicles..	EPA	243–1,104	161–248	We assumed the VOC emission reductions began in 1995 and rise linearly until 2020, after which point they remain at the 2020 level. Annualizing this stream results in an average of 468,000 tons per year. We valued these tons at $520–$2360 per ton.
Onboard Diagnostic Systems	EPA	421–2,383	226	Emission reductions and costs amortized over 15 years. We valued VOC reductions at $520–$2360 per ton and NO_X reductions at $700–$4900 per ton.
Phase II Land Disposal Restrictions	EPA	26	240–272	We valued each cancer case at $5 million.
Phase-out of Ozone-Depleting Chemicals and Listing of Methyl Bromide.	EPA	1,260–3,993	1,681	Present values amortized over 16 years.
Reformulated Gasoline	EPA	184–637	1,085–1,395	Estimates are for Phase II, which include Phase I benefits and costs. We used the benefit estimates that assume the enhanced I/M program is in place. We valued VOC reductions at $520–$2360 per ton and NO_X reductions at $700–$4900 per ton. We valued each cancer case at $5 million. We assumed the phase II aggregate costs are an additional 25 percent of the Phase I costs based on EPA's reported per-gallon cost estimates.
Acid Rain NO_X Title IV CAAA	EPA	661–4,725	372	Values are for Phase II. We valued NO_X reductions at $350–$2500 per ton.
Hazardous Organic NESHAP	EPA	520–2,360	292–333	We valued VOC emissions at $520–$2360 per ton and NO_X emissions (which are a cost in this instance) at $350–$2500 per ton. We did not value changes in CO emissions.
Refueling Emissions from Light-Duty Vehicles.	EPA	148–673	33	We assumed Stage II controls will remain in place and valued VOC emissions at $520–$2360 per ton.

TABLE 7.—ESTIMATE OF BENEFITS AND COSTS OF 47 MAJOR RULES OCTOBER 1, 1992 TO MARCH 31, 1995—Continued

[Millions of 2001 dollars]

Regulation	Agency	Benefits	Costs	Explanation
Non-Road Compression Ignition Engines	EPA	412–2,881	29–70	We annualized the NO_X emissions which yielded an average annual emission reduction of 588,000 tons beginning in 2000. We valued NO_X emissions at $700–$4900 per ton.
Bay/Delta Water Quality Standards	EPA	2–26	37–248	
Deposit Control Gasoline	EPA	374–1,480	197	We valued estimates of combined emission reductions at $520–$2360 per ton. Present value cost estimates amortized over 5 years.
Total		86,290–106,708	9,506–11,087	

TABLE 8.—ESTIMATE OF BENEFITS AND COSTS OF 3 MAJOR RULES, OCTOBER 1, 2001 TO SEPTEMBER 30, 2002

[Millions of 2001 dollars]

Regulation	Agency	Benefits	Costs	Explanation
Energy Conservation Standards for Central Air Conditioners and Heat Pumps.	DOE	710	636	Present value estimates amortized over 24 years. We valued NO_X emission reductions at $350–$2500 per ton.
Tire Pressure Monitoring Systems (TPMS)	DOT	409–944	749–1,206	We valued each equivalent fatality (see p. iv of the Executive Summary of the Final Economic Assessment) at $3 million.
Control of Emissions From Nonroad Large Spark-Ignition Engines, and Recreational Engines.	EPA	913–4,818	192	We amortized the benefit estimates in proportion to the estimated NO_X emission reductions. The lower end of the range reflects the alternative approach to valuing benefits of EPA rules discussed elsewhere.
Total		2,032–6,472	1,577–2,034	

Assumptions: 7 percent discount rate unless another rate explicitly identified by the agency. For DOL: $5 million VSL assumed for deaths averted when not already quantified. Injuries averted valued at $50,000 from Viscusi.[9] All values converted to 2001 dollars. All costs and benefits stated on a yearly basis.

[9] W. Kip Viscusi, Fatal Tradeoffs: Public & Private Responsibilities for Risk. New York, NY, Oxford University Press, 1992, p. 65.

Valuation Estimates for Regulatory Consequences [10]

Agencies continue to take different approaches to monetizing benefits for rules that affect small risks of premature death. As a general matter, we continue to defer to the individual agencies' judgment in this area. In cases where the agency both quantified and monetized fatality risks, we have made no adjustments to the agency's estimate. In cases where the agency provided a quantified estimate of fatality risk, but did not monetize it, we have monetized these estimates in order to convert these effects into a common unit.

The following is a brief discussion of OIRA's valuation estimates for other types of effects that agencies identified and quantified, but did not monetize. As a practical matter, the aggregate benefit and cost estimates are relatively insensitive to the values we have assigned for these rules because the aggregate benefit estimates are dominated by those rules where EPA provided quantified and monetized benefit and cost estimates.

Injury. For NHTSA's rules, we adopted NHTSA's approach of converting nonfatal injuries to ''equivalent fatalities.'' These ratios are based on NHTSA's estimates of the value individuals place on reducing the risk of injury of varying severity relative to that of reducing risk of death.[11] For the OSHA rules, we monetized only lost workday injuries using a value of $50,000 per injury averted.

I. Change in Gasoline Fuel Consumption. We valued reduced gasoline consumption at $.80 per gallon pre-tax. This equates to retail (at-the-pump) prices in the $1.10–$1.30 per gallon range.

II. Reduction in Barrels of Crude Oil Spilled. OIRA valued each barrel prevented from being spilled at $2,000. This is double the sum of the most likely estimates of environmental damages plus cleanup costs contained in a published journal article [Brown and Savage, ''The Economics of Double-Hulled Tankers,'' Maritime Policy and Management, Volume 23(2), 1996, pages 167–175].

III. Change in Emissions of Air Pollutants. We used estimates of the benefits per ton for reductions in hydrocarbon and nitrogen oxide emissions derived from recent EPA regulatory analyses, as follows (1996$):

Hydrocarbon: $520 and $2360 per ton
Nitrogen Oxide (stationary): $350 and $2500 per ton
Nitrogen Oxide (mobile): $700 and $4900 per ton
Sulfur Dioxide: $7300 per ton

The estimates for reductions in hydrocarbon emissions were obtained from EPA's RIA for the 1997 rule revising the primary NAAQS for ozone and fine PM. OIRA has revised the estimates for reductions in NO_X emissions to reflect a range of estimates from recent EPA analyses for several rules and for proposed legislation. In particular, OIRA has adopted different benefit transfer estimates for NO_X reductions from stationary sources (*e.g.*, electric utilities) and from mobile sources. EPA believes that there are a number of reasons to expect that reductions in NO_X emissions from utility sources achieve different air quality

[10] The following discussion updates the monetization approach used in previous reports and draws on examples from this and previous years.

[11] National Highway Traffic Safety Administration, *The Economic Cost of Motor Vehicle Crashes, 1994,* Table A–1. *http://www.nhtsa.dot.gov/people/economic/ecomvc1994.html.*

improvements relative to reductions from ground-level mobile sources. For example, mobile source tailpipe emissions are located in urban areas at ground level (with limited dispersal) while electric utilities emit NO_X from ''tall stacks'' located in rural (remote) locations with substantial geographic dispersal (Letter to Don Arbuckle, Deputy Administrator, OIRA from Tom Gibson, Associate Administrator, Office of Policy, Economics and Innovation, EPA, May 16, 2002.) There remain considerable uncertainties with the development of these estimates. The discussion below outlines the various EPA analyses serving as the basis for the NO_X benefit transfer values presented above and discusses the uncertainties that attend these estimates.

Analysis of recent EPA rules yield several estimates for the NO_X benefits per ton from electric utility sources. (See the Regulatory Impact Analyses for the ''NO_X SIP Call'' and the Section 126 rules, available on the Web at *http://www.epa.gov/ttn/ecas/econguid.html.* In addition, see Memo to NSR Docket from Bryan Hubbell, Senior Economist, Innovative Strategies and Economics Group, EPA.) Based on these studies, the upper end of the range for the benefits of NO_X reductions from stationary sources (electric utilities) is $2500 per ton. These studies also developed estimates for the benefits associated with reductions in SO_2 from electric utilities. Based on an analysis outlined in a June 20, 2001 EPA memo to the file, ''Benefits Associated with Electricity Generating Emissions Reductions Realized Under the NSR Program,'' we used $7300 per ton SO_2 emissions for the 1992 EPA Acid Rain rule.

For mobile sources, EPA recently published the final Tier 2/Gasoline Sulfur rule RIA (EPA, 1999) and Heavy Duty Engine/Diesel Fuel RIA (EPA, 2000). For the Tier 2 rule, which affects light-duty vehicles, NO_X reductions account for around 90 percent of PM precursor emissions and 86 percent of ozone precursor emissions. Based on the final Tier 2/Gasoline Sulfur RIA, EPA estimates that NO_X reductions will yield benefits of $4,900/ton (1996$). EPA believes this analysis provides a more appropriate source for the NO_X benefit transfer value for mobile sources. (Letter from Tom Gibson, pp. B2 and B3, May 16, 2002.) Additional details on the Tier 2 benefits analysis are available in the Tier 2/Sulfur Final Rulemaking RIA, available on the Web at *http://www.epa.gov/oms/fuels.htm.*

The Heavy Duty Engine/Diesel Fuel benefits analysis examined the impacts in 2030 of reducing SO_2 emissions by 141,000 tons and NO_X emissions by 2,750 thousand tons, as well as a 109,000 ton reduction in direct PM emissions. Based on this analysis, EPA estimates a value for NO_X reductions of $10,200/ton in 2030. (Letter from Tom Gibson, p. B3, May 16, 2002.) Complete details of the emissions, air quality, and benefits modeling conducted for the HD Engine/Diesel Fuel Rule can be found at *http://www.epa.gov/otaq/diesel.htm* and *http://www.epa.gov/ttn/ecas/regdata/tsdhddv8.pdf.* Because the Heavy Duty Engine/Diesel Fuel estimate includes an adjustment for income growth out to 2030 and involves reductions in several PM-related pollutants, OIRA has adopted a value of $4900 per ton from EPA's analysis of the Tier 2 rule as a benefits transfer value for reductions in NO_X emissions from mobile sources.

Reductions in the risk of premature mortality dominate the benefits estimates in all of these analyses. The size of the mortality risk estimates from the underlying epidemiological studies, the serious nature of the effect itself, and the high monetary value ascribed to prolonging life make mortality risk reduction the most important health endpoint quantified in these analyses.[12] Because of the importance of this endpoint and the considerable uncertainty among economists and policymakers as to the appropriate way to value reductions in mortality risks, EPA has developed alternative estimates for its ''Clear Skies'' legislation that show the potential importance of some of the underlying assumptions. (See ''Human Health and Environmental Benefit Achieved by the Clear Skies Initiative'' at *http://www.epa.gov/clearskies.*) OIRA has used this analysis to identify an alternative estimate of the benefits from NO_X reductions. In its Clear Skies analysis, EPA presented alternative benefits estimates of $14 billion and $96 billion per year in 2020, or a difference in the estimates of roughly a factor of seven.[13] Using this ratio, an alternative estimate of the benefits of NO_X reductions from stationary sources would be $350 per ton from stationary sources and $700 per ton from mobile sources.

OIRA recognizes that there are potential problems and significant uncertainties that are inherent in any benefits analysis based on $/ton benefit transfer techniques. The extent of these problems and the degree of uncertainty depends on the divergence between the policy situation being studied and the basic scenario providing the benefits transfer estimate. Examples of other factors include sources of emissions, meteorology, transport of emissions, initial pollutant concentrations, population density, and population demographics, such as the proportion of elderly and children and baseline incidence rates for health effects. Because of the uncertainties associated with benefits transfer, OIRA decided not to include three mobile source rules that are projected to achieve substantial reductions in SO_2 and PM emissions that OIRA included in previous years in the monetized estimates presented in Tables 5 and 6 of the 2002 Report.[14]

Adjustment for Differences in Time Frame Across These Analyses

Agency estimates of benefits and costs cover widely varying time periods. The differences in the time frames used for the various rules evaluated generally reflect the specific characteristics of individual rules such as expected capital depreciation periods or time to full realization of benefits. In order to allow us to provide an aggregate estimate of benefits and costs, we developed benefit and cost time streams for each of the rules. Where agency analyses provide annual or annualized estimates of benefits and costs, we used these estimates in developing streams of benefits and costs over time. Where the agency estimate provided only annual benefits and costs for specific years, we used a linear interpolation to represent benefits and costs in the intervening years.[15]

Further Caveats

In order for comparisons or aggregation to be meaningful, benefit and cost estimates should correctly account for all substantial effects of regulatory actions, including potentially offsetting effects, which may or may not be reflected in the available data. We have not made any changes to agency monetized estimates. To the extent that agencies have adopted different monetized values for effects—for example, different values for a statistical life or different discounting methods—these differences remain embedded in the tables. Any comparison or aggregation across rules should also consider a number of factors which our presentation does not address. For example, these analyses may adopt different baselines in terms of the regulations and controls already in place. In addition, the analyses for these rules may well treat uncertainty in different ways. In some cases,

[12] There are several key assumptions underlying the benefit estimates for reductions in NO_X emissions, including:

1. Inhalation of fine particles is causally associated with premature death at concentrations near those experienced by most Americans on a daily basis. While no definitive studies have yet established any of several potential biological mechanisms for such effects, the weight of the available epidemiological evidence supports an assumption of causality.

2. All fine particles, regardless of their chemical composition, are equally potent in causing premature mortality. This is an important assumption, because fine particles from power plant emissions are chemically different from directly emitted fine particles from both mobile sources and other industrial facilities, but no clear scientific grounds exist for supporting differential effects estimates by particle type.

3. The concentration-response function for fine particles is approximately linear within the range of outdoor concentrations under policy consideration. Thus, the estimates include health benefits from reducing fine particles in both attainment and non-attainment regions.

4. The forecasts for future emissions and associated air quality modeling are valid.

5. The valuation of the estimated reduction in mortality risk is largely taken from studies of the tradeoff associated with the willingness to accept risk in the labor market.

[13] The difference between the estimates reflects several assumptions, including differences in the estimation and valuation of mortality risk and the valuation of a reduction in the incidence of chronic bronchitis.

[14] These are: Municipal Waste Combustors (1995), Emission Standards for New Locomotives (1997) and Emission Standards for Non-Road Diesel Engines (1998).

[15] In other words, if hypothetically we had costs of $200 million in 2000 and $400 million in 2020, we would assume costs would be $250 million in 2005, $300 million in 2010, and so forth. For example, for the Regional Haze rule, EPA provided only an estimate of benefits and costs in 2015. To develop benefit and cost streams, we used a linear extrapolation of benefits and costs beginning in 2009 and scaling up to the reported 2015 estimates.

agencies may have developed alternative estimates reflecting upper- and lower-bound estimates. In other cases, the agencies may offer a midpoint estimate of benefits and costs. In still other cases the agency estimates may reflect only upper-bound estimates of the likely benefits and costs. While we have relied in many instances on agency practices in monetizing costs and benefits, our citation of or reliance on agency data in this report should not be taken as an OIRA endorsement of all the varied methodologies used to derive benefits and cost estimates.

Appendix B. Agency Estimates of Benefits and Costs

TABLE 9.—AGENCY ESTIMATES OF BENEFITS AND COSTS OF MAJOR RULES

[October 1, 1992 to September 30, 1993]

Rule	Agency	Benefits	Costs	Other information
Nutrition labeling of meat and poultry products.	USDA–FSIS	$1.75 billion (NPV)	$218–272 million (NPV) ..	20-year NPV discounted at 7%.
Food Labeling: Use of Nutrient Content Claims for Butter.	HHS–FDA	$4.4–$26.5 billion	$1.4–$2.3 billion plus $163 million in costs to Federal government.	HHS–FDA performed one analysis for the food labeling requirements imposed by this rule and the other 22 HHS–FDA rules in this table related to food labeling.
Food Labeling: Declaration of Ingredients.	HHS–FDA	$4.4–$26.5 billion	$1.4–$2.3 billion plus $163 million in costs to Federal government.	HHS–FDA performed one analysis for the food labeling requirements imposed by this rule and the other 22 HHS–FDA rules in this table related to food labeling.
Food Labeling, Declaration of Ingredients: Common or Usual Name Declaration for Protein Hydrolysates and Vegetable Broth in Canned Tuna ''and/or'' Labeling for Soft Drinks.	HHS–FDA	$4.4–$26.5 billion	$1.4–$2.3 billion plus $163 million in costs to Federal government.	HHS–FDA performed one analysis for the food labeling requirements imposed by this rule and the other 22 HHS–FDA rules in this table related to food labeling.
Food Labeling: Declaration of Ingredients for Dairy Products and Maple Syrup.	HHS–FDA	$4.4–$26.5 billion	$1.4–$2.3 billion plus $163 million in costs to Federal government.	HHS–FDA performed one analysis for the food labeling requirements imposed by this rule and the other 22 HHS–FDA rules in this table related to food labeling.
Food Labeling: Nutrient Content Claims, Definition of Term Healthy.	HHS–FDA	$4.4–$26.5 billion	$1.4–$2.3 billion plus $163 million in costs to Federal government.	HHS–FDA performed one analysis for the food labeling requirements imposed by this rule and the other 22 HHS–FDA rules in this table related to food labeling.
Food Labeling: Label Statements on Foods for Special Dietary Use.	HHS–FDA	$4.4–$26.5 billion	$1.4–$2.3 billion plus $163 million in costs to Federal government.	HHS–FDA performed one analysis for the food labeling requirements imposed by this rule and the other 22 HHS–FDA rules in this table related to food labeling.
Food Labeling: Health Claims, Zinc and Immune Function in the Elderly.	HHS–FDA	$4.4–$26.5 billion	$1.4–$2.3 billion plus $163 million in costs to Federal government.	HHS–FDA performed one analysis for the food labeling requirements imposed by this rule and the other 22 HHS–FDA rules in this table related to food labeling.
Food Labeling, Reference Daily Intakes and Daily Reference Values (Decision).	HHS–FDA	$4.4–$26.5 billion	$1.4–$2.3 billion plus $163 million in costs to Federal government.	HHS–FDA performed one analysis for the food labeling requirements imposed by this rule and the other 22 HHS–FDA rules in this table related to food labeling.
Food Labeling: Health Claims and Label Statements, Sodium and Hypertension.	HHS–FDA	$4.4–$26.5 billion	$1.4–$2.3 billion plus $163 million in costs to Federal government.	HHS–FDA performed one analysis for the food labeling requirements imposed by this rule and the other 22 HHS–FDA rules in this table related to food labeling.
Food Labeling: Health Claims and Label Statements: Omega-3 Fatty Acids and Coronary Heart Disease.	HHS–FDA	$4.4–$26.5 billion	$1.4–$2.3 billion plus $163 million in costs to Federal government.	HHS–FDA performed one analysis for the food labeling requirements imposed by this rule and the other 22 HHS–FDA rules in this table related to food labeling.
Food Labeling: Health Claims and Label Statements, Dietary Fat and Cancer.	HHS–FDA	$4.4–$26.5 billion	$1.4–$2.3 billion plus $163 million in costs to Federal government.	HHS–FDA performed one analysis for the food labeling requirements imposed by this rule and the other 22 HHS–FDA rules in this table related to food labeling.
Food Labeling: Health Claims, Calcium and Osteoporosis.	HHS–FDA	$4.4–$26.5 billion	$1.4–$2.3 billion plus $163 million in costs to Federal government.	HHS–FDA performed one analysis for the food labeling requirements imposed by this rule and the other 22 HHS–FDA rules in this table related to food labeling.
Food Labeling: Health Claims and Label Statement, Antioxidant Vitamins and Cancer.	HHS–FDA	$4.4–$26.5 billion	$1.4–$2.3 billion plus $163 million in costs to Federal government.	HHS–FDA performed one analysis for the food labeling requirements imposed by this rule and the other 22 HHS–FDA rules in this table related to food labeling.

TABLE 9.—AGENCY ESTIMATES OF BENEFITS AND COSTS OF MAJOR RULES—Continued

[October 1, 1992 to September 30, 1993]

Rule	Agency	Benefits	Costs	Other information
Food Labeling: Health Claims and Label Statements, Dietary Saturated Fat and Cholesterol and Coronary Heart Disease.	HHS–FDA	$4.4–$26.5 billion	$1.4–$2.3 billion plus $163 million in costs to Federal government.	HHS–FDA performed one analysis for the food labeling requirements imposed by this rule and the other 22 HHS–FDA rules in this table related to food labeling.
Regulation Impact Analysis of the Final Rules to Amend the Food Labeling Regulations.	HHS–FDA	$4.4–$26.5 billion	$1.4–$2.3 billion plus $163 million in costs to Federal government.	HHS-FDA performed one analysis for the food labeling requirements imposed by this rule and the other 22 HHS-FDA rules in this table related to food labeling.
Food Labeling: Health Claims and Label Statements, Folic Acid and Neural Tube Defects.	HHS–FDA	$4.4–$26.5 billion	$1.4–$2.3 billion plus $163 million in costs to Federal government.	HHS–FDA performed one analysis for the food labeling requirements imposed by this rule and the other 22 HHS–FDA rules in this table related to food labeling.
Food Labeling: Health Claims and Label Statements, Dietary Fiber and Cardiovascular Disease.	HHS–FDA	$4.4–$26.5 billion	$1.4–$2.3 billion plus $163 million in costs to Federal government.	HHS-FDA performed one analysis for the food labeling requirements imposed by this rule and the other 22 HHS-FDA rules in this table related to food labeling.
Food Labeling: Health Claims and Label Statements, Dietary Fiber and Cancer.	HHS–FDA	$4.4–$26.5 billion	$1.4–$2.3 billion plus $163 million in costs to Federal government.	HHS-FDA performed one analysis for the food labeling requirements imposed by this rule and the other 22 HHS-FDA rules in this table related to food labeling.
Food Labeling, General Requirements for Health Claims for Food.	HHS–FDA	$4.4–$26.5 billion	$1.4–$2.3 billion plus $163 million in costs to Federal government.	HHS-FDA performed one analysis for the food labeling requirements imposed by this rule and the other 22 HHS-FDA rules in this table related to food labeling.
Food Labeling, Mandatory Status of Nutrition Labeling and Nutrient Content Revision, Form for Nutrition Label.	HHS–FDA	$4.4–$26.5 billion	$1.4–$2.3 billion plus $163 million in costs to Federal government.	HHS-FDA performed one analysis for the food labeling requirements imposed by this rule and the other 22 HHS-FDA rules in this table related to food labeling.
Food Labeling, Nutrient Content Claims, General Principles, Petitions, Definition of Terms, Definitions of Nutrient Content Claims for the Fat, Fatty Acid, and Cholesterol.	HHS–FDA	$4.4–$26.5 billion	$1.4–$2.3 billion plus $163 million in costs to Federal government.	HHS-FDA performed one analysis for the food labeling requirements imposed by this rule and the other 22 HHS-FDA rules in this table related to food labeling.
Food Labeling Regulation Implementing the Nutrition Labeling and Education Act of 1990, Opportunity for Comments.	HHS–FDA	$4.4–$26.5 billion	$1.4–$2.3 billion plus $163 million in costs to Federal government.	HHS-FDA performed one analysis for the food labeling requirements imposed by this rule and the other 22 HHS-FDA rules in this table related to food labeling.
Food Labeling—Metric Labeling Requirements.	HHS–FDA	$4.4–$26.5 billion	$1.4–$2.3 billion plus $163 million in costs to Federal government.	HHS-FDA performed one analysis for the food labeling requirements imposed by this rule and the other 22 HHS-FDA rules in this table related to food labeling.
Real Estate Settlement Procedures Act (Regulation X), FR–1942.	HUD	$119,014,950 annually in greater competition in title insurance business; $89.1–148.5 million net benefit annually in reducing transaction costs by packaging services with affiliated services.	Cost of duplicate good-faith estimates: $56,824,627 per year; Cost of new disclosure for controlled business arrangements: $48,147,000 per year; Cost of computerized loan originations: $3,607,890 per year; Cost of two additional years for storage (discount rate = 6%): $24,305.	
Manufactured Housing Construction and Safety Standards.	HUD	Net Benefit: $300 million per year present value in energy savings; $50–160 million per year present value in reduced NO_X, SO_X, and PM emission.		

TABLE 9.—AGENCY ESTIMATES OF BENEFITS AND COSTS OF MAJOR RULES—Continued

[October 1, 1992 to September 30, 1993]

Rule	Agency	Benefits	Costs	Other information
Final frameworks for early-season migratory bird hunting regulations.	DOI	Not Estimated	Not Estimated.	
Migratory bird hunting, final frameworks for late-season migratory bird hunting regulations.	DOI	Not Estimated	Not Estimated.	
The Family and Medical Leave Act of 1993.	DOL-ESA	Not Estimated	$674 million annually	Estimate provided by U.S. General Accounting Office (Parental Leave: Estimated Costs of H.R. 925, the Family and Medical Leave Act of 1987—GAO/HRD–88–34, Nov. 10, 1987).
Permit Required Confined Spaces.	DOL–OSHA	Reduced annually: 54 fatalities; 5,931 lost-workday injury and illness cases; 5,908 non-lost-workday cases.	$202.4 million annually	''OSHA anticipates that improved worker productivity as a result of the standard will help to lower production costs and contribute to higher quality output. Although OSHA did not quantify these cost offsets, the Agency believes they will be substantial'' (RIA, pp. I–10, I–13). ''OSHA anticipates that greater use of mechanical ventilation to reduce atmospheric hazard in permit spaces may result in additional release of hazardous substances to the air. Incremental release quantities related to the permit space standard are not determinable at present, but are expected to be minor relative to current overall releases'' (RIA, pp. I–17—I–18).
Lead Exposure in Construction.	DOL–OSHA	Near-term avoided annual health effects; Reduced nerve conduction velocity: 16,199–22,831 cases; Reduced blood ALA–D levels: 130,056–164,044 cases; Increased urinary ALA: 60,389–78,676 cases; Gastrointestinal disturbances: 1,135–4,413 cases; Detected blood-lead levels above MRP trigger: 24,262–35,163 cases. Long-term avoided health effects over 10 years; Fatal/nonfatal infractions: 2,164–2,322 cases; Fatal/nonfatal stroke: 644–698 cases; Renal disease: 1,258–2,157 cases.	$365–445 million annually plus one-time start-up costs of $150–$183 million.	
Response Plans for Marine Transportation-Related Facilities.	DOT-USCG	58,838 barrels of oil not spilled (NPV).	$176,105,666 (NPV)	Timeline of the analysis: 1996–2025 Discount Rate: 7%; $1996.
Vessel Response Plans ...	DOT–USCG	50,312 barrels of oil not spilled (NPV).	$3,245,869,985 (NPV)	Timeline of the analysis: 1996–2025 Discount Rate: 7%; $1996.
Light Truck Average Fuel Economy Standard for Model Year 1995.	DOT	Not Estimated	Not Estimated.	

TABLE 9.—AGENCY ESTIMATES OF BENEFITS AND COSTS OF MAJOR RULES—Continued

[October 1, 1992 to September 30, 1993]

Rule	Agency	Benefits	Costs	Other information
Water quality standards regulation: Compliance with CWA Section 303(C)(2)(B) Amendments.	EPA	Not Estimated	Not Estimated	''The analysis performed was limited to assessing only the potential reduction in cancer risk; no assessment of potential reductions in risks due to reproductive, developmental, or other chronic and subchronic toxic effects was conducted. However, given the number of pollutants, there could be: (1) Decreased incidence of systemic toxicity to vital organs such as liver and kidney; (2) decreased extent of learning disability and intellectual impairment due to the exposure to such pollutants as lead; and (3) decreased risk of adverse reproductive effects and genotoxity.'' (57 FR 60848–). ''The ecological benefits that can be expected from today's rule include protection of both fresh and salt water organisms, as well as wildlife that consume aquatic organisms * * * In addition, the rule would result in the propagation and productivity of fish and other organisms, maintaining fisheries for both commercial and recreational purposes. Recreational activities such as boating, water skiing, and swimming would also be preserved along with the maintenance of an aesthetically pleasing environment'' (57 FR 60848–). ''EPA acknowledges that there will be a cost to some dischargers for complying with new water quality standards as those standards are translated into specific NPDES permit limits * * * Revised wasteload allocations may result in adjustments to individual NPDES permit limits for point source dischargers, and these adjustments could result in increased wastewater treatment costs or other pollution control activities such as recycling or process changes. The magnitude of these costs depends on the types of treatment or other pollution control, the number and type of pollutants being treated, and the level of control that can be achieved by technology-based effluent limits for each industry. Similar sources of costs and the variables affecting costs may also apply to indirect industrial dischargers to the extent that the industrial discharger is a source of toxic pollutants discharged by the POTW * * * Nonpoint sources of toxic pollutants may also incur increased costs to the extent that best management practices need to be modified or applied to more sources to reflect the revised water quality standards. Although there is no Federal permit program for nonpoint sources comparable to that for point sources, there are State regulatory programs to control nonpoint source discharges. Monitoring programs are another source of potential incremental costs to dischargers and States.'' (57 FR 60848–).

TABLE 9.—AGENCY ESTIMATES OF BENEFITS AND COSTS OF MAJOR RULES—Continued

[October 1, 1992 to September 30, 1993]

Rule	Agency	Benefits	Costs	Other information
Coastal nonpoint pollution control program development and approval guidance (EPA, NOAA), guidance specifying management measures for sources of nonpoint * * * Section 6217.	EPA	Not Estimated	$389,940,000–$590,640,000 (annualized).	The RIA identified generally the types of ''off-site benefits'' that could be related to water quality improvements, including 4 use benefits (in-stream, near stream, option value, and diversionary) and 3 non-use (intrinsic) benefits (aesthetic, bequest, and existence).
Oil and Gas Extraction Point Source Category, Offshore Subcategory, Effluent Limitations Guidelines and New Source Performance Standards (Final Rule).	EPA	$28.2–103.9 million per year.	Total annualized BAT and NSPS costs: 1st year = $122 million, 15th year = $32 million.	''Other benefits that are quantified, to the extent possible, but not monetized due to lack of appropriate data, include: (1) Human health risk reductions associated with systemics other than lead, pH-dependent leach rates, carcinogens for which there are no risk factors available, exposure to pollutants via sediment or food chair; (2) ecological risk reductions; (3) fishery benefits; and (4) intrinsic benefits * * * The non-quantified, non-monetized benefits assessed in this RIA include increased recreational fishing, increased commercial fishing, improved aesthetic quality of waters near the platform, and benefits to threatened or endangered species [the Kemp's Ridley Turtle and the Brown Pelican] in the Gulf of Mexico.'' (58 FR 12454–).
Acid Rain Permits, Allowance System, Emissions Monitoring, Excess Emissions and Appeals Regulations Under Title IV of the Clean Air Act Amendments of 1990.	EPA	10 million tons/year reduction in SO_2 emission (mandated by Title IV); Cost savings: $689–973 million (annualized).	$894–1,509 million (annualized).	SO_2 emission reductions are expected to: (1) reduce acidification of surface waters, thereby increasing the presence and diversity of aquatic species; (2) improve visibility by reducing haze; (3) may improve human health as lower SO_2 emissions reduce air concentrations of acid sulfate aerosols and thus acute and chronic exposure to the acid aerosols that adversely affect human health may even affect even mortality; (4) eliminate damage to forest soils and foliage, especially of high-elevation spruce trees in the eastern U.S. and allow recovery of previously damaged tree populations; (5) may reduce damage to auto paint, reduce soiling of buildings and monuments, and thus the life of some materials and structures may be extended and the costs of maintenance or repair reduced (RIA, pp. 1–5 to 1–6, and 6–1 to 6–3). Engineering costs associated with CEM retrofit were not analyzed (RIA, pp. 4–18). ''The annualized costs of the implementation regulations are estimated to increase the annual costs of generating electricity by 0.5 to 1.2 percent.'' (58 FR 3590–).

TABLE 9.—AGENCY ESTIMATES OF BENEFITS AND COSTS OF MAJOR RULES—Continued

[October 1, 1992 to September 30, 1993]

Rule	Agency	Benefits	Costs	Other information
Vehicle Inspection and Maintenance Requirements for State Implementation Plan (Final Rule).	EPA	Emission reductions from continuing current I/M program unchanged (baseline = no I/M program) in 2000: 116016 tons VOC, 1566395 tons CO (annual tons in 2000); Emission reductions from new I/M program in 2000 (baseline = no I/M program): 420415 tons VOC, 2845754 tons CO (annual tons in 2000).	Continuing current I/M program: NET COST = $894 million ($2000); New I/M program: NET COST = $541 million ($2000).	''These repairs have been found to produce fuel economy benefits that will at least partially offset the cost of repairs. Fuel economy improvements of 6.1% for repair of pressure test failures and 5.7% for repair of purge test failures were observed. Vehicles that failed the transient short test at the established cutpoints were found to enjoy a fuel economy improvement of 12.6% as a result of repairs.'' (57 FR 52950–). ''In conclusion, today's action may cause significant shifts in business opportunities. Small businesses that currently do both inspections and repairs in decentralized I/M programs may have to choose between the two. Significant new opportunities will exist in these areas for small businesses to continue to participate in the inspection and repair industry. This will mean shifts in jobs but an overall increase in jobs in the repair sector and a small to potentially large increase in the inspection sector, depending on state choices.'' (57 FR 52950–).
Evaporative emission regulations for gasoline-fueled and methanol-fueled light duty vehicles, light-duty trucks, and heavy-duty vehicles—SAN 2969.	EPA	Total VOC Reduction in 2020: 1,120,000 metric tons.	Annual total program cost without fuel savings: $130–200 million ($1992, NPV to the year of the sale).	''[Emission] projections are made for the year 2020 in order to provide benefit predictions for a fully turned-over fleet and to factor in other known trends, such as the effects of other new Clean Air Act programs. These new programs include high-technology inspection and maintenance and reformulated gasoline. Reformulated gasoline achieving a 25 percent overall VOC emission reduction standard is assumed to be used in 40 percent of the nation.'' (58 FR 16002–). ''[The cost] estimate does not include the offsetting fuel savings.'' (58 FR 16002–).
Control of air pollution from new motor vehicles and new motor vehicle engines, regulations requiring on-board diagnostic systems on 1994 and later model year light-duty vehicles.	EPA	4.0 million tons HC, 30.8 million tons CO, 2.5 million tons NO_X (NPV).	$16.6 billion (NPV) ($1993).	Discount rate: 7% (58 FR 9468–) Timeline: 2005–2020 (58 FR 9468–).''EPA has not been able to adequately quantify some potential cost savings not included in these estimates. Potential cost savings can accrue due to early repairs of malfunction which, if left undetected and unrepaired, could result in the need for even more costly repairs in the future. Also, improved repair effectiveness should reduce the potential for a part to be unnecessarily replaced in attempting to fix a problem. Repair facilities should also benefit from the availability of generic tools for accessing and using the OBD system in problem diagnosis and repair. These service facility benefits could be passed along to the consumer in the form of lower repair costs.'' (58 FR 9468–).

TABLE 10.—AGENCY ESTIMATES OF BENEFITS AND COSTS OF MAJOR RULES

[October 1, 1993 to September 30, 1994]

Rule	Agency	Benefits	Costs	Other information
Manufactured Home Construction and Safety Standards on Wind Standards.	HUD	$63,726,314 annually ...	$412,106,180 annually	The cost estimates do not include costs associated with ''out of pocket expenses related to deductibles or non-covered losses'' (RIA, pp. 1–2). Non-quantified benefits include: ''purchasers will experience less dislocation caused by damage to or destruction of their manufactured homes. Fourth, residents who choose to remain in their units during storms will suffer fewer injuries and deaths'' (RIA, p. 1) Discount rate used = 6.64 percent (RIA, p. 8) Basis for public benefit assessment: Hurricane Andrew (RIA, p. 9).
Designate critical habitat for four endangered Colorado River fishes.	DOI	Net benefit: $7.92 million.	.....	Increase employment by 710 jobs, increase earnings by $6.62 million, increase government revenue by $3.20 million from 1995–2020 (59 FR 13374–).
Occupational Exposure to Asbestos.	DOL–OSHA	Reduction in annual cancer risk: 2.12 cancer deaths in general industry, 40.48 cancer deaths in construction industry, 14.2 cancers among building occupants. Reduction in asbestosis: 14 cases annually.	$361.4 million annually	Non-quantified benefits include: avoided cases of asbestosis for building occupants and others secondarily exposed, reduced risks of cancer and fires (from rages contaminated with solvent), more rapid building reoccupation, reduced probability of asbestos-related lawsuits (RIA, pp 52–57).
Financial Responsibility for Water Pollution (Vessels).	DOT–USCG	525,316 barrels of oil not spilled (NPV).	$451,440,918 (NPV)	Timeline of the analysis: 1996–2025; Discount Rate: 7%; $1996.
Antidrug Program for Personnel Engaged in Specified Aviation Activities.	DOT–FAA	$206.64 million (NPV) ..	$138.13 million (NPV) ..	Timeline of the analysis: 1994–2003 (RIA, p. 12); $1992 (RIA, p. 12); Discount rate = 7% (RIA, p. 20).
Controlled Substances and Alcohol Use and Testing.	DOT–FHWA	Reduced fatal accidents: $680 million in 1st year, $952 million per year in 2nd and subsequent years. Reduced injury cost: $152.4 million in 1st year, $213.4 million per year in 2nd and subsequent years assuming the highest deterrence scenario. Reduced property damage: $47.5 million in 1993, $66.5 million per year from 1994–2002. Reduced traffic delays: $3.5 million in 1993, $4.9 million per year thereafter assuming highest deterrence rate; Reduced other costs of freeway accidents: $1.9 million in 1995 and $2.7 million thereafter.	$93,947,750 in 1995, and $92,453,950 per year in 1996 and thereafter.	
Light Truck Average Fuel Economy standards, Model Years 1996–1997.	DOT	Not Estimated	Not Estimated.	
Prevention of Prohibited Drug Use in Transit Operations.	DOT	$608,520,643 (NPV)	$208,970,087 (NPV)	Timeline: 1995–2004; Discount rate: 7%; $1991.

TABLE 10.—AGENCY ESTIMATES OF BENEFITS AND COSTS OF MAJOR RULES—Continued

[October 1, 1993 to September 30, 1994]

Rule	Agency	Benefits	Costs	Other information
Land disposal restrictions phase II, universal treatment standards and treatment standards for organic toxicity, characteristic wastes, and newly listed wastes.	EPA	0.22 cancer cases per year avoided from groundwater, 0.037 cancer cases per year avoided from air; $20 million avoided property value damage (annualized).	$194–219 million (annualized).	''The timeframe to which these benefits are attributable begins 30 years following promulgation of the rule.'' (59 FR 47982–). ''However, there are some benefits which the Agency has not attempted to quantify which are potentially attributable to today's rule. For example, the agency has not attempted to quantify any potential non-use-value benefits from protection of resources through treatment of hazardous wastes. Furthermore, the risk analysis performed by the Agency for today's rule does not account for many other potential benefits from today's rule. Ecological risk reduction from treatment of wastes under today's rule has not been quantified. Nor do the Agency's air and groundwater benefit estimates account for karst terrain, complex flow situations, or other factors which could contribute to underestimates of benefits.'' (59 FR 47982–).
Accelerated phase-out of ozone depleting chemicals and listing and phase-out of methyl bromide.	EPA	Ozone depleting chemicals: $8–24 billion (NPV) Methyl Bromide: $1.6–6.4 billion (NPV).	Ozone depleting chemicals: $12 billion (NPV); Methyl Bromide: $0.8 billion (NPV).	Discount rate: 7% (58 FR 65018–). Timeline for methyl bromide cost: 1994–2010 (58 FR 65018–). Timeline for methyl bromide benefits: 1994–2001 (58 FR 65018–).
Fuel and fuel additives: standards for reformulated gasoline.	EPA	Phase I—Summertime VOC emission reduction: 90–140 thousand tons per year; Reduction in cancer incidence: 16 per year (assuming enhanced I/M in place) or 24 per year (assuming basic I/M in place). Phase II—(incremental to Phase I): Summertime VOC emission reduction: approximately 42,000 tons Summer time NO_x emission reduction: approximately 22,000 tons Number of cancer avoided: 3–4 fewer cancer incidence per year.	Phase I—Annual costs: $700–940 million. Phase II—(incremental to Phase I): Increase gasoline production cost by 1.2 cents/gallon during the VOC control period, since only the toxics standard changes, and there is not expected to be a cost for year-round toxics control above that required for Phase I; EPA doesn't expect non-production related costs, such as distribution costs, recordkeeping and reporting costs, etc., to increase isgnificantly relative to Phase I.	''Reductions in mobile source emissions of the air toxics addressed in the reformulated gasoline program (benzene, 1,3-butadiene, formaldehyde, acetaldehyde and POM) may result in fewer cancer incidences. A number of adverse noncancer health effects have also been associated with exposures experience in particular microenvironments such as parking garages and refueling stations. These other health effects include blood disorders, heart and lung diseases, and eye, nose and throat irritation. Some of the toxics may also be developmental and reproductive toxicants, while very high exposure can cause effects on the brain leading to respiratory paralysis and even death. The uses of reformulated gasoline meeting the Phase II standards will likely help to reduce some of these health effects as well.'' (59 FR 7716–). Phase I: The cost of producing reformulated gasoline is expected to increase by approximately 3–5 cents per gallon in 1995. (59 FR 7716–). The cost of testing, enforcement, and recordkeeping not reflected in the annual cost estimate. (59 FR 7716–).

TABLE 10.—AGENCY ESTIMATES OF BENEFITS AND COSTS OF MAJOR RULES—Continued

[October 1, 1993 to September 30, 1994]

Rule	Agency	Benefits	Costs	Other information
Acid Rain NO_X Regulations under Title IV of the Clean Air Act Amendments of 1990.	EPA	Phase I: 400,000 tons NO_X reduced Phase II: 1.89 million tons NO_X reduced.	Phase I: $77 million/year Phase II: $300 million/year.	Qualitative human health benefits: Lower ambient levels of NO_X (and associated lower PM and lower ozone levels) may mean fewer lost school days, fewer disability days for children; for all, less eye irritation and its associated acute and chronic health effects; for exercising asthmatics, improved pulmonary function. Also ambient concentrations of nitrates will be lower and fewer toxic nitrogenous compounds will be formed. (RIA, pp. 9–1 to 9–4) Qualitative welfare effects: reduced materials damage, increased visibility that is associated with enhanced enjoyment of vistas and fewer aircraft and motor vehicle accidents. The potential ecological effect include minimizing the adverse effects of excess nitrogen deposition in forest soils and surface waters, including the ''acid pulses'' that precede fish kills and consequently, reduced biodiversity. (RIA, pp. 9–1 to 9–4) ''Moreover, EPA expects that most or all utility expenses from meeting NO_X requirements will be passed along to ratepayers * * * Under today's rule the cost to ratepayers is very small, relative to their current expenditures on electricity. The average increase in electric rates across the United States is estimated to be only 0.03 and 0.13 percent under Phases I and II respectively.'' (59 FR 13538–).
Hazardous Organic NESHAP (HON) for the Synthetic Organic Chemical Manufacturing Industry (SOCMI) and Other Processes Subject to the Negotiated Regulation for Equipment Leaks.	EPA	HAP reduction: 510,000 tons/year; VOC reduction: 1,000,000 tons/year.	Total nationwide annual cost: $230 million/year ($1989); CO emission increase: 1,900 tons/year; NO_x emission increase: 19,000 tons/year.	''Thus, the estimates represent annual impacts occurring in the fifth year.'' (59 FR 19402–). ''As discussed in section III.B.3 of this preamble, the EPA has deferred the final decision regarding control of medium-sized storage vessels at existing sources. Therefore, emission reductions for storage vessels shown in Table 1, and consequently the total, may be slightly overstated.'' (59 FR 19402–). ''Because of the EPA's deferral of a final decision on control of medium-sized storage vessels at existing sources, as discussed in section III.B.3 of this preamble, the cost impacts for storage vessels, and consequently the total cost impact, may be slightly overstated.'' (59 FR 19402–). ''Market analyses for a subset of 21 of the chemicals estimated price increases from 0.1 percent to 3.9 percent and quantity decreases from 0.1 percent to 4 percent.'' (59 FR 19402–).
Control of air pollution from new motor vehicles and new motor vehicle engines, refueling emission regulations for light-duty vehicles and trucks and heavy-duty vehicles.	EPA	Without Stage II controls, average VOC annual emission reductions: over 420,000 tons per year; With Stage II phase-out when ORVR and Stage II would cover the same percent of fuel, average annual emission reduction: 378,000 tons; If retain Stage H controls, an incremental emission reduction: 285,000 tons.	Without Stage II controls, the average annual cost: −$6 million (1998–2020); With Stage II and phasing out at 2010, the average annual cost: $2 million (1998–2020); With Stage II and no phase out, the average annual cost: $27 million (1998–2020); In 1998 NPV, costs are $102 million, $264 million and $435 million respectively.	''It should be noted that the RIA was completed prior to EPA's decision to delay the requirements for LDTs and to exclude HDVs. These controls were included in the analysis and were assumed to begin in 1998. EPA expects that inclusion of these items in the analysis has no significant effect on the results and does not affect the conclusions which are based on the analysis.'' (59 FR 16262–). ''In the cases where costs are negative, it is because the value of the recovery credits exceeds the hardware and R, D, & T costs.'' (59 FR 16262–).

TABLE 10.—AGENCY ESTIMATES OF BENEFITS AND COSTS OF MAJOR RULES—Continued

[October 1, 1993 to September 30, 1994]

Rule	Agency	Benefits	Costs	Other information
Determination of significance for nonroad sources and emission standards for new nonroad compression ignition engines at or above 37 kilowatts, control of air pollution * * *—SAN 3112.	EPA	NO_X annual reduction in 2010: 800,000 tons; NO_x annual reduction in 2025: over 1,200,000 tons.	Average annual cost: $29–70 million (59 FR 31306).	''EPA maintains that the impact of this rule on fleet average fuel consumption will be minimal.'' (59 FR 31306–).

TABLE 11.—AGENCY ESTIMATES OF BENEFITS AND COSTS OF MAJOR RULES

Rule	Agency	Benefits	Costs	Other information
The Family and Medical Leave Act of 1993.	DOL–ESA	Not Estimated	$674 million annually	Estimate provided by U.S. General Accounting Office (Parental Leave: Estimated Costs of H.R. 925, the Family and Medical Leave Act of 1987—GAO/HRD–88–34, Nov. 10, 1987).
Double Hull Standards for Vessels Carring Oil in bulk.	DOT–USCG	94,172 barrels of oil not spilled (NPV).	$6,413,027,637 (NPV)	Timeline of the analysis: 1996–2025.
FMVSS: Stablity and Control of Medium and Heavy Vehicles During Braking.	DOT–NHTSA	Equivalent fatalities forgone: 415–683 per year; Forgone property damage: $327–394.9 million annually.	Total consumer cost = $560.5 million annually.	Discount rate: 7%.
Bay/Delta water quality standards.	EPA	$2.1–21.5 million annually in economic benefits to commercial and recretional fisheries and have associated employment gains of an estimated 145–1585 full-time equivalent jobs annually (RIA ES–7).	For the urban sector, $4.3 million/yr on average and $15.8 million/yr during dry years; $28.3 million/yr on average gains $165.3 million/yr during dry years without water transfers or waterbanks. For agriculture sector, $27 million/yr on average, $43 million/year in the driest 10% of years (RIA ES–5) If using sharing approach (spread water supply impacts to entities diverting water from the Sacramento and San Joaquin River systems), −$0.5 million/yr average years, −$5.5 million/yr for dry years for agricultural sector, −$10.5 million/yr for average years and −$54 million/yr for day years (RIA ES–6).	''Important benefits of the water quality regulations include the following: Biological productivity and health for many estuarine species are expected to increase. The decline of species is expected to be reversed and the existence of species unique to the Bay/Delta, such as Delta smelt, winter-run Chinook salmon, long fin smelt, and Sacramento splittail, will be protected. Populations of a variety of estuarine species are expected to increase; although the extent of the population increases has not been determined for all species, the increases are anticipated to benefit the recreational and commercial fisheries.'' (60 FR 4703–)

TABLE 11.—AGENCY ESTIMATES OF BENEFITS AND COSTS OF MAJOR RULES—Continued

Rule	Agency	Benefits	Costs	Other information
Water quality guidance for Great Lakes system.	EPA	Given the site-specific nature of water quality benefits and the unavailability of site-specific data across the Great Lakes Basin, only case study monetized benefits are estimated in the RIA. Average monetized benefits across the three case studies evaluated are $0.3 million per year to $6.2 million per year, with a midpoint of $2.9 million per year (in 1996 dollars); average annual costs across case studies are also $2.8 million per year (1996 dollars)..	$64.0–394.6 million ($1996, annualized).	''The benefit analysis is based on a case study approach, suing benefits transfer applied sources to three case studies . . . The case studies include: (1) the lower Fox River drainage, including Green Bay, located on Lake Michigan in northeastern Wisconsin; (2) the Saginaw River and Saginaw Bay, located on Lake Huron in Northeastern Michigan; and (3) the Black River, located on Lake Erie in north-central Ohio . . . EPA did attempt to calculate longer-term benefits to human health, wildlife, and aquatic life once the final Guidance provisions are fully implemented by nonpoint sources as well as point sources and the minimum protection levels are attained in the ambient water.'' (60 FR 15382). ''The three case studies combine to account for nearly 14 percent of the total cost of the final Guidance, nearly 17 percent of the loadings reductions, and from four percent to 10 percent of the benefits proxies (i.e.,. basin-wide population, recreational angling, nonconsumptive recreation, and commercial fishery harvest.'' (60 FR 15382). ''In addition to the cost estimates described above, EPA estimated the cost to comply with requirements consistent with the antidegradation provisions of the final Guidance. This potential future cost is expressed as a 'lost opportunity' cost for facilities impacted by the antigradation requirements. This cost could result in the addition of about $22 million each year.'' (60 FR 15381).
Interim Requirements for Deposit Control Gasoline Additives, Regulations of Fuels and Fuel Additives.	EPA	HC, CO and NO_X reduction during the 18-month interim period: 700,000 tons (59 FR 54678–); HC, CO and NO_X reduction after the interim period: 600,000 tons per year (59 FR 54678–) Fuel economy savings: 390 million gallons in 1995–2000 (59 FR 54678–).	$650 million (NPV, discount rate = 7%, 1995–2000 (59 FR 54678–)).	

Appendix C. OMB Draft Guidelines for the Conduct of Regulatory Analysis and the Format of Accounting Statements

Preface

This Circular provides OMB's guidance to federal agencies on the development of regulatory analysis as required under Executive Order No. 12866 and a variety of related authorities. The Circular also provides guidance to agencies on the regulatory accounting statements that are required under the Regulatory Right-to-Know Act.

This draft Circular refines OMB's ''best practices'' document of 1996 *http://www.whitehouse.gov/omb/inforeg/riaguide.html,* which was issued as a guidance in 2000 *http://www.whitehouse.gov/omb/memoranda/m00–08.pdf,* and reaffirmed in 2001 *http://www.whitehouse.gov/omb/memoranda/m01–23.html.* It will replace both the 1996 ''best practices'' and the 2000 guidance. Before issuing the Circular, this draft will go through a process of peer review, public comment and interagency review.

Introduction

These guidelines are designed to help analysts in the regulatory agencies by encouraging good regulatory impact analysis—called either ''regulatory analysis'' or ''analysis'' for brevity—and standardizing the way benefits and costs of Federal regulatory actions are measured and reported.

Why Analysis of Proposed[16] Regulatory Actions Is Needed

Regulatory analysis is a tool regulatory agencies use to anticipate and evaluate the likely consequences of their actions. It provides a formal way of organizing the evidence on the key effects—good and bad—of the various alternatives that should be considered in developing regulations. The motivation is to (1) learn if the benefits of an action are likely to justify the costs or (2) discover which of various possible alternatives would be the most cost-effective. By choosing actions that maximize net

[16] We use the term ''proposed'' to refer to any regulatory actions under consideration regardless of the stage of the regulatory process.

benefits, agencies direct resources to their most efficient use.

A good regulatory analysis informs the public and other parts of the Government as well as the agency conducting the analysis of the effects of alternative actions. Regulatory analysis will sometimes show that a proposed action is misguided, but it can also demonstrate that well-conceived actions are reasonable and justified.

Where all significant benefits and costs can be quantified and expressed in monetary units, benefit-cost analysis provides decisionmakers with a clear indication of the most efficient alternative, that is, the alternative that generates the largest net benefits to society ignoring distributional effects. This is useful information for the public to receive, even when economic efficiency is not the only or the overriding public policy objective.

It will not always be possible to assign monetary values to all of the important benefits and costs, and when it is not, the most efficient alternative will not necessarily be the one with the largest net-benefit estimate. In such cases, you should exercise professional judgment in determining how important the non-quantifiable benefits or costs may be in tipping the analysis one way or the other, but you should not use non-quantifiables as ''trump cards,'' especially in cases where the measured net benefits overwhelmingly favor a particular alternative. When there are other competing public policy objectives, as there often are, they must be balanced with efficiency objectives.

What Should Go Into a Regulatory Analysis?

A good regulatory analysis should include the following three basic elements:

(1) A statement of the need for the proposed action.

(2) An examination of alternative approaches.

(3) An evaluation of the benefits and costs of the proposed action and the main alternatives identified by the analysis.

To properly evaluate the benefits and costs of regulations and their alternatives, you will need to do the following:

- Explain how the actions required by the rule are linked to the expected benefits. For example, indicate how additional safety equipment will reduce safety risks. A similar analysis should be done for each of the alternatives.
- Identify a baseline. Benefits and costs are defined in comparison with a clearly stated alternative. This is normally a ''no action'' baseline, what the world would be like if the proposed rule was not adopted.
- Identify the expected undesirable side-effects and ancillary benefits of the proposed regulatory action and the alternatives. These should be added to the direct costs and benefits as appropriate.

With this information, you should be able to assess quantitatively the benefits and costs of the proposed rule and its alternatives. When your analysis is complete, you should present a summary of the benefit and cost estimates for each alternative, sometimes called a ''regulatory accounting statement,'' so that readers can evaluate them.

As you proceed through your regulatory analysis, you should seek out the opinions of those who will be directly affected by the regulation you are considering as well as the views of those individuals and organizations with special knowledge or insight into the regulatory issues. Consultation can be useful in making sure your analysis addresses all of the relevant issues and that you have access to all the pertinent data. Early consultation can be especially helpful. You should not limit consultation to the final stages of your analytical efforts.

A good analysis is transparent. It should be possible for anyone reading the report to see clearly how you arrived at your estimates and conclusions. For transparency's sake, you should state in your report what assumptions were used, such as the discount rates or the monetary value of a statistical life. It is usually helpful to provide a sensitivity analysis to reveal whether, and to what extent, the results of the analysis are influenced by plausible changes in the main assumptions.

You will find that you cannot conduct a good regulatory analysis according to a formula. The conduct of high-quality analysis requires competent professional judgment. Different regulations may call for different emphases in the analysis, depending on the nature and complexity of the regulatory issues and the sensitivity of the benefit and cost estimates to the key assumptions.

I. Why Regulatory Action is Needed

Before proceeding with a regulatory action, you must demonstrate that the proposed action is necessary. Executive Order 12866 states that ''Each agency shall identify the problem that it intends to address (including, where applicable, the failures of private markets or public institutions that warrant new agency action) as well as assess the significance of that problem.'' This means that you should try to explain whether the action is intended to address a significant market failure or to meet some other compelling public need such as improving governmental processes or promoting distributional fairness, privacy, or personal freedom. If you are trying to correct a significant market failure, the failure should be described both qualitatively and (where feasible) quantitatively, and you should show that a government intervention is likely to do more good than harm. For other interventions, you should also provide a demonstration of compelling social purpose and the likelihood of effective action.

If your regulatory intervention results from a statutory or judicial directive, you should describe the specific authority for your action, the extent of discretion available to you, and the regulatory instruments you might use.

A. There Is a Market Failure or Other Social Purpose To Address

The major types of market failure include: externality, market power, and inadequate or asymmetric information. Correcting market failures is a reason for regulation, but it is not the only reason. Other possible justifications include improving the functioning of government, removing distributional unfairness, or promoting privacy and personal freedom.

1. Externality

An externality occurs when one party's actions impose uncompensated benefits or costs on another. Environmental problems are a classic case of externality—for example, the smoke from a factory may adversely affect the health of local residents while soiling the property in nearby neighborhoods. Common property resources that may become congested or overused, such as fisheries or the broadcast spectrum, represent a second example. ''Public goods,'' such as defense or basic scientific research, provide a positive externality, where provision of the good to some individuals cannot occur without providing the same benefits free of charge to other individuals.

2. Market Power

Firms exercise market power when they reduce output below what would be offered in a competitive industry. They may exercise market power collectively or unilaterally. Government action can be a source of market power, for example, if regulatory actions exclude low-cost imports. Generally, regulations that increase market power should be avoided. However, there are some circumstances in which government may choose to validate a monopoly. If a market can be served at lowest cost only when production is limited to a single producer—local gas and electricity distribution services, for example—a natural monopoly is said to exist. In such cases, the government may choose to approve the monopoly and to regulate its prices and production decisions.

3. Inadequate or Asymmetric Information

Market failures may also result from inadequate or asymmetric information. The market will often supply less than the appropriate level of information because it is infeasible to exclude people from reaping the benefits from the information others have provided even though they have not paid for the information. The providers will not willingly supply the socially optimal quantity of information, unless they are paid for it, and that may not be possible.

Because information, like other goods, is costly, your evaluation will need to do more than demonstrate the possible existence of less than optimal or asymmetric information. Even though the market may supply a less than an optimal amount of information, the amount it does supply may be reasonably adequate and therefore not require government regulation. Sellers do have an incentive to provide information through advertising that can increase sales by highlighting distinctive characteristics of their products. Buyers may also obtain reasonably adequate information about product characteristics through other channels, for example, if a buyer's search costs are low (as when the quality of a good can be determined by inspection at the point of sale), if a buyer has previously used the product, if the seller offers a warranty, or if adequate information is provided by third parties.

In the case of uncertain information about low-probability high-consequence events,

markets may underreact or overreact depending on the rules-of-thumb and other mental assumptions that people use to cope with difficult issues. Regulators should be aware of such mental quirks and not adopt policies based on a misunderstanding of the underlying reality.

4. Other Social Purposes

There are justifications for regulations in addition to correcting market failures. A regulation may be appropriate when you have a clearly identified measure that can make government operate more efficiently. In other cases, regulation may be used to reduce unfairness. Regulatory action may also be appropriate to protect privacy or to promote civil rights or permit more personal freedom.

B. Showing That Regulation at the Federal Level Is the Best Way To Solve the Problem

Even where a market failure clearly exists, you should consider other means of dealing with the failure before turning to regulation. Alternatives to regulation include the courts acting through the product liability system, antitrust enforcement, consumer-initiated litigation, or workers' compensation systems.

In assessing whether Federal regulation is the best solution, you should also consider the possibility of regulation at the State or local level. In some cases, the nature of the market failure may itself suggest the most appropriate governmental level of regulation. For example, problems that spill across State lines (such as acid rain whose precursors are transported widely in the atmosphere) are probably best addressed by Federal regulation. More localized problems, including those that are common to many areas, may be more efficiently addressed locally.

A diversity of regulation may generate gains for the public as governmental units compete with each other to serve the public, but duplicative regulations can also be costly. Where Federal regulation is clearly appropriate, for example, to address interstate commerce issues, you should try to examine whether it would be more efficient to reduce State and local regulation. For example, the burdens on interstate commerce arising from different State and local regulations such as compliance costs for firms operating in several States, may exceed any advantages associated with the diversity of State and local regulation. Your analysis should consider the possibility of reducing as well as expanding State and local rulemaking.

The role of federal regulation in facilitating U.S. participation in global markets should also be considered. Harmonization of U.S. and international rules may require a strong Federal regulatory role. Concerns that new U.S. rules could act as non-tariff barriers to imported goods should be evaluated carefully.

C. The Presumption Against Economic Regulation

Government actions can be unintentionally harmful, and even useful regulations can impede the efficiency with which markets function. For this reason, there is a presumption against certain types of regulatory action. In light of both economic theory and actual experience, a particularly demanding burden of proof is required to demonstrate the need for any of the following types of regulations:

- Price controls in competitive markets;
- Production or sales quotas in competitive markets;
- Mandatory uniform quality standards for goods or services if the potential problem can be adequately dealt with through voluntary standards or by disclosing information of the hazard to buyers or users; or
- Controls on entry into employment or production, except (a) where indispensable to protect health and safety (*e.g.,* FAA tests for commercial pilots) or (b) to manage the use of common property resources (*e.g.,* fisheries, airwaves, Federal lands, and offshore areas).

II. Alternative Approaches To Consider

Once you have determined that Federal regulatory action is appropriate, you will need to consider alternative regulatory approaches. Ordinarily, it will be possible to eliminate some alternatives through a preliminary analysis, leaving a manageable number of alternatives to be evaluated according to the formal principles of the Executive Order. The number and choice of alternatives selected for detailed analysis is a matter of judgment. There must be some balance between thoroughness and the practical limits on your analytical capacity. With this qualification in mind, you should nevertheless explore modifications of some or all of a regulation's attributes or provisions to identify appropriate alternatives. The following is a list of alternative regulatory actions that you should consider:

A. Different Choices Defined by Statute

When a statute establishes a specific regulatory requirement and the agency plans to exercise its discretion to adopt a more stringent standard, you should examine the benefits and costs of reasonable alternatives that reflect the range of the agency's statutory discretion, including the specific statutory requirement.

B. Different Compliance Dates

The timing of a regulation may also have an important effect on its net benefits. For example, costs of a regulation may vary substantially with different compliance dates for an industry that requires a year or more to plan its production runs efficiently. In this instance, a regulation that provides sufficient lead time is likely to achieve its goals at a much lower overall cost than a regulation that is effective immediately, although delay would also typically lower the value of the benefits.

C. Different Enforcement Methods

Compliance alternatives for Federal, State, or local enforcement include on-site inspections, periodic reporting, and compliance penalties structured to provide the most appropriate incentives. When alternative monitoring and reporting methods vary in their costs and benefits, you should consider promising alternatives in identifying the most appropriate enforcement framework. For example, in some circumstances random monitoring or parametric monitoring will be less expensive and nearly as effective as continuous monitoring in achieving compliance.

D. Different Degrees of Stringency

In general, both the benefits and costs associated with a regulation will increase with the level of stringency (although marginal costs generally increase with stringency, whereas marginal benefits may decrease). You should study alternative levels of stringency to understand more fully the relationship between stringency and the size and distribution of benefits and costs among different groups.

E. Different Requirements for Different Sized Firms

You should consider setting different requirements for large and small firms basing any difference in the standards on perceptible differences in the costs of compliance or in the expected benefits. The balance of costs and benefits can shift depending on the size of the firms being regulated. Small firms may find it more costly to comply with regulation, especially if there are large fixed costs required for regulatory compliance. On the other hand, it is not efficient to place a heavier burden on one segment of a regulated industry solely because it can better afford the higher cost; this has the potential to load costs on the most productive firms, costs that are disproportionate to the damages they create.

You should also remember that a rule with a significant impact on a substantial number of small entities will trigger the requirements set forth in the Regulatory Flexibility Act.

F. Different Requirements for Different Geographic Regions

Rarely do all regions of the country benefit uniformly from government regulation and it is also unlikely that costs will be uniformly distributed across the country. Where there are significant regional variations in costs and/or benefits, you should consider the possibility of setting different requirements for the different regions.

G. Performance Standards Rather Than Design Standards

Performance standards are generally superior to engineering or design standards because performance standards give the regulated parties the flexibility to achieve regulatory objectives in the most cost-effective way. This is only possible, of course, if there is more than one feasible way to meet the performance standard. In general, you should consider setting a performance standard if performance can be measured or reasonably imputed and where controlling performance provides a scope appropriate to the problem the regulation seeks to address. For example, compliance with air emission standards can be allowed on a plant-wide, firm-wide, or region-wide basis rather than vent by vent, provided this does not produce unacceptable local air quality outcomes (such as ''hot spots'' from local pollution concentration).

H. Market-Oriented Approaches Rather Than Direct Controls

Market-oriented approaches that use economic incentives should be explored. These alternatives include fees, penalties, subsidies, marketable permits or offsets, changes in liability or property rights (including policies that alter the incentives of insurers and insured parties), and required bonds, insurance or warranties.

I. Informational Measures Rather Than Regulation

If intervention is contemplated to address a market failure that arises from inadequate or asymmetric information, informational remedies will often be the preferred approach. Measures to improve the availability of information include government establishment of a standardized testing and rating system (the use of which could be made mandatory or left voluntary), mandatory disclosure requirements (*e.g.*, by advertising, labeling, or enclosures), and government provision of information (*e.g.*, by government publications, telephone hotlines, or public interest broadcast announcements). A regulatory measure to improve the availability of information (particularly about the concealed characteristics of products) provides consumers a greater choice, than a mandatory product standard or ban.

Specific informational measures should be evaluated in terms of their benefits and with a comprehensive view of their costs. Some effects of informational measures are easily overlooked. For example, the costs of a mandatory disclosure requirement for a consumer product will include not only the cost of gathering and communicating the required information, but also the loss of net benefits of any information displaced by the mandated information, the effect of providing too much information that is ignored or information that is misinterpreted, and inefficiencies arising from the incentive that mandatory disclosure may give to overinvest in a particular characteristic of a product or service.

Where information on the benefits and costs of alternative informational measures is insufficient to provide a clear choice between them, you should consider the least intrusive informational alternative sufficient to accomplish the regulatory objective. For example, to correct an informational market failure it may be sufficient for government to establish a standardized testing and rating system without mandating its use, because competing firms that score well according to the system should thereby have an incentive to publicize the fact.

III. Analytical Approaches

Both benefit-cost analysis (BCA) and cost-effectiveness analysis (CEA) provide a systematic framework for identifying and evaluating the likely outcomes of alternative regulatory choices. A major rulemaking should be supported by both types of analysis wherever possible. Specifically, you should prepare a CEA for all major rulemakings for which the primary benefits are improved public health and safety. You should also perform a BCA for major health and safety rulemakings to the extent that valid monetary values can be assigned to the expected health and safety outcomes. For all other major rulemakings, you should carry out a BCA. If some of the primary benefit categories cannot be expressed in monetary units, you should also conduct a CEA.

A. Benefit-Cost Analysis

The distinctive feature of BCA is that both benefits and costs are expressed in monetary units, which allows you to evaluate different regulatory options with a variety of attributes using a common measure. This can be especially helpful in choosing the appropriate scope for your regulatory intervention. By measuring incremental benefits and costs of successively more stringent regulatory alternatives, you can identify the alternative that maximizes societal net benefits.

The size of net benefits, the absolute difference between total benefits and total costs, is the key to determining whether one policy is more efficient than another. That will be achieved at the point where the cost of a marginal increment in regulatory stringency is just matched by the marginal benefit. The ratio of total benefits to total costs is not a meaningful indicator of net benefits and should not be used for that purpose. It is well known that considering such ratios alone can yield misleading results.

Even when a benefit or cost cannot be expressed in monetary units, you should still try to measure it in terms of its physical units, and if it is not possible to measure the physical units, you should still describe the benefit or cost qualitatively. When important benefits and costs cannot be expressed in monetary units, BCA is less useful, and it can even be misleading, because the calculation of net benefits in such cases does not provide a full evaluation of all relevant benefits and costs.

You should exercise professional judgment in identifying the importance of non-quantifiable factors, where they exist, and assess as best you can how they might change the ranking of alternatives based on estimated net benefits. Non-quantifiable benefits or costs may be important in tipping an analysis one way or the other, but you should not use non-quantifiables as ''trump cards,'' especially in cases where the measured net benefits overwhelmingly favor a particular alternative.

B. Cost-Effectiveness Analysis (CEA)

Cost-effectiveness analysis provides a rigorous way to identify options that achieve the most effective use of the resources available without requiring you to monetize all of the relevant benefits or costs. Generally, cost-effectiveness analysis is most helpful for comparing a set of regulatory actions with the same primary outcome (*e.g.*, an increase in the acres of wetlands protected) or multiple outcomes that can be integrated into a single numerical index (*e.g.*, units of health improvement).

Cost-effectiveness results based on averages need to be treated with great care. They suffer from the same drawbacks as benefit-cost ratios. The alternative that exhibits the smallest cost-effectiveness ratio may not be the one that maximizes net benefits, just as the alternative with the highest benefit-cost ratio is not always the one that maximizes net benefits. Incremental cost-effectiveness analysis (discussed below) can help to avoid mistakes that can occur when policy choices are based on average cost-effectiveness.

CEA can also be misleading when the ''effectiveness'' measure does not weight appropriately the consequences of each of the alternatives. For example, when effectiveness is measured in tons of reduced pollutant emissions, cost-effectiveness estimates will be misleading unless the reduced emissions of diverse pollutants result in the same health and environmental benefits.

When you have identified a range of alternatives (*e.g.*, different levels of stringency), you should determine the cost-effectiveness of each option compared with the baseline as well as its incremental cost-effectiveness compared with successively more stringent requirements. Ideally, your CEA would present an array of cost-effectiveness estimates that would allow comparison across different alternatives. However, analyzing all possible combinations is not practical where there are many options (including possible interaction effects). In these cases, you should use your judgment to choose reasonable alternatives for careful consideration.

Accuracy of CEA depends on the consistency of analysis across a diverse set of possible regulatory actions. To achieve consistency, you need to construct very carefully the two key components of any CEA: The cost and the ''effectiveness'' or performance measures for the alternative policy options.

With regard to measuring costs, you should be sure to include all the relevant costs to society—whether public or private. Rulemakings may also yield cost savings (*e.g.*, energy savings associated with new technologies). The numerator in the cost-effectiveness ratio should reflect net costs, defined as the gross cost incurred in meeting the requirements (sometimes called ''total'' costs) minus any cost savings.

Where regulation may yield several different beneficial outcomes, a cost-effectiveness comparison becomes more difficult to interpret because there is more than one measure of effectiveness to incorporate in the analysis. To arrive at a single measure you will need to weigh the value of disparate benefit categories, but this computation raises some of the same difficulties you will encounter in BCA. If you can assign a reasonable monetary value to all of the regulation's different benefits, then you should do so, but in that case you will be doing BCA not CEA.

When you can estimate the monetary value of some but not all of the ancillary benefits of a regulation, but cannot assign a monetary value to the primary measure of effectiveness, you should subtract the monetary estimate of the ancillary benefits from the gross cost estimate to yield an estimated net cost. This net cost estimate for the rule may turn out to be negative—that is, the other benefits exceed the cost of the rule. If you are unable to estimate the value of

some of the ancillary benefits, the cost-effectiveness ratio will be overstated, and this should be acknowledged in your analysis. CEA does not yield an unambiguous choice when there are benefits that have not been incorporated in the net cost estimates.

You also may use CEA to compare regulatory alternatives in cases where the statute specifies the level of benefits to be achieved.

C. The Effectiveness Metric for Public Health and Safety Rulemakings

The validity of cost-effectiveness analysis depends on the application of appropriate ''effectiveness'' or performance measures that permit comparison of the regulatory options being considered. Agencies currently use a variety of methods for determining effectiveness, including number of lives saved, number of equivalent lives saved, and number of quality-adjusted life years saved. It is difficult for OMB to draw meaningful cost-effectiveness comparisons between rulemakings that employ different cost-effectiveness measurements. As a result, agencies should provide OMB with the underlying data, including mortality and morbidity data, the age distribution of the affected population, and the severity and duration of disease conditions or trauma, so that OMB can make apples-to-apples comparisons between rulemakings that employ different measures.

D. Evaluating Distributional Effects

Both benefit-cost analysis and cost-effectiveness analysis tend to focus on economic efficiency. Decision-makers may desire (or be required) to consider other values as well such as fairness. Your regulatory analysis should provide a separate description of distributional effects (*i.e.*, how both benefits and costs are distributed among sub-populations of particular concern) so that decisionmakers can properly consider them along with the effects on economic efficiency. E.O. 12866 authorizes this approach. The presentation of distributional effects is especially important when you have reason to believe that there will be significant disparities in how your regulatory actions may affect different groups of people. Effects that fall most heavily on those least able to bear the cost should be highlighted for policymakers' attention. Actions that benefit small groups at the expense of the larger public also deserve special scrutiny.

IV. Identifying and Measuring Benefits and Costs

This Section provides guidelines for your preparation of the benefit and cost estimates required by Executive Order No. 12866 and the ''Regulatory Right-to-Know Act.'' The preliminary analysis described in Sections I, II and III will help you identify a workable number of alternatives for consideration in your analysis and an appropriate analytical approach to use.

A. How To Develop a Baseline

1. General Issues

You need to measure the benefits and costs of a rule against a baseline. This baseline should be the best assessment of the way the world would look absent the proposed action. The choice of a proper baseline may require consideration of a wide range of potential factors, including:

- Evolution of the market,
- Changes in external factors affecting expected benefits and costs,
- Changes in regulations promulgated by the agency or other government entities, and the degree of compliance by regulated entities with other regulations.

You may often find it reasonable to forecast that the world absent the regulation will resemble the present. If this is the case, however, your baseline should reflect the future effect of current programs and policies. For review of an existing regulation, a baseline assuming ''no change'' in the regulatory program generally provides an appropriate basis for evaluating reasonable regulatory alternatives. When more than one baseline is reasonable and the choice of baseline will significantly affect estimated benefits and costs, you should consider measuring benefits and costs against alternative baselines. In doing so you can analyze the effects on benefits and costs of making different assumptions about other agencies' regulations, or the degree of compliance with your own existing rules. In all cases, you must evaluate benefits and costs against the same baseline. You should also discuss the reasonableness of the baselines used in these sensitivity analyses.

EPA's 1998 final PCB disposal rule provides a good example. EPA used several alternative baselines, each reflecting a different interpretation of existing regulatory requirements. In particular, one baseline reflected a literal interpretation of EPA's 1979 rule and another the actual implementation of that rule in the year immediately preceding the 1998 revision. The use of multiple baselines illustrated the substantial effect changes in EPA's implementation policy could have on the cost of a regulatory program. In the years after EPA adopted the 1979 PCB disposal rule, changes in EPA policy—especially allowing the disposal of automobile ''shredder fluff'' in municipal landfills—reduced the cost of the program by more than $500 million per year.

In some cases, substantial portions of a rule may simply restate statutory requirements that would be self-implementing even in the absence of the regulatory action. In these cases, you should use a pre-statute baseline. If you are able to separate out those areas where the agency has discretion, you may also use a post-statute baseline to evaluate the discretionary elements of the action.

2. Evaluation of Alternatives

You should decide on and describe the number and choice of alternatives available to you and discuss the reasons for your choice. Alternatives that rely on incentives and offer increased flexibility are often more cost-effective than more prescriptive approaches. For example, user fees and information dissemination may be good alternatives to direct command-and-control regulation. Within a command-and-control regulatory program, performance-based standards generally offer advantages over standards specifying design, behavior, or manner of compliance.

You should carefully consider all appropriate alternatives for the key attributes or provisions of the rule. Section II above outlines examples of appropriate alternatives.

Where there is a ''continuum'' of alternatives for a standard (for example, the level of stringency), you should generally analyze at least three options:

- The option serving as a focus for the Agency or program office regulatory initiative;
- A more stringent option that achieves additional benefits (and presumably costs more) beyond those realized by the preferred option; and
- A less stringent option that costs less (and presumably generates fewer benefits) than the preferred option.

You should choose options that are reasonable alternatives deserving careful consideration. In some cases, the regulatory program will focus on an option that is near or at the limit of technical feasibility or that fully achieves the objectives of the regulation. In these cases, the analysis would not need to examine a more stringent option. For each of the options analyzed, you should compare the anticipated benefits to the corresponding costs. It is not adequate to simply compare the Agency's preferred option to a ''do nothing'' or ''status quo'' option.

Whenever you can compare the benefits and costs of alternative options, you should present them in terms of both total and incremental benefits and costs. You must measure total benefits and costs against the same baseline. By contrast, you should present incremental benefits and costs as differences from the corresponding estimates associated with the next less-stringent alternative.[17] It is important to emphasize incremental effects are simply differences between successively more stringent alternatives.

In some cases, you may decide to analyze a wide array of options. For example, DOE's 1998 rule setting new energy efficiency standards for refrigerators and freezers analyzed a large number of options and produced a rich amount of information on their relative effects. This analysis—examining more than 20 alternative performance standards for one class of refrigerators with top-mounted freezers—enabled DOE to select an option that produced $200 more in net benefits per refrigerator than the least attractive option.

You should analyze the benefits and costs of different regulatory provisions separately when a rule includes a number of distinct provisions. If the existence of one provision affects the benefits or costs arising from another provision, the analysis becomes more complicated, but the need to examine provisions separately remains. In this case, you should evaluate each specific provision by determining the net benefits of the proposed regulation with and without it.

[17] For the least stringent alternative, you should estimate the incremental benefits and costs relative to the baseline. Thus, for this alternative, the incremental effects would be the same as the corresponding totals.

Analyzing all possible combinations of provisions in this way is impractical if their number is large and interaction effects are widespread. You need to use judgment to select the most significant or relevant provisions for such analysis.

You should also discuss the statutory requirements that affect the selection of regulatory approaches. If legal constraints prevent the selection of a regulatory action that best satisfies the philosophy and principles of Executive Order No. 12866, you should identify these constraints and estimate their opportunity cost.

B. How To Develop Benefit and Cost Estimates

1. Some General Considerations

You should discuss the expected benefits and costs of the selected regulatory option and any reasonable alternatives for each rule. How is the proposed action expected to provide the anticipated benefits and costs? What are the monetized values of the potential real incremental benefits and costs to society? To present your results, you should:

- Include separate schedules of the monetized benefits and costs that show the type and timing of benefits and costs and express the estimates in this table in constant, undiscounted dollars (for more on discounting see part C below).
- List the benefits and costs you can quantify, but cannot monetize, including their timing.
- Describe benefits and costs you cannot quantify.
- Identify or cross-reference the data or studies on which you base the benefit and cost estimates.

Similarly, you should discuss the expected cost of the selected regulatory option and any reasonable alternatives.

When benefit and cost estimates are uncertain (for more on this see part D below):

- You should calculate benefits (including benefits of risk reductions) and costs that reflect the full probability distribution of potential consequences. Where possible, present probability distributions of benefits and include the upper and lower bound estimates as complements to central tendency and other estimates.
- If fundamental scientific disagreement or lack of knowledge prevents construction of a scientifically defensible probability distribution, you should describe benefits under plausible assumptions and characterize the evidence underlying each alternative.

2. The Key Concepts Needed To Estimate Benefits and Costs

''Opportunity cost'' is the appropriate concept for valuing both benefits and costs. The principle of ''willingness-to-pay'' (WTP) captures the notion of opportunity cost by measuring what individuals are willing to forgo to enjoy a particular benefit. In general, economists tend to view WTP as the most appropriate measure of opportunity cost, but an individual's ''willingness-to-accept'' (WTA) compensation for not receiving the improvement can also provide a valid measure of opportunity cost. WTP and WTA are comparable measures when the change being evaluated is small and especially where there are reasonably close substitutes available. WTP is generally considered to be more readily measurable and to provide a more conservative measure of benefits. Adoption of WTP as the measure of value implies that individual preferences of the affected population should be a guiding factor in the regulatory decision and that the existing distribution of income is acceptable.

Market prices provide the richest data for estimating benefits based on willingness-to-pay if the goods and services affected by the regulation trade in well-functioning free markets. The opportunity cost of an alternative includes the value of the benefits forgone as a result of choosing that alternative. The opportunity cost of banning a product—a drug, food additive, or hazardous chemical—is the forgone net benefit (*i.e.*, lost consumer and producer surplus [18]) of that product, taking into account the mitigating effects of potential substitutes. The use of any resource has an opportunity cost regardless of whether the resource is already owned or has to be purchased. That opportunity cost is equal to the net benefit the resource would have provided in the absence of the requirement. For example, if regulation of an industrial plant affects the use of additional land or buildings within the existing plant boundary, the cost analysis should include the opportunity cost of using the additional land or facilities. To the extent possible, you should monetize any such forgone benefits and add them to the other costs of that alternative. You should also try to monetize any costs averted as a result of an alternative and either add it to the benefits or subtract it from the costs of that alternative.

Estimating benefits and costs when market prices are hard to measure or markets do not exist is more difficult. In these cases, regulatory analysts need to develop appropriate proxies that simulate market exchange. Estimates of willingness-to-pay based on observable and replicable behavior generally are the most reliable. As one example, analysts sometimes use ''hedonic price equations'' based on multiple regression analysis of market behavior to simulate market prices for the commodity of interest.[19] Going through the analytical process of deriving benefit estimates by simulating markets may also suggest alternative regulatory strategies that create such markets.

Other approaches may be necessary when a commodity is not directly or indirectly traded in markets. Valuation estimates developed using these approaches are less certain than estimates derived from market transactions or based on behavior that is observable and replicable. While innovative estimation methods are sometimes necessary, they increase the need for quality control to ensure that estimates conform closely to what would be observed if markets did exist.

Ultimately, the method selected to develop a monetized estimate should focus on a value for the specific attribute or end-point of interest (for example, lost school-days). As a cautionary note, the transfer of a valuation estimate from an unrelated context (say, for example, the valuation of lost work-days from labor market studies) as a measure of the value of the attribute (lost school-days) may yield an incorrect benefits estimate.

You also need to guard against double-counting, since some attributes are embedded in other broader measures. For example, when a regulation improves the quality of the environment in a community, the value of real estate in the community generally rises to reflect the greater attractiveness of living in a better environment. Simply adding the increase in property values to the estimated value of improved public health would be double counting if the increase in property values reflects the improvement in public health. To avoid this problem you should separate the embedded effects on the value of property arising from improved public health. At the same time, of course, valuation estimates that fail to incorporate the consequence of land use changes will not capture the full effects of regulation.

3. How To Use Market Data Directly

Economists ordinarily consider market prices as the most accurate measure of the value of goods and services to society. In some instances, however, market prices may not reflect the true value of goods and services. If a regulation involves changes to goods or services where the market price is not a good measure of the value to society, you should use an estimate that reflects the true value to society (often called the ''shadow price''). For example, suppose a particular air pollutant damages crops. One of the benefits of controlling that pollutant is the value of the increase in crop yield as a result of the controls. That value is typically measured by the price of the crop. If the price is held above the market price by a government program that affects supply, however, a value estimate based on this price would overstate the true benefits of controlling the pollutant. In this case, you should calculate the value to society of the increase in crop yields by estimating the

[18] Consumers' surplus is the difference between what a consumer pays for a unit of a good and the maximum amount the consumer would be willing to pay for that unit. It is measured by the area between the price and the demand curve for that unit. Producers' surplus is the difference between the amount a producer is paid for a unit of a good and the minimum amount the producer would accept to supply that unit. It is measured by the area between the price and the supply curve for that unit.

[19] The hedonic technique allows analysts to develop an estimate of the price for specific attributes associated with a product. For example, houses are a product characterized by a variety of attributes including the number of rooms, total floor area, and type of heating and cooling. If there are enough data on transactions in the housing market, it is possible to develop an estimate of the implicit price for specific attributes, such as the implicit price of an additional bathroom or for central air conditioning. This technique can be extended, as well, to develop an estimate for the implicit price of public goods that are not directly traded in markets. For example, the analyst can develop implicit price estimates for public goods like air quality and access to public parks by adding measures for these attributes to the hedonic price equation for housing.

shadow price, which reflects the value to society of the marginal use of the crop. If the marginal use is for exports, you should use the world price. If the marginal use is to add to very large surplus stockpiles, you should use the value of the last units released from storage minus storage cost. If stockpiles are large and growing, the shadow price may be low or even negative.

4. Indirect Uses of Market Data

Some benefits or costs correspond to goods or services that are indirectly traded in the marketplace. Their value is reflected in the prices of related goods that are directly traded. Examples include reductions in health and safety risks, the use-values of environmental amenities (for example, recreational fishing or hiking and camping), and the value of improved scenic visibility. You should use willingness-to-pay measures as the basis for estimating the monetary value of such indirectly traded goods. When practical obstacles prevent the use of direct ''revealed preference'' methods based on actual market behavior to measure willingness-to-pay, you may consider the use of alternative ''stated preference'' methods based on survey techniques. As discussed below, you may use alternative methods where there are practical obstacles to the accurate application of direct willingness-to-pay methodologies.

A variety of methods have been developed for estimating indirectly traded goods or services. Examples include estimates of the value of environmental amenities derived from travel-cost studies, hedonic price models that measure differences or changes in the value of land, and statistical studies of occupational-risk premiums in wage rates. Under each of these methods, care is needed in designing protocols for reliably estimating the value of these attributes. For example, the use of occupational-risk premiums can be a source of bias because the risks, when recognized, may be voluntarily rather than involuntarily assumed,[20] and the sample of individuals upon which premium estimates are based may be skewed toward more risk-tolerant people.

Many goods that are affected by regulation—such as preserving environmental or cultural amenities—are not traded directly in markets. These ''non-market'' values arise both from use and non-use. Estimation of these values is difficult because of the absence of an organized market. However, overlooking or ignoring these values in your regulatory analysis may significantly understate the benefits of regulatory actions.

a. Use Values—the value an individual derives from directly using the resource now (or in the future). Use values are associated with activities such as swimming, hunting, and hiking where the individual comes into direct contact with the environment. These values also include commercial uses of natural resources, such as fishing, and consumptive uses, such as clean air and drinking water.

[20] Distinctions between ''voluntary'' and ''involuntary'' are arbitrary and should be treated with care. These terms are merely a proxy for differences in the cost of avoiding risks.

b. Nonuse Values—the value an individual places on an environmental resource even though the individual will not use the resources now or in the future. Non-use value includes bequest, existence and option values.

Use values are typically estimated through ''revealed'' preference models, which rely on observed behavior. It is important that you utilize revealed preference models that adhere to economic criteria that are consistent with utility maximizing behavior [example of RUM study]. Examining averting or defensive expenditures (as distinct from avoided cost of compliance with other regulatory requirements) is another way to estimate use values. This approach may reveal a minimum willingness to pay, particularly if there is reason to believe the market for averting behavior is not in equilibrium.

5. Contingent Valuation

Contingent valuation (CV) methods have become increasingly common for estimating indirectly traded benefits. However, the reliance of these methods on stated preferences regarding hypothetical scenarios and the complexities of the goods being valued by this technique raise issues about its accuracy in estimating willingness to pay compared to methods based on (indirect) revealed preferences. Accordingly, value estimates derived from contingent-valuation studies require greater analytical care than studies based on observable behavior. For example, the contingent valuation instrument must portray a realistic choice situation for respondents—where the hypothetical choice situation corresponds closely with the policy context to which the estimates will be applied. Below we provide a more complete list of important criteria that affect the reliability of results from contingent valuation surveys. The practice of contingent valuation is rapidly evolving, and agencies relying upon this tool for valuation should judge the reliability of their estimates using this technique in light of advances in the state of the art.

Some types of goods, such as preserving environmental or cultural amenities apart from their use and direct enjoyment by people, are not traded directly or indirectly in markets. The practical obstacles to accurate measurement are similar to (but generally more severe than) those arising with respect to indirectly traded goods and services, principally because there are no related market transactions to provide data for willingness-to-pay estimates.

For many of these goods, particularly goods providing a substantial ''nonuse'' component of value, contingent-valuation methods may provide the only analytical approaches currently available for estimating values. The absence of observable and replicable behavior with respect to the good or service, combined with the complex and often unfamiliar nature of the goods being valued, argues for great care in the design and execution of surveys, rigorous analysis of the results, and a full characterization of the uncertainties in the estimates to meet best practices in the use of this method. Current ''best practices'' for CV surveys include the following:

Sampling, etc.

- Probability sampling: this usually requires the guidance of a professional sampling statistician;
- Low non-response rate: high non-response rates would make the results unreliable;
- Personal interview: face-to-face and telephone interviews may elicit more reliable information.

Survey Instrument Design

- Accurate description: adequate information must be provided to respondents about the good or amenity they are being asked to value;
- Reminder of substitute commodities: respondents must be reminded of substitute commodities, and this reminder should be introduced forcefully and directly prior to the main valuation question;
- Reminder of alternative expenditure possibilities: respondents must be reminded that their willingness to pay would reduce their expenditures for other goods;
- Deflection of transaction value: the survey should be designed to deflect the general ''warm glow'' of giving or a particular dislike of the source of the problem being addressed.

Transparency and Replicability of Results

- Reporting: CV studies should make clear the definition of population sampled, sampling frame used, overall sample non-response rate, and item non-response rate on all important questions; the report should also include the exact wording and sequence of questionnaire and other communications to respondents;
- Data quality: special care should be taken to ensure compliance with OMB's ''Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies' (''data quality guidelines'') *http://www.whitehouse.gov/omb/fedreg/reproducible.html;*
- Since there is no economic theory that can describe hypothetical behavior, it is important to assure the respondents that their decisions are consequential and may influence policy.

As with all other estimates of benefits and costs, your CV results should be consistent with economic theory. First, as price increases and the amount of the good is held constant, the number of respondents willing to pay a particular price should fall. This is akin to negative own-price elasticity for a marketed good. Second, respondents should be willing to pay more for a larger amount (or higher quality) of the good. This is often referred to as being sensitive to scope. If your only test of consistency with economic theory is a scope test, it should be an external (split sample) test rather than an internal (within sample) test.

6. Benefit Transfer Methods

In many cases, conducting an original study may not be possible due to the time and expense involved. The alternative to an original study is the use of benefit transfer methods. Benefit transfer is defined as the practice of transferring existing estimates of

non-market values from the context of study to a new context.

Although benefit transfer offers a quick, low cost approach for establishing values for goods and attributes of goods, you should consider it as a last resort option. Several studies have documented difficulties in applying benefit transfer methods. If a benefit transfer approach is necessary, you should adopt the approach of transferring the entire demand function (referred to as benefit function transfer) rather than adopting a single point estimate (referred to as benefit point transfer). The former approach has been shown to yield more precise estimates than the latter approach.

In conducting benefit transfer, the first step is to specify the value to be estimated at the policy site. The analyst should identify the relevant measure of the policy change at this initial stage. For instance, you can derive the relevant willingness-to-pay measure by specifying an indirect utility function. This identification allows an analyst to ''zero in'' on key aspects of the benefit transfer.

The next step is to identify appropriate studies to conduct benefit transfer. In selecting transfer studies for either point transfers or function transfers, you should base your choices on the following criteria:

a. The selected studies should be based on adequate data, sound empirical methods and defensible empirical techniques.

b. The selected studies should document parameter estimates of the valuation function.

c. The study context and policy context should have similar populations (*e.g.*, demographic characteristics, target population size).

d. The good, and the magnitude of change in that good, should be similar in the study and policy contexts.

e. The relevant characteristics of the study and the policy contexts should be similar. For example, are they similar in the following respects?

- The reversibility of the policy change
- The degree of embedding of other values
- The order in which the good is supplied
- The functional relationship between the consumer surplus and its determinants.

f. The distribution of property rights should be similar so that the analysis uses the same welfare measure. If the property rights in the study context support the use of willingness-to-accept (WTA) measures while the rights in the policy context support the use of willingness-to-pay (WTP) measures, benefit transfer is not appropriate.

g. The availability of substitutes across study and policy contexts should be similar.

Clearly, all of these criteria are difficult to meet. However, you should attempt to satisfy as many as possible when choosing studies from the existing economic literature. In addition to the above criteria, an analyst should keep in mind some of the difficulties in transferring benefit estimates or functions from one context to another:

- Is the policy change irreversible?
- Does the order in which the good is supplied affect valuation?
- Is the embedding problem significant?
- Is the assumed functional relationship between the consumer surplus measure and its determinants explicit and appropriate?

Finally, you should not use benefit transfer in estimating benefits if:

- Resources are unique or have unique attributes.
- If the study examines a resource that is unique or has unique attributes, you should not transfer benefit estimates or functions to value a different resource and vice versa. For example, if a study values visibility improvements at the Grand Canyons, these results should not be used to value visibility improvements in urban areas.
- There are significant problems with applying an ex ante valuation estimate to an ex post policy context. If a policy yields a significant change in the attributes of the good, you should not use the study estimates to value the change using a benefit transfer approach.
- You also should not use a value developed from a study involving, small marginal changes in a policy context involving large changes in the quantity of the good.

7. Methods for Treating Nonmonetized Benefits and Costs

Sound quantitative estimates of benefits and costs are preferable to qualitative descriptions of benefits and costs to help decision-makers understand the full effects of alternative actions. Although we prefer that agencies use acceptable monetized benefit and cost estimates, we recognize that monetizing some of the effects of regulations is difficult, and even quantifying some effects may not be feasible.

a. What To Do With Benefits and Costs That Are Difficult To Monetize?

You should monetize quantitative estimates whenever possible. Use sound and defensible values or procedures to monetize costs and benefits, and ensure that key analytical assumptions are defensible. If monetization is impossible, explain why and present all available quantitative information. For example, if you can quantify, but cannot monetize, improvements in water quality and increases in fish populations resulting from water quality regulation, you can describe benefits in terms of stream miles of improved water quality for boaters and increases in game fish populations for anglers. You should describe the timing and likelihood of such effects and avoid double-counting of benefits when estimates of monetized and physical effects are mixed in the same analysis. You should also apply the discounting procedures described above to all quantified effects, whether or not you are able to monetize them.

b. What To Do With Benefits and Costs That Are Difficult To Quantify?

If you are not even able to quantify the effects, you should present any relevant quantitative information along with a description of the unquantifiable effects. Such descriptions could include ecological gains, improvements in quality of life, and aesthetic beauty. For cases in which the presence of unquantifiable benefits or costs affects a policy choice, you should provide a clear explanation of the rationale behind the choice. Such an explanation could include detailed information on the nature, timing, likelihood, location, and distribution of the unquantified benefits and costs. Also, please include a summary table that lists all the unquantifiable benefits and costs, ordered by expected magnitude, if possible.

8. Monetizing Health and Safety Benefits and Costs

We expect you to provide a benefit and cost analysis of major health and safety rulemakings in addition to a CEA. The BCA provides additional insight because (a) it provides some indication of what the public is willing to pay for improvements in health and safety and (b) it offers additional information on preferences for health using a different research design than is used in CEA. Since the health-preference methods used to support CEA and BCA have some different strengths and drawbacks, it is important that you provide decision makers with both perspectives.

In monetizing health benefits, a willingness-to-pay measure is the conceptually appropriate measure as compared to other alternatives (*e.g.*, cost of illness or lifetime earnings), in part because it attempts to capture pain and suffering and other quality-of-life effects. Using the willingness-to-pay measure for health and safety allows you to directly compare your results to the other costs and benefits in your analysis, which will also typically be based on willingness to pay.

If well-conducted, revealed-preference studies of relevant health and safety risks are available, you should consider using them in developing your monetary estimates. If appropriate revealed-preference data are not available, you may consider whether valid and relevant data from stated-preference studies are available. You will need to use your professional judgement when you are faced with limited information on revealed preference and substantial information based on stated preference studies.

A key advantage of stated-preference and health-utility methods (compared to revealed preference) is that they can be tailored in their design to address ranges of probabilities, types of health risks and specific populations affected by your rule. In many rulemakings there will be no relevant information from revealed-preference studies. In this situation you should consider commissioning a stated-preference study or using values from published stated-preference studies. For the reasons discussed in the section above IVB5, you should be cautious about using values from stated-preference studies and describe in the analysis some of the inherent drawbacks of this approach.

a. Nonfatal Health and Safety Risks

With regard to nonfatal health and safety risks, there is enormous diversity in the nature and severity of impaired health states. A minor traumatic injury that can be treated effectively in the emergency room without hospitalization or long-term care is different from a traumatic injury resulting in paraplegia. Severity differences also are important in evaluation of chronic diseases. A severe bout of bronchitis, though perhaps less frequent, is far more painful and debilitating than the more frequent bouts of

mild bronchitis. The duration of an impaired health state, which can range from a day or two to several years or even a lifetime (*e.g.*, birth defects inducing mental retardation), need to be considered carefully. Information on both the severity and duration of an impaired health state are necessary before the task of monetization can be performed.

When monetizing nonfatal health effects, it is important to consider two components: (1) The private demand for prevention of the nonfatal health effect, to be represented by the preferences of the target population at risk, and (2) the net financial externalities associated with poor health such as net changes in public medical costs and any net changes in economic production. Revealed-preference or stated-preference studies are necessary to estimate the private demand; health economics data from published sources can typically be used to estimate the financial externalities of poor health. If you use literature values to monetize nonfatal health and safety risks, it is important to make sure that the values you have selected are appropriate for the severity and duration of health effects to be addressed by your rule.

If data are not available to support monetization, you might consider an alternative approach that makes use of health-utility studies. Although the economics literature on the monetary valuation of impaired health states is growing, there is a much larger clinical literature on how patients, providers and community residents value diverse health states. This literature typically measures health utilities based on the standard gamble, the time tradeoff or the rating scale methods. This health utility information may be combined with known monetary values for well-defined health states to estimate monetary values for a wide range of health states of different severity and duration. If you use this approach, you should be careful to acknowledge your assumptions and the limitations of your estimates.

b. Premature Mortality Risks

The adoption of a monetary value for projected reductions in premature mortality is the subject of continuing research and discussion within the economics and policy analysis communities. Although there is a substantial academic literature on this topic, the methods used and resulting estimates vary substantially. The two most widely used measures consider the number of statistical lives saved and the number of expected years of life saved and their associated monetary values. Both of these measures are applicable to settings where a rule changes small probabilities of death faced by the public.

The phrase ''statistical life'' is widely used in the technical literature but it can be misleading and easily misinterpreted. Unlike an identified life, whose name and background are known (*e.g.*, a trapped coal miner or patient dying of kidney failure), a statistical life refers to the sum of risks experienced by a population. For example, if 10,000 people each face a risk of 1 in 10,000 of immediate death, one statistical life is expected to be lost. Statistical lives that are lost are real people but, given the background rate of fatal events in the population, it is not feasible to determine which actual lives will be saved or lost by a specific rule.

The monetary value of saving a statistical life (VSL) is derived by assessing the public's willingness to pay to avert one statistical fatality. The bulk of the studies in the literature, which address wage premiums for hazardous jobs, are based on revealed preference. A small but growing number of stated-preference studies have also been used to derive VSLs. The estimates of VSL in the literature vary considerably but this is not surprising because VSL is not expected to be a universal constant. Economic theory predicts that VSLs may vary in different lifesaving contexts depending upon factors such as the magnitude of the probabilities and the health preferences of the target population.

You should not use a VSL estimate without considering whether it is appropriate for the size and type of risks addressed by your rule. Studies aimed at deriving VSL values for middle-aged populations are not necessarily applicable to rules that address lifesaving among children or the elderly. Moreover, VSL values based on fatal cancers or heart attacks are not necessarily relevant to a rule that prevents fatal causes of trauma, violence, or infectious disease. If you choose to apply a VSL derived in one setting to a different setting, you should disclose the salient differences in the lifesaving contexts and, where feasible, make appropriate quantitative adjustments to the VSL value.

Since everyone is expected to die sooner or later, it has been suggested that the VSL be replaced or augmented by the monetary value of a statistical life year (VSLY). The assumption is that the public is willing to pay more money for a rule that saves an average of 10 life years per person than a rule that saves one life year per person. A key assumption implicit in this approach is that public willingness to pay for risk reduction is strictly proportional to the number of life years at risk. This may not always be the case. For example, the elderly may have substantial willingness to pay for reductions in their mortality risk precisely because they have relatively few life years remaining. Where there is good reason to believe that these values are not strictly proportional, you should attempt to develop appropriate estimates. In all instances, whether or not you are able to develop ideal estimates, agencies should consider providing estimates of both VSL and VSLY, while recognizing the developing states of knowledge in this area.

In summary, you should use valid, relevant data and methods to assign monetary values to changes in the risk of premature death, illness or injury. Some of the key issues include:

- Whether the monetary valuations have been shown to be appropriately sensitive to the scope of the health change, considering probability, severity and longevity.
- Whether the specific data and methods used for monetization are relevant to the specific health change induced by a proposed regulation.

The valuation of fatal and nonfatal risk reduction is an evolving area in terms of research design, methods and results. You should utilize valuation methods that you consider appropriate for the regulatory circumstances. You should present estimates based on alternative approaches, and if you monetize mortality risk reduction, you should do so on a consistent basis to the extent feasible. You should clearly indicate your methodology and document your choice of a particular methodology. If you use different methodologies in different rules, you should clearly disclose the fact and explain your reasons.

C. What Discount Rate To Use

Benefits and their associated costs do not always take place in the same time period, and when they do not, it is usually incorrect simply to add up all of the expected benefits or costs without taking account of when they actually occur. If benefits or costs are delayed or otherwise separated in time from each other, the difference in timing should be reflected in your analysis.

As a first step, you should present the annual time stream of benefits and costs expected to result from the rule, clearly identifying when the benefits and costs are expected to occur. The beginning point for your stream of estimates should be the year in which the final rule will begin to have effects, even if that is expected to be some time in the future. In presenting the stream of benefits and costs, it is important to measure them in constant dollars. That way you avoid the misleading effects of inflation on your estimates. If the benefits or costs are initially measured in prices reflecting expected future inflation, you can convert them to constant dollars by dividing through by an appropriate inflation index, one that corresponds to the inflation rate underlying the initial estimates of benefits or costs.

Once these preliminaries are out of the way, you can begin to adjust your estimates for differences in timing. This is a separate calculation from the adjustment needed to remove the effects of future inflation. Whether or not inflation is expected, it is generally true that the sooner benefits occur the more valuable they are. Resources that are invested will normally earn a positive return, so current consumption is more expensive than future consumption, because you are giving up that expected return when you consume today. Looking at it another way, postponed benefits have a cost because people are impatient and generally prefer present to future consumption. Also, if consumption continues to increase over time, as it has for most of U.S. history, an increment of consumption will be less valuable in the future than it would be today, because as total consumption increases, its marginal value tends to decline. These are all reasons for valuing future costs and benefits less than those occurring in the present.

A discount factor should be used to adjust the estimated costs and benefits for differences in timing . The further in the future the costs and benefits are expected to occur, the larger is this discount factor. The discount factor can be calculated given a discount rate. The formula is $1/(1+\text{the discount rate})^t$ where ''t'' measures the number of years in the future that the benefits or costs are expected to occur. Benefits or costs that have been adjusted in

this way are called discounted present values. Once the estimated benefits and costs have been discounted, they can be combined to determine the overall value of net benefits.

OMB's basic guidance on the discount rate is provided in OMB Circular A–94. This Circular states that a real discount rate of 7 percent should be used as a base-case for regulatory analysis. The 7 percent rate is an estimate of the average before-tax rate of return to private capital in the U.S. economy. It is a broad measure that reflects the returns to real estate and small business capital as well as corporate capital. It approximates the opportunity cost of capital and is the appropriate discount rate whenever the main effect of a regulation is to displace or alter the use of capital in the private sector. OMB revised Circular A–94 in 1992 after extensive internal review and following public comment. The average rate of return to capital remains near the 7 percent rate estimated in 1992. Circular A–94 also recommends using other discount rates to show the sensitivity of the estimates to the discount rate assumption.

The effects of regulation do not always fall exclusively on the allocation of capital. When regulation primarily affects private consumption (*e.g.*, through higher consumer prices for goods and services), a lower discount rate may be appropriate. The alternative most often used is called the ''social rate of time preference.'' This simply means the rate at which ''society'' discounts future consumption flows to their present value. Economic distortions, including taxes on capital, create a divergence between this social rate and the private rate of return to capital. If we take the rate that the average saver uses to discount future consumption as our measure of the social rate of time preference, then the real rate of return on long-term government debt may provide a fair approximation. This rate has averaged around 3 percent since the mid-1950s.

For regulatory analysis, you should provide estimates of net benefits using both 7 percent and 3 percent. An example of this approach is EPA's analysis of its 1998 rule setting both effluent limits for wastewater discharges and air toxic emission limits for pulp and paper mills. In this analysis, EPA developed its present discounted value estimates using real discount rates of 3 and 7 percent applied to benefit and cost streams that extended forward for 30 years. (*See* EPA, Economic Analysis, October 1997, pages 10–3 and 10–4.) You should present a similar sensitivity analysis in your own work.

In some instances, if there is reason to expect that the regulation will cause resources to be reallocated away from private investment in the corporate sector, then the opportunity cost may be appreciably greater than the 3 to 7 percent discount rate. For example, Tresch suggests that rates in the range of 10 to 25 percent may be appropriate to reflect this opportunity cost, depending on the sector affected by the regulation. If you are uncertain about the nature of the opportunity cost, then you should present benefit and cost estimates using a higher discount rate as a sensitivity analysis as well as using 3 percent and 7 percent.

Circular A–94 points out that the analytically preferred method of handling timing differences between benefits and costs would be to adjust all the benefits and costs to reflect their value in equivalent units of consumption.[21] Due to distortions in the economy such calculations require you to value the costs and benefits using shadow prices, especially for capital goods. If all costs and benefits are measured in terms of consumption equivalents, it is appropriate to discount them using the social rate of discount. Any agency that wishes to tackle this challenging analytical task should check with OMB before proceeding.

When future benefits or costs are health-related, some have questioned whether discounting is appropriate. Although some of the rationales for discounting money may not seem to be applicable to health (*e.g.*, lives saved today cannot be invested in the bank to save more lives in the future, although the resources that would have been used to save those lives can often be saved with a higher pay-off in future lives saved). However, people do prefer health gains that occur immediately to identical health gains that occur only in the future, which would justify discounting the future gains. Also, if future health gains are not discounted while future costs are, then the following perverse result occurs: an attractive investment today in future health improvement can always be made more attractive by delaying the investment. For such reasons, there is a professional consensus that future health effects, including both benefits and costs, should be discounted at the same rate as generally used in both BCA and CEA.

A common challenge in health-related analyses is to quantify the time lag between when a rule takes effect and when the resulting physical improvements in health status will be observed in the target population. In such situations, you must carefully consider the timing of health benefits before present-value calculations are performed. It is not reasonable to assume that all of the benefits of reducing chronic diseases such as cancer and cardiovascular disease will occur immediately when the rule takes effect. For rules addressing traumatic injury, this lag period may be short while for chronic diseases it may take years or even decades for a rule to induce its full beneficial effects in the target population. When a time period between exposure to a toxin and increased probability of disease is likely (*e.g.*, a so-called latency period), it is also likely that there will be a lag between exposure reduction and reduced probability of disease. This latter period has sometimes been referred to as a ''cessation lag'' and it may or may not be the same as the latency period. As a general matter, cessation lags will apply only to populations with at least some higher-level exposure (*i.e.*, before the rule takes effect). For populations with no such prior exposure, such as those born after the rule takes effect, only the latency period will be relevant.

Ideally, your exposure-risk model would allow calculation of reduced risk for each year following exposure cessation, perhaps incorporating total cumulative exposure and age at the time of exposure reduction into the calculation as well. The present value calculation of benefits could then reflect an appropriate discount factor for each year's risk reduction. Recent analyses of the cancer benefits of reducing public exposure to radon in drinking water have adopted this approach, supported by formal risk-assessment models that allow estimates of how the timing of lung cancer incidence and mortality are affected by different radon exposure levels. In many cases, you will not have the benefit of such detailed risk assessment modeling. You will need to use your professional judgement as to the average cessation lag for the chronic diseases affected by your rule. In situations where information exists on latency but not on cessation lags, it may be reasonable to use latency as a proxy for the cessation lag, unless there is reason to believe, based on data, modeling, or knowledge of the mechanism of action, that the two are different. When the average lag time between exposures and disease is unknown, a range of alternative yet plausible values for the time lag should be used in your analysis.

Special ethical considerations arise when comparing benefits and costs across generations. Although most people demonstrate in their own consumption behavior a preference for consumption now rather than in the future, it may not be appropriate for society to demonstrate a similar preference when deciding between the well-being of current and future generations. Future citizens who are affected by such choices cannot take part in making them, and today's society must act in their interest. One way to do this would be to follow the same discounting techniques described above, but to supplement the analysis with an explicit discussion of the intergenerational concerns and how they will be affected by the regulatory decision. Policymakers would be provided with additional information when the analysis covers many generations, but without changing the general approach to discounting.

Some have argued, however, that it is ethically impermissible to discount the utility of future generations. On this view, government should treat all generations equally. Even under this approach, it would still be correct to discount future costs and consumption benefits, although perhaps at a lower rate than for intragenerational analysis. There are two reasons for thinking that a nonzero discount rate is the appropriate assumption for intergenerational analysis, even when all generations are to be treated equally. First, future generations are likely to be wealthier than those currently living, so a marginal dollar of benefits or costs will be worth less to them than it would be to those alive today, at least on average. If that holds true, it is appropriate to discount future benefits and costs relative to currently consumed benefits and costs even if the welfare of future generations is not being discounted. Estimates of the discount rate

[21] A thorough discussion of this approach to discounting is provided in Robert C. Lind (ed.), Discounting for Time and Risk in Energy Policy, Baltimore: The Johns Hopkins University Press for Resources for the Future, 1982.

appropriate in this case made in the 1990s ranged from 1 to 3 percent per annum.[22]

A second reason for discounting the benefits and costs accruing to future generations at a lower rate is increased uncertainty about the appropriate value of the discount rate, the longer the horizon for the analysis. Aversion to uncertainty discourages any such long-term investments. Private market rates provide a reliable reference for determining how society values time within a generation, but for extremely long time periods no comparable private rates exist. Symmetric uncertainty would have the effect of lowering the discount factor applied to future costs and benefits. Again the reasonable range might be expanded to include rates as low as 1 percent per annum.

If you choose to use a lower discount rate for intergenerational analysis, you should still be sure to show the calculated net benefits using discount rates of 3 and 7 percent as well. Discounting is appropriate whether you are doing a BCA or a CEA. Even costs and benefits that are not expressed in monetary units should be discounted if they are separated in time. This also includes health benefits for reasons discussed above. For example, in its 1998 rule, ''Control of Emissions from Nonroad Diesel Engines,'' EPA estimated cost-effectiveness by discounting both the monetary costs and the emission reduction benefits over the useful expected life of the engines at the 7 percent real rate recommended in OMB Circular A–94.

It may be possible in some cases to avoid discounting non-monetized benefits, if the expected flow of benefits begins as soon as the cost is incurred and if it is expected to be constant over time. In such cases, annualizing the cost stream is sufficient, and further discounting of benefits is unnecessary. As an example, such an analysis might produce an estimate of the annualized cost per ton of reducing emissions of a pollutant.

D. Treatment of Uncertainty

The precise consequences (benefits and/or costs) of regulatory options are not always known for certain, but the probability of their occurrence can often be predicted. The important uncertainties connected with your regulatory decisions need to be analyzed and presented as part of the overall regulatory analysis. Your analysis of uncertainty should consider both the quantifiable risk associated with the potential outcomes of alternative regulatory actions (for example, the expected change in the distribution of automobile accidents that might result from a change in automobile safety standards) and the incomplete knowledge or uncertainty about the relevant relationships (for example, the uncertain science of how some economic activities might affect future climate change).

The treatment of uncertainty must be guided by the same principles of full disclosure and transparency that apply to other elements of your regulatory analysis. Any data and models that you use to analyze uncertainty should be fully identified. Inferences and assumptions used in your analysis should also be identified, and your analytical choices should be explicitly evaluated and adequately justified. Your presentation should explain how your analytical choices have affected your analysis.

Uncertainty arises from various and fundamentally different sources. These include the fundamental unpredictability of various natural and social phenomena, but they also include lack of data and the lack of knowledge about key relationships resulting from limitations in fundamental scientific knowledge (both social and natural). The different sources of uncertainty suggest different approaches for dealing with it. For example, when the uncertainty is due to a lack of data, you might consider deferring the decision, as an explicit regulatory alternative, pending further study to obtain sufficient data. We recognize that delaying a decision will also have costs, as will further efforts at data gathering and analysis. You will need to weigh the benefits of delay against these costs in making your decision. Formal tools for assessing the value of additional information are now well developed in the applied decision sciences and can be used to help resolve this type of complex regulatory question.

In some cases, the level of scientific uncertainty may be so large that you can only present discrete alternative scenarios without assessing the relative likelihood of each scenario quantitatively. For example, in assessing the potential outcomes of an environmental effect, there may be a limited number of scientific studies with strongly divergent results. In such cases, you might present results from a range of plausible scenarios, together with any available information that might help in qualitatively determining which scenario is most plausible.

Your analysis should include two fundamental components: A quantitative analysis characterizing the probabilities of the relevant outcomes and an assignment of economic value to the projected outcomes. It is essential that both parts be conceptually consistent. In particular, the quantitative analysis should be conducted in a way that permits it to be applied within a more general analytical framework, such as BCA. Similarly, the general framework needs to be flexible enough to incorporate the quantitative analysis without oversimplifying the results. For example, you should address explicitly the implications for benefits and costs of any probability distributions developed in your analysis.

1. Quantitative Analysis of Uncertainty

Examples of quantitative analysis, broadly defined, would include formal estimates of the probabilities of environmental damage to soil or water, the possible loss of habitat, or risks to endangered species as well as probabilities of harm to human health and safety. There are also uncertainties associated with estimates of economic benefits and costs, *e.g.*, the cost savings associated with increased energy efficiency. Your analysis should be credible, objective, realistic, and scientifically balanced. In your presentation, you should delineate its strengths along with any lingering uncertainties about its conclusions. You should describe the assumptions and the models you used and their impact on the overall analysis. You should also discuss the quality of the available data used.

As with other elements of regulatory analysis, you will need to balance thoroughness with the practical limits on your analytical capabilities. Your analysis does not have to be exhaustive, nor is it necessary to evaluate each alternative at every step. In the absence of adequate data, you will need to make assumptions. These should be clearly identified and consistent with the relevant science. Your analysis should provide sufficient information for decision-makers to grasp the degree of scientific uncertainty and the robustness of estimated probabilities, benefits, and costs to changes in key assumptions. For major rules involving threshold costs of $1 billion, you should present a formal quantitative analysis of the relevant uncertainties.

In your analysis, you should try to provide some estimate of the probability distribution of risks with and without the regulation, and you must do this for rules that exceed the $1 billion threshold. In characterizing the probability distributions quantitatively, you should provide some estimate of the central tendency (*e.g.*, mean and median) along with any other information you think will be useful such as ranges, variances, specified low-end and high-end percentile estimates, and other characteristics of the distribution.

Your estimates cannot be more precise than their most uncertain component. Thus, your analysis should report estimates in a way that reflects the degree of uncertainty and not create a false sense of precision. Your analysis should not reflect any unstated or unsupported preferences, even for such worthy objectives as protecting public health or the environment. Unstated assumptions can affect the analysis in unsuspected ways, making it difficult for decision-makers to evaluate the true magnitude of the uncertainties involved.

Acceptable Analytical Approaches: Whenever possible, you should use appropriate statistical techniques to determine a probability distribution of the relevant outcomes, and for rules that exceed the $1 billion threshold a formal quantitative analysis is required.

You may consider the following analytical approaches. They entail increasing levels of complexity:

- Disclose qualitatively the main uncertainties in each important input to the calculation of benefits and costs. These disclosures should address the uncertainties in the data as well as in the analytical results. However, major rules above the $1 billion threshold require a formal treatment.
- Use a numerical sensitivity analysis to examine how the results of your analysis vary with plausible changes in assumptions, choices of input data, and alternative analytical approaches. Sensitivity analysis is especially valuable when the information is

[22] Approaches to discounting across generations are discussed in a recent symposium volume published by Resources for the Future. Paul R. Portney and John P. Weyant (eds.), Discounting and Intergenerational Equity, Washington, DC: Resources for the Future, 1999.

lacking to carry out a formal probabilistic simulation. Sensitivity analysis can be used to find ''switch points''—critical parameter values at which estimated net benefits change sign or the low cost alternative switches. Sensitivity analysis usually proceeds by changing one variable or assumption at a time, but it can also be done by varying a combination of variables simultaneously to learn more about the robustness of your results to widespread changes. Again, however, major rules above the $1 billion threshold require a formal treatment.

• Apply a formal probabilistic analysis of the relevant uncertainties—possibly using simulation models and/or expert judgment as revealed, for example, through Delphi methods. Such a formal analytical approach is appropriate for complex rules where there are large multiple uncertainties whose analysis raises technical challenges, or where the effects cascade, and it is required for rules that exceed the $1 billion threshold. For example, in the analysis of regulations addressing air pollution, there is uncertainty about the effects of the rule on future emissions, uncertainty about how the change in emissions will affect air quality, uncertainty about how changes in air quality will affect health, and finally uncertainty about the economic and social value of the change in health outcomes. You should make a special effort to portray the probabilistic results—in graphs and/or tables—clearly and meaningfully.

• New methods may become available in the future. This document is not intended to discourage or inhibit their use, but rather to encourage and stimulate their development.

2. Assigning Economic Values to Uncertain Outcomes

Uncertainty affects the values that you assign to the costs and benefits of regulatory actions. Because the outcome of regulatory action is not certain, but is instead best represented by a probability distribution of potential outcomes, the value assigned to the expected outcome from this probability distribution may be different from that for an expected outcome of the same magnitude that is certain to occur. In the financial world, for example, riskier instruments must generally earn a higher rate of return, and investors receive a higher expected reward for bearing uncertainty. This principle can carry over to the analysis of regulations depending on who bears the uncertainties from regulatory decisions.

When reporting benefit and cost estimates, where there is a distribution of outcomes, you will often find it useful to emphasize summary statistics or figures that can be readily understood and compared to achieve the broadest public understanding of your findings. It is a common practice to compare the ''best estimates'' of both benefits and costs with those of competing alternatives. These ''best estimates'' are usually the average or the expected value of benefits and costs. Emphasis on these expected values is appropriate as long as society is ''risk neutral'' with respect to the regulatory alternatives. This, however, may not always be the case. For a risk-averse individual, the certainty equivalent of an uncertain net benefit stream is less than its expected cash value, because the uncertainty itself is valued negatively.

E. Other Key Considerations

1. Other Cost Considerations

You should include these effects in your analysis and provide estimates of their monetary values wherever possible.

- Private-sector compliance costs;
- Government administrative costs;
- Losses in consumers' or producers' surpluses;
- Discomfort or inconvenience; and
- Loss of time.

Estimates of costs should be based on credible changes in technology over time. For example, a slowing in the rate of innovation or of adoption of new technology because of delays in the regulatory approval process or the setting of more stringent standards for new facilities than existing ones may entail significant costs. On the other hand, a shift to regulatory performance standards and incentive-based policies may lead to cost-saving innovations that should be taken into account. The weight you give to a study of past rates of cost savings resulting from innovation (including ''learning curve'' effects) should depend on both their timeliness and their direct relevance to the processes affected by the regulatory alternative under consideration. In some cases agencies are limited under statute to considering only technologies that have been demonstrated to be feasible. In these situations, it may also be useful to estimate costs and cost savings assuming a wider range of technical possibilities.

Occasionally, one or more components of the analysis address cost savings to one of the parties directly affected by the rule. For example, a requirement that manufacturers reduce emissions from engines they produce may lead to technologies that improve fuel economy. These fuel savings will normally accrue to the purchasers of the engines. There is no apparent market failure with regard to the market value of fuel saved because one would expect that consumers would be willing to pay for increased fuel economy that exceeded the cost of providing it. When these cost savings are substantial, and particularly when you estimate them to be greater than the cost associated with achieving them, it is incumbent on you to demonstrate convincingly why the market has not already captured these gains. As a general matter, any costs that are averted as a result of an alternative should be monetized wherever possible and either added to the benefits or subtracted from the costs of that alternative.

2. The Difference Between Costs (or Benefits) and Transfer Payments

Distinguishing between real costs and transfer payments is an important, but sometimes difficult, problem in cost estimation. Cost and benefit estimates should reflect real resource use. Transfer payments are monetary payments from one group to another that do not affect total resources available to society. For example, a regulation that restricts the supply of a good, causing its price to rise, produces a transfer of income from buyers to sellers. The reduction in the total value of the supply of the good is a real cost to society, but the transfer of income from buyers to sellers resulting from the higher price is not. You should not include transfers in the estimates of the benefits and costs of a regulation.[23] Instead, address them in a separate discussion of the regulation's distributional effects.

Examples of transfer payments include the following:

- Scarcity rents and monopoly profits.
- Insurance payments.
- Indirect taxes and subsidies.
- Distribution expenses.

3. Alternative Assumptions

If benefit or cost estimates depend heavily on certain assumptions, you should make those assumptions explicit and carry out sensitivity analyses using plausible alternative assumptions. If the value of net benefits changes from positive to negative (or vice versa) or if the relative ranking of regulatory options changes with alternative plausible assumptions, you should conduct further analysis to determine which of the alternative assumptions is more appropriate. Because different estimation methods may have hidden assumptions, you should analyze estimation methods carefully to make any hidden assumptions explicit.

V. Specialized Analytical Requirements

In preparing analytical support for your rulemaking, you should be aware that there are a variety of analytic requirements imposed by law and Executive order. In addition to the regulatory impact analysis requirements of E.O. 12866, you should also consider whether your rule will need specialized analysis of any of the following issues.

A. Impact on Small Businesses and Other Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. chapter 6), agencies must prepare a proposed and final ''regulatory flexibility analysis'' (RFA) if the rulemaking could ''have a significant impact on a substantial number of small entities.'' Your agency should have guidelines on how to prepare an RFA and you are encouraged to consult with the Chief Counsel for Advocacy of the Small Business Administration on expectations concerning what is an adequate RFA. Executive Order 13272 (67 FR 53461, August 16, 2002) requires you to notify the Chief Counsel for Advocacy of any draft rules that might have a significant economic impact on a substantial number of small entities. E.O. 13272 also directs agencies to give every appropriate consideration to any comments provided by the Advocacy Office.

B. Analysis of Unfunded Mandates

Under the Unfunded Mandates Act (2 U.S.C. 1532), you must prepare a written statement about costs and benefits prior to issuing a proposed or final rule (for which

[23] However, transfers from the United States to other nations should be included as costs, and transfers from other nations to the United States as benefits.

your agency published a proposed rule) that may result in 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 (adjusted annually for inflation). Your analytical requirements under Executive Order 12866 are similar to the analytical requirements under this Act, and thus the same analysis may permit you to comply with both analytical requirements.

C. Information Collection, Paperwork and Recordkeeping Burdens

Under the Paperwork Reduction Act (44 U.S.C. chapter 35), you will need to consider whether your rulemaking (or other actions) will create any additional information collection, paperwork or recordkeeping burdens. These burdens are permissible only if you can justify the practical utility of the information for the implementation of your rule. OMB approval will be required of any new requirements for a collection of information imposed on 10 or more persons and a valid OMB control number must be obtained for any covered paperwork. Your agency's CIO should be able to assist you in complying with the Paperwork Reduction Act.

D. Information Quality Guidelines

Under the Information Quality Law, agency guidelines, in conformance with the OMB government-wide guidelines (67 FR 8452, February 22, 2002), have established basic quality performance goals for all information disseminated by agencies, including information disseminated in support of proposed and final rules. The data and analysis that you use to support your rule must meet these agency and OMB quality standards. Your agency's CIO should be able to assist you in assessing information quality. The Statistical and Science Policy Branch of OMB's Office of Information and Regulatory Affairs can provide you assistance.

E. Environmental Impact Statements

The National Environmental Policy Act (42 U.S.C. 4321–4347) and related statutes and executive orders require agencies to consider the environmental impacts of agency decisions, including rulemakings. An environmental impact statement must be prepared for ''major federal actions significantly affecting the quality of the human environment.'' You must complete NEPA documentation before issuing a final rule. The White House Council on Environmental Quality has issued regulations (40 CFR 1500–1508) and associated guidance for implementation of NEPA, available through CEQ's Web site (see NEPANet).

F. Impacts on Children

Under Executive Order 13045, ''Protection of Children from Environmental Health Risks and Safety Risks,'' each agency must, with respect to its rules, ''to the extent permitted by law and appropriate, and consistent with the agency's mission,'' each agency must ''address disproportionate risks to children that result from environmental health risks or safety risks.'' For any substantive rulemaking action that ''is likely to result in'' an economically significant rule that concerns ''an environmental health risk or safety risk that an agency has reason to believe may disproportionately affect children,'' the agency must provide OMB/OIRA ''an evaluation of the environmental health or safety effects of the planned regulation on children,'' as well as ''an explanation of why the planned regulation is preferable to other potentially and reasonably feasible alternatives considered by the agency.''

G. Energy Impacts

Under Executive Order 13211 (66 FR 28355, May 22, 2001), agencies are required to prepare and submit to OMB a Statement of Energy Effects for significant energy actions, to the extent permitted by law. This Statement is to include a detailed statement of ''any adverse effects on energy supply, distribution, or use (including a shortfall in supply, price increases, and increased use of foreign supplies)'' for the action and reasonable alternatives and their effects. You need to publish the Statement or a summary in the related NPRM and final rule. For further ''Guidance on Implementing E.O. 13211,'' see OMB Memorandum 01–27 (July 13, 2001), available on OMB's Web site.

VI. Accounting Statement

You need to provide an accounting statement with tables reporting benefit and cost estimates for each major final rule for your agency. You should use the guidance outlined above to report these estimates. We have included a suggested format for your consideration.

Categories of Benefits and Costs

To the extent feasible, you should quantify all potential incremental benefits and costs. You should report benefit and cost estimates within the following three categories:

- Monetized
- Quantified, but not monetized; and
- Qualitative, but not quantified.

These categories are mutually exclusive and exhaustive. Throughout the process of listing preliminary estimates of costs and benefits, agencies should avoid double-counting. This problem may arise if more than one way exists to express the same change in social welfare.

Quantifying and Monetizing Benefits and Costs

Yes, you should develop quantitative estimate and covert them to dollar amounts if possible. In many cases, quantified estimates are readily convertible, with a little effort, into dollar equivalents.

Treatment of Benefits and Costs Over Time

You should monetize and quantify effects as real, undiscounted streams of estimates for each year over the entire period for which you have estimated them. You should also annualize these same effects using real discount rates of 3 and 7 percent. The stream of annualized estimates should begin in the year the final rule is published even if the rule does not take effect immediately. Please report all monetized effects in 2000 dollars. You may convert dollars expressed in different years to 2000 dollars using the GDP deflator.

Treatment of Risk and Uncertainty

You should provide central tendency or primary estimates as well as distributions about the estimates, where such information exists. When you provide only upper and lower bounds (in addition to best estimates), you should, if possible, use the 95 and 5 percent confidence bounds. Although we encourage you to develop estimates that capture the distribution of plausible outcomes for a particular alternative, detailed reporting of such distributions is not required.

The principles of full disclosure and transparency apply to the treatment of uncertainty. Where there is significant uncertainty and the resulting inferences and/or assumptions have a critical effect on the benefit and cost estimates, you should describe the benefits and costs under plausible alternative assumptions. You may add footnotes to the table as needed to provide documentation and references, or to express important warnings.

In our discussion in Section I above, we identified some of the issues associated with developing estimates of the value of reductions in premature mortality risk. Based on this discussion, you should present alternative primary estimates where you use alternative estimates for valuing reductions in premature mortality risk.

Precision of Estimates

Reported estimates should reflect, to the extent feasible, the precision in the analysis. For example, an estimate of $220 million implies rounding to the nearest $10 million and thus a precision of ±$5 million; similarly, an estimate of $222 million implies rounding to the nearest $1 million and thus, a precision of ±$0.5 million.

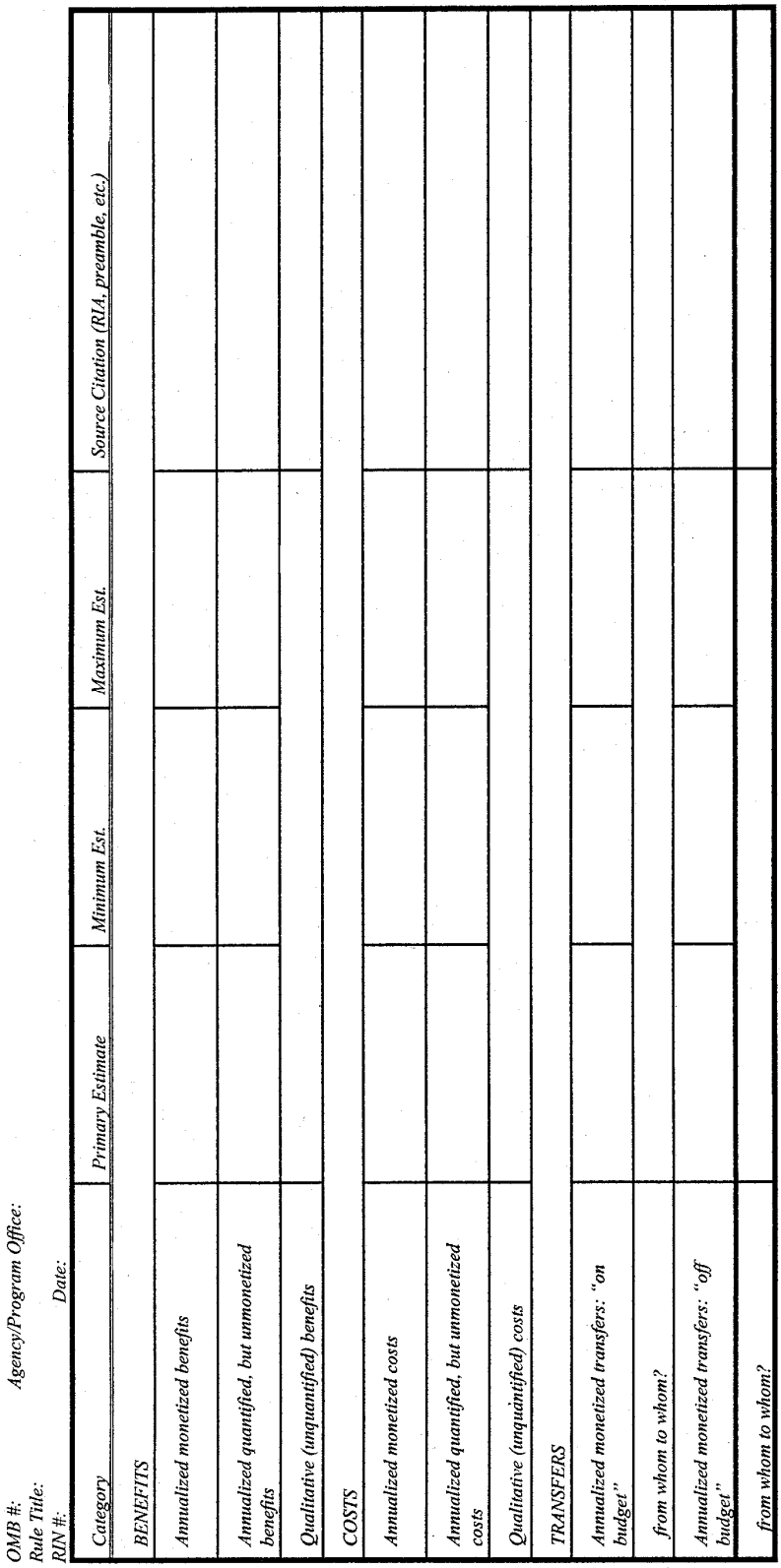
Separate Reporting of Transfers

You should report transfers separately and avoid the misclassification of transfer payments as costs or benefits. Transfers occur when wealth or income is redistributed without any direct change in aggregate social welfare. To the extent that regulatory outputs reflects transfers rather than welfare gains to society, you should identify them as transfers rather than costs or benefits. You should also distinguish transfers caused by Federal budget actions—such as those stemming from a rule affecting Social Security payments—from those that involve transfers between non-governmental parties—such as monopoly rents a rule may confer on a private party. You should use as many categories as necessary to describe the major redistributive effects of a regulatory action. If transfers have significant effects in addition to distributional effects, you should evaluate them also.

Effects on State, Local, and Tribal Governments, Small Business, Wages and Economic Growth

You need to identity the portions of benefits, cost, and transfers received by State, local, and tribal governments. To the extent feasible, you also should identify the effects of the rule or program on small businesses, wages, and economic growth. Note that rules with annual costs that are less than one

billion dollars are likely to have minimal effect on economic growth.



OMB #: *Agency/Program Office:*
Rule Title:
RIN #: *Date:*

Category	*Primary Estimate*	*Minimum Est.*	*Maximum Est.*	*Source Citation (RIA, preamble, etc.)*
BENEFITS				
Annualized monetized benefits				
Annualized quantified, but unmonetized benefits				
Qualitative (unquantified) benefits				
COSTS				
Annualized monetized costs				
Annualized quantified, but unmonetized costs				
Qualitative (unquantified) costs				
TRANSFERS				
Annualized monetized transfers: "on budget"				
from whom to whom?				
Annualized monetized transfers: "off budget"				
from whom to whom?				

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[FR Doc. 03–2542 Filed 1–31–03; 8:45 am]

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REMINDERS

The items in this list were editorially compiled as an aid to Federal Register users. Inclusion or exclusion from this list has no legal significance.

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Atlantic mackerel, squid, and butterfish; published 1-2-03

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300–499	(869–048–00063–1)	29.00	Apr. 1, 2002
500–599	(869–048–00064–0)	46.00	Apr. 1, 2002
600–799	(869–048–00065–8)	16.00	Apr. 1, 2002
800–1299	(869–048–00066–6)	56.00	Apr. 1, 2002
1300–End	(869–048–00067–4)	22.00	Apr. 1, 2002
22 Parts:			
1–299	(869–048–00068–2)	59.00	Apr. 1, 2002
300–End	(869–048–00069–1)	43.00	Apr. 1, 2002
23	(869–048–00070–4)	40.00	Apr. 1, 2002
24 Parts:			
0–199	(869–048–00071–2)	57.00	Apr. 1, 2002
200–499	(869–048–00072–1)	47.00	Apr. 1, 2002
500–699	(869–048–00073–9)	29.00	Apr. 1, 2002
700–1699	(869–048–00074–7)	58.00	Apr. 1, 2002
1700–End	(869–048–00075–5)	29.00	Apr. 1, 2002
25	(869–048–00076–3)	68.00	Apr. 1, 2002
26 Parts:			
§§ 1.0-1–1.60	(869–048–00077–1)	45.00	Apr. 1, 2002
§§ 1.61–1.169	(869–048–00078–0)	58.00	Apr. 1, 2002
§§ 1.170–1.300	(869–048–00079–8)	55.00	Apr. 1, 2002
§§ 1.301–1.400	(869–048–00080–1)	44.00	Apr. 1, 2002
§§ 1.401–1.440	(869–048–00081–0)	60.00	Apr. 1, 2002
§§ 1.441-1.500	(869-048-00082-8)	47.00	Apr. 1, 2002
§§ 1.501–1.640	(869–048–00083–6)	44.00	[6] Apr. 1, 2002
§§ 1.641–1.850	(869–048–00084–4)	57.00	Apr. 1, 2002
§§ 1.851–1.907	(869–048–00085–2)	57.00	Apr. 1, 2002
§§ 1.908–1.1000	(869–048–00086–1)	56.00	Apr. 1, 2002
§§ 1.1001–1.1400	(869–048–00087–9)	58.00	Apr. 1, 2002
§§ 1.1401–End	(869–048–00088–7)	61.00	Apr. 1, 2002
2–29	(869–048–00089–5)	57.00	Apr. 1, 2002
30–39	(869–048–00090–9)	39.00	Apr. 1, 2002
40–49	(869–048–00091–7)	26.00	Apr. 1, 2002
50–299	(869–048–00092–5)	38.00	Apr. 1, 2002
300–499	(869–048–00093–3)	57.00	Apr. 1, 2002
500–599	(869–048–00094–1)	12.00	[5] Apr. 1, 2002
600–End	(869–048–00095–0)	16.00	Apr. 1, 2002
27 Parts:			
1–199	(869–048–00096–8)	61.00	Apr. 1, 2002

Title	Stock Number	Price	Revision Date
200–End	(869–048–00097–6)	13.00	Apr. 1, 2002
28 Parts:			
0-42	(869–048–00098–4)	58.00	July 1, 2002
43-end	(869-048-00099-2)	55.00	July 1, 2002
29 Parts:			
0–99	(869–048–00100–0)	45.00	[8]July 1, 2002
100–499	(869–048–00101–8)	21.00	July 1, 2002
500–899	(869–048–00102–6)	58.00	July 1, 2002
900–1899	(869–048–00103–4)	35.00	July 1, 2002
1900–1910 (§§ 1900 to 1910.999)	(869–048–00104–2)	58.00	July 1, 2002
1910 (§§ 1910.1000 to end)	(869–048–00105–1)	42.00	[8]July 1, 2002
1911–1925	(869–048–00106–9)	29.00	July 1, 2002
1926	(869–048–00107–7)	47.00	July 1, 2002
1927–End	(869–048–00108–5)	59.00	July 1, 2002
30 Parts:			
1–199	(869–048–00109–3)	56.00	July 1, 2002
200–699	(869–048–00110–7)	47.00	July 1, 2002
700–End	(869–048–00111–5)	56.00	July 1, 2002
31 Parts:			
0–199	(869–048–00112–3)	35.00	July 1, 2002
200–End	(869–048–00113–1)	60.00	July 1, 2002
32 Parts:			
1–39, Vol. I		15.00	[2]July 1, 1984
1–39, Vol. II		19.00	[2]July 1, 1984
1–39, Vol. III		18.00	[2]July 1, 1984
1–190	(869–048–00114–0)	56.00	July 1, 2002
191–399	(869–048–00115–8)	60.00	July 1, 2002
400–629	(869–048–00116–6)	47.00	July 1, 2002
630–699	(869–048–00117–4)	37.00	July 1, 2002
700–799	(869–048–00118–2)	44.00	July 1, 2002
800–End	(869–048–00119–1)	46.00	July 1, 2002
33 Parts:			
1–124	(869–048–00120–4)	47.00	July 1, 2002
125–199	(869–048–00121–2)	60.00	July 1, 2002
200–End	(869–048–00122–1)	47.00	July 1, 2002
34 Parts:			
1–299	(869–048–00123–9)	45.00	July 1, 2002
300–399	(869–048–00124–7)	43.00	July 1, 2002
400–End	(869–048–00125–5)	59.00	July 1, 2002
35	(869–048–00126–3)	10.00	[7]July 1, 2002
36 Parts			
1–199	(869–048–00127–1)	36.00	July 1, 2002
200–299	(869–048–00128–0)	35.00	July 1, 2002
300–End	(869–048–00129–8)	58.00	July 1, 2002
37	(869–048–00130–1)	47.00	July 1, 2002
38 Parts:			
0–17	(869–048–00131–0)	57.00	July 1, 2002
18–End	(869–048–00132–8)	58.00	July 1, 2002
39	(869–048–00133–6)	40.00	July 1, 2002
40 Parts:			
1–49	(869–048–00134–4)	57.00	July 1, 2002
50–51	(869–048–00135–2)	40.00	July 1, 2002
52 (52.01–52.1018)	(869–048–00136–1)	55.00	July 1, 2002
52 (52.1019–End)	(869–048–00137–9)	58.00	July 1, 2002
53–59	(869–048–00138–7)	29.00	July 1, 2002
60 (60.1–End)	(869–048–00139–5)	56.00	July 1, 2002
60 (Apps)	(869–048–00140–9)	51.00	[8]July 1, 2002
61–62	(869–048–00141–7)	38.00	July 1, 2002
63 (63.1–63.599)	(869–048–00142–5)	56.00	July 1, 2002
63 (63.600–63.1199)	(869–048–00143–3)	46.00	July 1, 2002
63 (63.1200-End)	(869–048–00144–1)	61.00	July 1, 2002
64–71	(869–048–00145–0)	29.00	July 1, 2002
72–80	(869–048–00146–8)	59.00	July 1, 2002
81–85	(869–048–00147–6)	47.00	July 1, 2002
86 (86.1–86.599–99)	(869–048–00148–4)	52.00	[8]July 1, 2002
86 (86.600–1–End)	(869–048–00149–2)	47.00	July 1, 2002
87–99	(869–048–00150–6)	57.00	July 1, 2002
100–135	(869–048–00151–4)	42.00	July 1, 2002
136–149	(869–048–00152–2)	58.00	July 1, 2002
150–189	(869–048–00153–1)	47.00	July 1, 2002
190–259	(869–048–00154–9)	37.00	July 1, 2002
260–265	(869–048–00155–7)	47.00	July 1, 2002
266–299	(869–048–00156–5)	47.00	July 1, 2002
300–399	(869–048–00157–3)	43.00	July 1, 2002
400–424	(869–048–00158–1)	54.00	July 1, 2002
425–699	(869–048–00159–0)	59.00	July 1, 2002
700–789	(869–048–00160–3)	58.00	July 1, 2002
790–End	(869–048–00161–1)	45.00	July 1, 2002
41 Chapters:			
1, 1–1 to 1–10		13.00	[3]July 1, 1984
1, 1–11 to Appendix, 2 (2 Reserved)		13.00	[3]July 1, 1984
3–6		14.00	[3]July 1, 1984
7		6.00	[3]July 1, 1984
8		4.50	[3]July 1, 1984
9		13.00	[3]July 1, 1984
10–17		9.50	[3]July 1, 1984
18, Vol. I, Parts 1–5		13.00	[3]July 1, 1984
18, Vol. II, Parts 6–19		13.00	[3]July 1, 1984
18, Vol. III, Parts 20–52		13.00	[3]July 1, 1984
19–100		13.00	[3]July 1, 1984
1–100	(869–048–00162–0)	23.00	July 1, 2002
101	(869–048–00163–8)	43.00	July 1, 2002
102–200	(869–048–00164–6)	41.00	July 1, 2002
201–End	(869–048–00165–4)	24.00	July 1, 2002
42 Parts:			
1–399	(869–048–00166–2)	56.00	Oct. 1, 2002
400–429	(869–048–00167–1)	59.00	Oct. 1, 2002
430–End	(869–048–00168–9)	61.00	Oct. 1, 2002
43 Parts:			
1–999	(869–048–00169–7)	47.00	Oct. 1, 2002
1000–end	(869–048–00170–1)	59.00	Oct. 1, 2002
44	(869–048–00171–9)	47.00	Oct. 1, 2002
45 Parts:			
1–199	(869–048–00172–7)	57.00	Oct. 1, 2002
200–499	(869–048–00173–5)	31.00	[9]Oct. 1, 2002
500–1199	(869–048–00174–3)	47.00	Oct. 1, 2002
1200–End	(869–048–00175–1)	57.00	Oct. 1, 2002
46 Parts:			
1–40	(869–048–00176–0)	44.00	Oct. 1, 2002
41–69	(869–048–00177–8)	37.00	Oct. 1, 2002
70–89	(869–048–00178–6)	14.00	Oct. 1, 2002
90–139	(869–048–00179–4)	42.00	Oct. 1, 2002
140–155	(869–048–00180–8)	24.00	[9]Oct. 1, 2002
156–165	(869–048–00181–6)	31.00	[9]Oct. 1, 2002
166–199	(869–048–00182–4)	44.00	Oct. 1, 2002
200–499	(869–048–00183–2)	37.00	Oct. 1, 2002
500–End	(869–048–00184–1)	24.00	Oct. 1, 2002
47 Parts:			
0–19	(869–048–00185–9)	57.00	Oct. 1, 2002
20–39	(869–048–00186–7)	45.00	Oct. 1, 2002
40–69	(869–048–00187–5)	36.00	Oct. 1, 2002
70–79	(869–048–00188–3)	58.00	Oct. 1, 2002
80–End	(869–048–00189–1)	57.00	Oct. 1, 2002
48 Chapters:			
1 (Parts 1–51)	(869–048–00190–5)	59.00	Oct. 1, 2002
1 (Parts 52–99)	(869–048–00191–3)	47.00	Oct. 1, 2002
2 (Parts 201–299)	(869–048–00192–1)	53.00	Oct. 1, 2002
3–6	(869–048–00193–0)	30.00	Oct. 1, 2002
7–14	(869–048–00194–8)	47.00	Oct. 1, 2002
*15–28	(869–048–00195–6)	55.00	Oct. 1, 2002
29–End	(869–048–00196–4)	38.00	[9]Oct. 1, 2002
49 Parts:			
1–99	(869–048–00197–2)	56.00	Oct. 1, 2002
100–185	(869–044–00198–5)	60.00	Oct. 1, 2001
186–199	(869–048–00199–9)	18.00	Oct. 1, 2002
200–399	(869–044–00200–1)	60.00	Oct. 1, 2001
400–999	(869–048–00201–4)	61.00	Oct. 1, 2002
1000–1199	(869–048–00202–2)	25.00	Oct. 1, 2002

Title	Stock Number	Price	Revision Date
1200–End	(869–048–00203–1)	30.00	Oct. 1, 2002
50 Parts:			
1–199	(869–044–00204–3)	63.00	Oct. 1, 2001
200–599	(869–048–00206–5)	38.00	Oct. 1, 2002
600–End	(869–044–00206–0)	55.00	Oct. 1, 2001
CFR Index and Findings Aids	(869–048–00047–0)	59.00	Jan. 1, 2002
Complete 2001 CFR set		1,195.00	2001
Microfiche CFR Edition:			
Subscription (mailed as issued)		298.00	2000
Individual copies		2.00	2000
Complete set (one-time mailing)		290.00	2000
Complete set (one-time mailing)		247.00	1999

[1] Because Title 3 is an annual compilation, this volume and all previous volumes should be retained as a permanent reference source.

[2] The July 1, 1985 edition of 32 CFR Parts 1–189 contains a note only for Parts 1–39 inclusive. For the full text of the Defense Acquisition Regulations in Parts 1–39, consult the three CFR volumes issued as of July 1, 1984, containing those parts.

[3] The July 1, 1985 edition of 41 CFR Chapters 1–100 contains a note only for Chapters 1 to 49 inclusive. For the full text of procurement regulations in Chapters 1 to 49, consult the eleven CFR volumes issued as of July 1, 1984 containing those chapters.

[4] No amendments to this volume were promulgated during the period January 1, 2001, through January 1, 2002. The CFR volume issued as of January 1, 2001 should be retained.

[5] No amendments to this volume were promulgated during the period April 1, 2000, through April 1, 2001. The CFR volume issued as of April 1, 2000 should be retained.

[6] No amendments to this volume were promulgated during the period April 1, 2001, through April 1, 2002. The CFR volume issued as of April 1, 2001 should be retained.

[7] No amendments to this volume were promulgated during the period July 1, 2000, through July 1, 2001. The CFR volume issued as of July 1, 2000 should be retained.

[8] No amendments to this volume were promulgated during the period July 1, 2001, through July 1, 2002. The CFR volume issued as of July 1, 2001 should be retained.

[9] No amendments to this volume were promulgated during the period October 1, 2001, through October 1, 2002. The CFR volume issued as of October 1, 2001 should be retained.

TABLE OF EFFECTIVE DATES AND TIME PERIODS—FEBRUARY 2003

This table is used by the Office of the Federal Register to compute certain dates, such as effective dates and comment deadlines, which appear in agency documents. In computing these dates, the day after publication is counted as the first day.

When a date falls on a weekend or holiday, the next Federal business day is used. (See 1 CFR 18.17)

A new table will be published in the first issue of each month.

DATE OF FR PUBLICATION	15 DAYS AFTER PUBLICATION	30 DAYS AFTER PUBLICATION	45 DAYS AFTER PUBLICATION	60 DAYS AFTER PUBLICATION	90 DAYS AFTER PUBLICATION
Feb 3	Feb 18	March 5	March 20	April 4	May 5
Feb 4	Feb 19	March 6	March 21	April 7	May 5
Feb 5	Feb 20	March 7	March 24	April 7	May 6
Feb 6	Feb 21	March 10	March 24	April 7	May 7
Feb 7	Feb 24	March 10	March 24	April 8	May 8
Feb 10	Feb 25	March 12	March 27	April 11	May 12
Feb 11	Feb 26	March 13	March 28	April 14	May 12
Feb 12	Feb 27	March 14	March 31	April 14	May 13
Feb 13	Feb 28	March 17	March 31	April 14	May 14
Feb 14	March 3	March 17	March 31	April 15	May 15
Feb 18	March 5	March 20	April 4	April 21	May 19
Feb 19	March 6	March 21	April 7	April 21	May 20
Feb 20	March 7	March 24	April 7	April 21	May 21
Feb 21	March 10	March 24	April 7	April 22	May 22
Feb 24	March 11	March 26	April 10	April 25	May 27
Feb 25	March 12	March 27	April 11	April 28	May 27
Feb 26	March 13	March 28	April 14	April 28	May 27
Feb 27	March 14	March 31	April 14	April 28	May 28
Feb 28	March 17	March 31	April 14	April 29	May 29